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

November 21, 2025

Ms. Jennifer Marinas
Director of Quality Assurance
Operation Technology, Incorporated
17 Goodyear
Irvine, CA 92618

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF OPERATION TECHNOLOGY, INCORPORATED NO. 99901350/2025-201, AND NOTICE OF NONCONFORMANCE

Dear Ms. Marinas,

On August 25 – 29, 2025, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Operation Technology, Incorporated (hereafter referred to OTI) facility in Irvine, California. The purpose of this limited-scope routine inspection was to evaluate OTI's compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically-focused inspection specifically evaluated OTI's implementation of quality activities associated with the supply of electrical power system analysis and operation software for NRC regulated facilities. The enclosed report presents the results of the inspection. In addition, the NRC inspection team reviewed OTI's closure of the inspection findings documented in the inspection report No. 99901350/2003-201, dated March 7, 2003 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML030660635). This NRC inspection report does not constitute the NRC's endorsement of OTI's overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program did not meet certain regulatory requirements imposed on you by your customers or NRC licensees. Specifically, the NRC inspection team determined that OTI was not fully implementing its QA program in the area of its corrective action program. This specific finding and references to the pertinent requirements are identified in the enclosures in this letter. In response to the enclosed notice of nonconformance (NON), OTI should document the results of the extent of condition review for the finding and determine if there are any effects on other safety-related components.

Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NON. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, “Public Inspections, Exemptions, Requests for Withholding,” of the NRC’s “Rules of Practice,” the NRC will make available electronically for public inspection a copy of this letter, its enclosure, and your response through the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System, which is accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, “Protection of Safeguards Information: Performance Requirements.”

Sincerely,

Signed by Kavanagh, Kerri
on 11/21/25

Kerri Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Docket No.: 99901350

EPID No.: I-2025-201-0019

Enclosure:

1. Notice of Nonconformance
2. Inspection Report No. 99901350/2025
-201 and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF OPERATION TECHNOLOGY, INCORPORATED NO. 99901350/2025-201, AND NOTICE OF NONCONFORMANCE DATE: November 21, 2025

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ADAMS Accession No.: ML25321A063 **NRR-106**

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NAME	Sray	KKavanagh	EBrothman
DATE	11/17/2025	11/21/2025	11/18/2025

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NOTICE OF NONCONFORMANCE

Operation Technology, Incorporated
17 Goodyear
Irvine, CA 92618

Docket No. 99901350
Report No. 2025-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Operation Technology, Incorporated's (hereafter referred to as OTI) facilities in Irvine, CA, from August 25, 2025, through August 29, 2025, OTI did not conduct certain activities in accordance with NRC requirements that were contractually imposed OTI by its customers or NRC licensees:

A. 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.

This issue has been identified as Nonconformance 99901350/2025-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality Assurance and Vendor Inspection Branch, Division of Regulatory Oversight, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliance; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

In accordance with the requirements of 10 CFR 2.390, “Public inspections, exemptions, requests for withholding,” of the NRC’s “Rule of Practice,” your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, “Protection of safeguards information: performance requirements.”

Dated this the 21st day of November 2025.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
VENDOR INSPECTION REPORT

Docket No.:	9901350
Report No.:	99901350/2025-201
Vendor:	Operation Technology, Incorporated 17 Goodyear Irvine, CA 92618
Vendor Contact:	Ms. Jennifer Marinas Director of Quality Assurance Phone: (949) 900-1056 Email: jennifer.marinas@etap.com
Nuclear Industry Activity:	Operation Technology, Incorporated's (hereafter referred to as OTI) scope of supply includes electrical transient analyzer program (ETAP) software to NRC regulated facilities.
Inspection Dates:	August 25 – 29, 2025
Inspectors:	Deanna Zhang — NRR/DRO/IQVB, Team Leader Yiu Law — NRR/DRO/IQVB Sheila Ray — NRR/DEX/EEEB, technical specialist Tiffany Lee — NRR/DRO/IQVB, Trainee
Approved by:	Kerri Kavanagh, Chief Quality Assurance and Vendor Inspection Branch Division of Reactor Oversight Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

Operation Technology, Incorporated
99901350/2025-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a limited-scope routine vendor inspection at the Operation Technology, Incorporated's (hereafter referred to as OTI) facility in Irvine, CA, to verify it had implemented an adequate quality assurance (QA) program that complies 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, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC inspection team conducted this inspection on-site during the week of August 25 – 29, 2025. This was the second NRC inspection at this facility.

This technically-focused inspection specifically evaluated OTI's implementation of the quality activities associated with the electrical transit analyzer program (ETAP) software used in safety-related applications at NRC regulated facilities. In addition, the NRC inspection team evaluated OTI's closure of the inspection findings documented in the inspection report No. 99901350/2003-201, dated March 7, 2003 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML030660635).

The following regulations served as the basis for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During this inspection, the NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated February 10, 2023; and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting of Defects and Noncompliance," dated February 10, 2023.

With the exception of the nonconformance described below, the NRC inspection team concluded that OTI's QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that OTI's personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspection team reviewed a sample in the area of 10 CFR Part 21. The NRC inspection team concluded that the policies and procedures are implemented consistently with the requirements of 10 CFR Part 21. One minor finding was identified with respect to the OTI's 10 CFR Part 21 procedure.

Design Control, Test Control, Nonconforming Parts, Materials, or Components, and Internal Audits

The NRC inspection team review of OTI's design control program, including the software QA program, test control program, nonconforming parts, materials, or components program, and internal audits program. No findings of significance were identified.

Corrective Action Program

The NRC inspection team issued Notice of Nonconformance (NON) 99901350/2025-201-01. NON 99901350/2025-201-01 cites OTI's failure to establish a documented corrective action program that met the regulatory requirements of Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50. Specifically, OTI's Quality Assurance Manual, Revision 23 and its referenced 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. Details regarding this NON are documented in the report details.

The NRC inspection team reviewed the corrective actions that OTI took to address Nonconformance Nos. 99901350/2003-201-01, 99901350/2003-201-02, 99901350/2003-201-03, 99901350/2003-201-04, and 99901350/2003-205-05, as documented in inspection report No. 99901350/2003-201, dated March 7, 2003. The NRC inspection team reviewed the documentation that provided the objective evidence that all the corrective actions were completed and adequately implemented. Based on this review, the NRC inspection team closed Nonconformance Nos. 99901350/2003-201-01, 99901350/2003-201-02, 99901350/2003-201-03, 99901350/2003-201-04, and 99901350/2003-205-05.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed Operation Technology, Incorporated's (hereafter referred to as OTI) policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. The NRC inspection team also evaluated OTI's 10 CFR Part 21 postings and verified compliance with the requirements of 10 CFR 21.6, "Posting Requirements." The NRC inspection team observed that OTI does not procure safety-related items. The NRC inspection team also verified that OTI's corrective action procedures provide a link to the 10 CFR Part 21 program.

The NRC inspection team also discussed the 10 CFR Part 21 program with OTI's management and technical staff. The attachment to this inspection report lists the documents reviewed and the personnel interviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team reviewed OTI's 10 CFR Part 21 procedure and observed that it did not appropriately document all the requirements of 10 CFR Part 21. Specifically, OTI's Part 21 procedure did not define:

- A deviation as a departure from technical requirements within a procedure document
- What and when the point of discovery of a potential deviation is
- Required actions to be taken if the evaluation of a potential deviation cannot meet the reporting requirement of sixty-days

The NRC inspection team determined this issue to be no more than minor due to substantial objective evidence that OTI is implementing the requirements of 10 CFR Part 21 in their processes. During the time of the inspection, OTI created Audit Finding (AF)-193 to address the deficiencies that the NRC inspection team observed for this minor issue.

c. Conclusion

With the exception of the minor issue described above, the NRC inspection team concluded that OTI is implementing the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the NRC inspection team determined that OTI is adequately implementing its policies and procedures associated with 10 CFR Part 21. No findings of significance were identified.

2. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed OTI's policies and implementing procedures for governing the control of nonconforming materials, parts, or components and corrective action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," respectively.

The NRC inspection team reviewed a sample of incident reports created to address software nonconformances. For the incident reports reviewed, the NRC inspection team verified that these nonconformances were (1) adequately documented, and (2) properly reviewed and dispositioned in accordance with OTI's processes and procedures.

The NRC inspection team also reviewed a sample of corrective action reports, including error reports created to address software errors and audit findings to address programmatic deficiencies identified during internal and external audits. For these reports the NRC inspection team verified: (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the nature of software problems and the effect of the results; and (3) recommended workaround actions and corrective actions. In addition, the NRC inspection team confirmed that the corrective action process provides a link to OTI's 10 CFR Part 21 program.

Additionally, the NRC inspection team discussed the nonconformance and corrective action program with OTI's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observation and Findings

The NRC inspection team reviewed OTI's corrective action program and OTI's procedures for implementing OTI's corrective action program. The NRC inspection team observed that Part 3 of OTI's Quality Assurance (QA) Manual, Revision 23, did not establish requirements for prompt identification and correction of conditions adverse to quality for OTI's product and its QA program. The NRC inspection team also observed that OTI's QA Manual and its implementing procedures do not address QA program deficiencies when such deficiencies are not identified during internal and external audits. The NRC inspection team observed that Part 3 of OTI's QA Manual did not establish requirements for classifying when conditions adverse to quality should be elevated to a significant condition adverse to quality. As such, there are no criteria in OTI's policies to ensure that (1) significant conditions adverse to quality have appropriate corrective actions to preclude repetition and (2) significant conditions adverse to quality are documented and reported to appropriate levels of management. Further, the NRC inspection team observed that although OTI's procedure for software deficiencies specifies that a root cause be determined for all deficiencies/problems identified, the sampled incident reports only analyzed for apparent causes.

This issue has been identified as Nonconformance 9991350/2025-201-01.

During the time of the inspection, OTI created AF-195 to address the deficiencies that the NRC inspection team observed for this nonconformance.

Corrective Actions Associated with Nonconformance 99901350/2003-201-01

Following the 2003 inspection of OTI, the NRC issued Nonconformance 99901350/2003-201-01 for OTI's failure to ensure that appropriate quality assurance program controls/procedures to ensure that original equipment manufacturer's (OEM's) technical data, that it obtained from entities other than applicable OEMs, was verified to assure its accuracy, correctness and completeness before inputting the OEM data into the ETAP Powerstation (ETAP-PS) software library design bases.

In its response to the NRC dated April 8, 2003 (Agencywide Document Access and Management System (ADAMS) Accession No. ML031040224), and its follow-up responses dated August 14, 2003 (ADAMS Accession No. ML032310169) and dated December 9, 2003 (ADAMS Accession No. ML033490454), OTI also stated that controls would be established to ensure that ETAP library data are based on OEM's technical data, applicable standards, or calculated values. OTI stated that new plans and procedures would be established to ensure that to validate the source of data, provide guidelines for data entry, verify the entered data, audit of the verification and validation (V&V) process, and retention of the quality records. These corrective actions would be reflected in the ETAP 5.0 release.

The NRC inspection team reviewed the documentation that provided objective evidence that all the corrective actions were completed and adequately implemented. Specifically, the current OTI Software Quality Assurance Plan (SQAP) ensures that in the V&V process, the library data provided by OTI are now based on the OEM's technical data, applicable standards, or calculated values to ensure the accuracy, correctness and completeness of the data. The NRC inspection team verified that this is implemented in subsequent versions of the ETAP software. Based on its review, the NRC inspection team closed Nonconformance 99901350/2003-201-01.

Corrective Actions Associated with Nonconformance 99901350/2003-201-02

Following the 2003 inspection of OTI, the NRC issued Nonconformance 99901350/2003-201-02 for OTI's failure to ensure that OEM's technical data, that it obtained from entities other than applicable OEMs, was verified in accordance with documented procedures to assure its accuracy, correctness and completeness before inputting the OEM data into its ETAP-PS software library design bases, and failed to ensure that sufficient QA records were maintained for objective evidence of activities affecting quality.

In its response to the NRC dated April 8, 2003 (ADAMS Accession No. ML031040224), and its follow-up responses dated August 14, 2003 (ADAMS Accession No. ML032310169) and dated December 9, 2003 (ADAMS Accession No. ML033490454), OTI stated that ETAP nuclear users have been informed that the OEM's technical data for the three libraries identified in the nonconformance were received from an entity other than the OEM. OTI also stated that new procedures would be established to ensure that the V&V would include controls to ensure that OEM's technical data would be inputted into the ETAP-PS software library design bases and this would be reflected in the ETAP 5.0 release.

The NRC inspection team reviewed the documentation that provided objective evidence that all the corrective actions were completed and adequately implemented. Specifically, the current OTI SQAP ensures that in the V&V process, the library data provided by OTI are now based on the OEM's technical data, applicable standards, or calculated values to ensure the accuracy, correctness and completeness of the data. The NRC inspection team verified that the ETAP software library data, including software library data references, guidelines for library data entries, incident reports generated for library data, and audit records, are now considered as QA records and are maintained permanently. The NRC inspection team verified that this is implemented in subsequent versions of the ETAP software. Based on its review, the NRC inspection team closed Nonconformance 99901350/2003-201-02.

Corrective Actions Associated with Nonconformance 99901350/2003-201-03

Following the 2003 inspection of OTI, the NRC issued Nonconformance 99901350/2003-201-03 for failure to ensure that its ETAP-ES library ampacity derating design data for free air licensee applications was the same as that specified in the Insulated Cable Engineers Association (ICEA) standard P-46-426 for free air values.

In its response to the NRC dated April 8, 2003 (ADAMS Accession No. ML031040224), and its follow-up responses dated August 14, 2003 (ADAMS Accession No. ML032310169) and dated December 9, 2003 (ADAMS Accession No. ML033490454), OTI stated that to avoid any possible confusion with ETAP users, the ETAP 5.0 user guide and help file will provide information regarding the application of magnetically installed cables in free air cable tray, which is continuously surrounding the cable to create circulating currents. In addition, ETAP will include the information that describes the application of Cable Base Ampacities, including all the details that inform the users about the application of magnetically install cables in free air cable trays, and that these changes would be implemented in the ETAP 5.0 release.

The NRC inspection team reviewed the documentation that provided objective evidence that all the corrective actions were completed and adequately implemented. Specifically, the NRC inspection team verified that the ETAP 5.0 and the subsequent revision User Guide and Help File provided information regarding the application of magnetically installed cables in free air cable trays, and that these Help Files included all the detailed information to inform its users about the application of magnetically installed cables in free air cable trays. The NRC inspection team verified that these changes were implemented in ETAP 5.0 and subsequent version of the ETAP software. Based on its review, the NRC inspection team closed Nonconformance 99901350/2003-201-03.

Corrective Actions Associated with Nonconformance 99901350/2003-201-04

Following the 2003 inspection of OTI, the NRC issued Nonconformance 99901350/2003-201-02 for OTI's failure to provide adequate objective evidence to indicate that the regression test would verify the adequacy of ETAP-PS version 4.0.0N even though it was corrected by TCS-CAB-016.

In its response to the NRC dated April 8, 2003 (ADAMS Accession No. ML031040224), and its follow-up responses dated August 14, 2003 (ADAMS Accession No. ML032310169) and dated December 9, 2003 (ADAMS Accession No. ML033490454), OTI stated that a Test

Design Specification Review (TDSR) would be added to the existing V&V review as a second review for completeness of the test cases. Specifically, the Test Design Specification (TDS) forms would consist of a listing of program features to be tested for a particular ETAP module. This document would be compiled by managers and engineers who have expert technical knowledge of the assigned modules, and that a review of the assigned TDS would be conducted prior to each release of the ETAP. In addition, the TDSR reports are considered a quality record and would be maintained permanently with the release V&V package. These changes would be implemented in the ETAP 5.0 release.

The NRC inspection team reviewed the documentation that provided objective evidence that all the corrective actions were completed and adequately implemented. Specifically, OTI implemented a TDSR to ensure that the test methodology is reflected in test plan, test requirements are based on the TDS, test benchmarks are valid, and that all test cases are added to the ETAP's electronic storage system. These are reflected in the OTI-609/PTR, "Preliminary Test Review (PTR)" and OTI-609/CTR, "Critical Test Review (CTR)" forms. The NRC inspection team verified that these changes are implemented in subsequent versions of the ETAP software. Based on its review, the NRC inspection team closed Nonconformance 99901350/2003-201-04.

Corrective Actions Associated with Nonconformance 99901350/2003-201-05

Following the 2003 inspection of OTI, the NRC issued Nonconformance 99901350/2003-201-05 for OTI's failure to ensure that adequate records were developed and maintained to provide objective evidence of test results. Specifically, the test results for two tests regarding ETAP-PS version 4.0.0 N did not contain adequate documentation in their applicable test packages to provide evidence of satisfactory test performance to assure that the test requirements were satisfied.

In its response to the NRC dated April 8, 2003 (ADAMS Accession No. ML031040224), and its follow-up response dated August 14, 2003 (ADAMS Accession No. ML032310169), OTI stated that test engineers are required to provide evidence of test case results for all test cases in the form of table comparisons of appropriate attachments regardless of how simple the test case may be. In addition, OTI stated that additional measures would be added to ensure that each test case would be furnished with evidence of test results.

In NRC Acknowledgement Letter to OTI (ADMAS Accession No. ML033080019), the NRC inspection team closed Nonconformance 99901350/2003-201-05.

c. Conclusion

The NRC inspection team concluded that OTI has established controls for nonconforming software in accordance with Criterion XV of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that OTI is implementing its policies and procedures consistent with the requirements of Criterion XV of Appendix B to 10 CFR Part 50. No findings of significance were identified.

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.

3. Design Control

a. Inspection Scope

The NRC inspection team reviewed OTI's policies and implementing procedures that govern the implementation of its design control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team reviewed OTI's policies and procedures for implementation of OTI's development for its ETAP software product. The NRC inspection team performed a walkthrough of ETAP's software lifecycle processes and verified that new and modified functional and software requirements are appropriately incorporated into the lifecycle process. The NRC inspection reviewed a select sample of software design and release documents associated with ETAP 24.0.3N and verified that for the select sample software requirements specifications, these requirements appropriately reflected the OTI's procedure for software requirements specification. The NRC inspection team also reviewed OTI's policies and procedures for software tools used for software development, enhancements, testing, and error tracking, and configuration management and verified that OTI has established processes to evaluate the acceptability of these tools.

The NRC inspection team also discussed OTI's design control and software development processes with OTI's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that OTI has established its design control program in accordance with Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that OTI is implementing its policies and procedures consistent with the requirements of Criterion III of Appendix B to 10 CFR Part 50. No findings of significance were identified.

4. Test Control

a. Inspection Scope

The NRC inspection team reviewed OTI's policies and implementing procedures that govern the implementation of its test control program to verify compliance with the regulatory requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspection team reviewed the Software Verification and Validation plan (SVVP) and the Software Verification and Validation Report (SVVR) for ETAP 24.0.3N. The NRC inspection team verified that the (1) SVVP was developed in

accordance with OTI's SQAP, and (2) SVVR adequately summarized the results of the V&V and test activities, including disposition of any exceptions/anomalies identified during these activities. The NRC inspection team also reviewed the SVVP Review report, which documents the evaluation of the adequacy and completeness of the SVVP and implementation, and verified that the SVVP Review was performed in accordance OTI's SQAP.

The NRC inspection reviewed a select sample of (1) TDSs, (2) test design benchmarks, (3) test case specifications, (4) test logs, and (5) test summary reports for the uninterruptible power supply (UPS) and short circuit three phase modules of the ETAP software. The NRC inspection team verified that the test process provides specific procedures, criteria, and benchmarks for adequately testing the modules and software. The NRC inspection team further verified the testing validates that the software requirement specifications are met.

The NRC inspection team also discussed OTI's test control program and processes with OTI's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that OTI has established its test control program in accordance with Criterion XI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that OTI is implementing its policies and procedures consistent with the requirements of Criterion XI of Appendix B to 10 CFR Part 50. No findings of significance were identified.

5. Internal Audits

a. Inspection Scope

The NRC Inspection team reviewed OTI's policies and implementing procedures that govern its internal audit program to verify compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of OTI's internal audit plans, reports, and corrective actions generated during their internal audits. The NRC inspection team verified that the reviewed audit documents were adequately completed and that OTI adequately corrected the conditions identified in audit findings generated during internal audits. Additionally, the NRC inspection team verified that OTI's procedures described the scope and purpose of audits to be performed, the frequency, audit criteria, and corrective actions when required. The NRC inspection team verified that the audit teams were selected using qualified auditors and that they were not auditing their own work. The qualification records of the lead auditors conducting the audits were reviewed and verified that their qualification activities met OTI's requirements for lead auditors.

The NRC inspection team also reviewed the physical and functional audit report for the ETAP 24.0.3N release and verified that the (1) physical and functional audit for this release were conducted in accordance with OTI's software lifecycle processes and procedures, and (2) the audits were conducted by qualified individuals who did not perform the work being audited.

The NRC inspection team discussed the internal audits program with OTI's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that OTI has established its internal audits program in accordance with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that OTI is implementing its policies and procedures consistent with the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. No findings of significance were identified.

6. Entrance and Exit Meetings

On August 25, 2025, the NRC inspection team discussed the scope of the inspection during the entrance meeting with Tanuj Khandelwal, OTI's Chief Executive Officer, and other members of OTI management and technical staff. On August 29, 2025, the NRC inspection team presented the inspection results during an exit meeting with Tanuj Khandelwal and other members of OTI's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Position	Affiliation	Entrance	Exit	Interviewed
Jennifer Marinas	Director of Quality Assurance (QA)	Operation Technology, Incorporated (OTI)	X	X	X
Rachel Au	QA Assistant	OTI	X	X	X
Tanuj Khandelwal	Chief Executive Officer	OTI	X	X	X
Claudia Khandelwal	Trade Compliance Engineering Operations Manager	OTI	X	X	X
Tuan Lam	Chief Technology Officer	OTI	X		
Mohammed Zadeh	Vice President (V.P.) Engineering	OTI	X	X	X
Mary Beal	V.P. Sales	OTI	X	X	X
Weijia Wang	Principal Electrical Engineer	OTI			X
Mustafa Delshad	Principal Electrical Engineer	OTI			X
Viviana Le	Verification & Validation Test Manager	OTI	X	X	X
Ben Boronow	Senior V.P. of Development	OTI	X	X	

Name	Position	Affiliation	Entrance	Exit	Interviewed
Ricardo Duentas	R&O Coordinator, Test Manager, QA V&V Manager	OTI	X		X
Avelardo Morales	Department Manager, Low Voltage Senior Electrical Engineer	OTI	X		X
Alberto Marroquin	Chief Innovation Officer	OTI	X		X
Deanna Zhang	Inspection Team Leader	Nuclear Regulatory Commission (NRC)	X	X	
Yiu Law	Inspector	NRC	X*	X*	
Sheila Ray	Inspector	NRC	X*		
Tiffany Lee	Inspector	NRC	X	X	
Kerri Kavanagh	Branch Chief	NRC	X*	X	

*Remote

2. INSPECTION PROCEDURES USED:

- Inspection Procedure (IP) 43002, “Routine Inspections of Nuclear Vendors,” dated February 10, 2023
- IP 36100, “Inspection of 10 CFR Part 21 and Programs for Reporting of Defects and Noncompliance,” dated February 10, 2023

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901350/2025-201-01	Opened	Notice of Nonconformance (NON)	Criterion XVI of Appendix B to 10 CFR 50
99901350/2003-201-01	Closed	NON	Criteria I and V of Appendix B to 10 CFR 50
99901350/2003-201-02	Closed	NON	Criteria III, V and XVII of Appendix B to 1 CFR 50
99901350/2003-201-03	Closed	NON	Criteria III, V and XVII of

			Appendix B to 1 CFR 50
99901350/2003-201-04	Closed	NON	Criteria III, V and XVII of Appendix B to 10 CFR 50
99901350/2003-201-5	Closed	NON	Criterion XI of Appendix B to 10 CFR 50

4. DOCUMENTS REVIEWED

Quality Manual

Operation Technology, Inc. Quality Assurance Manual, Revision 23, dated January 30, 2024

Quality Assurance Procedures (QAP)

- ETAPQA20, “Incident Reports,” Revision 4, dated June 30, 2025
- ETAPQA50, “OTI Backup and Restore Procedure,” Revision 4, dated July 25, 2023
- ETAPQA90, “ETAP Quality records receipt, Storage, preservation and Safekeeping,” Revision 2, dated January 16, 2024
- ETAPQA100, “Internal Quality System Audits,” Revision 3, dated July 25, 2023
- ETAPQA200, “ETAP Life Cycle,” Revision 2, dated March 4, 2019
- ETAPQA300, “Software Requirements Specification Guideline,” Revision 0, dated November 11, 2013
- ETAP IT Security – Secure Development Life Cycle, Revision 1.1, dated June 19, 2025

Design and Test Documents

- Software Requirement Specification for ETAP24.03.N, Revision 30, dated March 19, 2025
- Software Verification and Validation Plan for ETAP 2024 v24.0.3N, Revision 0, dated June 11, 2025
- Software Verification and Validation Report for ETAP 24.0.3N, Revision 0, dated August 5, 2025
- Software Verification and Validation Plan Review for ETAP 24.0.3N, dated August 5, 2025
- ETAP 22.0.2N Postmortem Review, dated May 17, 2023
- ETAP 24.0.3N Postmortem Review, dated August 20, 2025
- Test Design Specification (TDS)-UBSC-001
- Test Case Benchmark (TCB)-UBSC-089, dated February 20, 2025
- Test Case Specification (TCS)-UBSC-089
- Test Log Activities and Event Entries (TL)-UBSC-001
- Test Summary Report (TSR)-UBSC, dated June 20, 2025
- TDS-UPS-001
- TCB-UPS-005, dated November 14, 2023
- TCS-UPS-005
- TL-UPS-001
- TSR-UPS, dated April 1, 2024

Audit Reports and Reviews

- Internal Quality Systems Audit Report, dated November 13, 2023
- Internal Quality Systems Audit Report, dated October 29, 2024

- ETAP 24.0.3N Physical and Functional Audit Report, dated August 12, 2025
- Quality Management System Review, dated November 17, 2023
- Quality Management System Review, dated November 6, 2024
- Controls & Measurement Review, dated November 17, 2023
- Controls & Measurement Review, dated November 6, 2024

Corrective Action Reports

- Audit Finding (AF)-191, dated December 8, 2023
- AF-192, dated September 19, 2024
- Error Reporting & Corrective Action (ERCA)-24-003, Revision 1, dated July 10, 2024
- ERCA-24-004, dated July 9, 2024
- ERCA-24-005, dated October 8, 2024
- AF-70, dated November 4, 2023

Incident Reports:

- Incident Report (IR)-97231, dated June 19, 2024
- IR-96931, dated June 3. 2024
- IR-96663, dated June 24, 2024

Corrective Action Reports Opened During the Inspection

- AF-193, AF-194, AF-195

Training Records

- Lead Auditor Qualifications for Jennifer Marinas
- Lead Auditor Qualifications for Mary Beal

Miscellaneous/Other

- INFR-03-008, “ETAP PowerStation 4.7.4N and Earlier Release,” dated August 4, 2003
- INFR-03-009, “ETAP PowerStation 4.7.4N and Earlier Release,” dated August 4, 2003
- INFR-03-010, “ETAP PowerStation 4.7.4N and Earlier Release,” dated August 4, 2003