



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001**

June 23, 2003

Mr. Farrokh Shokooh
President and CEO
Operation Technology, Incorporated
23692 Birtcher Drive
Lake Forest, California 92630

**SUBJECT: RESPONSE TO NRC INSPECTION REPORT 99901350/2003-201 and
NOTICE OF NONCONFORMANCE**

Dear Mr. Shokooh:

Thank you for your April 8, 2003, letter in response to the Notice of Nonconformance (NON) that was discussed in the subject U.S. Nuclear Regulatory Commission (NRC) Inspection Report. We have reviewed your letter and find that your reply to the five nonconformances did not appropriately address the stated nonconformances or actual weaknesses identified in Operation Technology, Incorporated (OTI) electrical transient analyzer program ETAP® PowerStation® (ETAP-PS) software program control, nor in some cases address the actual NRC concern.

As a result, you did not provide ample information to the NRC that would allow us to determine whether OTI has taken adequate steps to correct the identified nonconformances and whether you have taken appropriate steps to prevent recurrence. OTI's responses are discussed in the enclosure to this letter.

We noted in your response to nonconformance 04 and 05 that you stated "this item was discussed and agreed upon as a nonissue in the NRC exit meeting." NRC exit meeting results express the inspector's concerns and findings at the time of the exit. However, those results are subject to revision during the Inspection Report documentation phase and NRC senior management review. If any significant changes occur regarding what was discussed in the exit meeting the vendor or licensee is contacted, as you were prior to the NRC sending out Inspection Report 99901350/2003-201. Additionally, OTI has "strongly requested a documented clarification on a number of issues." Those issues, which were discussed with OTI during the NRC inspection, are also addressed in the enclosure to this letter.

As we previously stated in our March 7, 2003, letter which transmitted the Inspection Report, the NRC inspectors found that the establishment and implementation of OTI's quality assurance program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the inspectors determined that compliance with 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," that was contractually imposed on OTI by its nuclear utility customers was not met in certain areas. These failures to comply were characterized as nonconformances and were cited in the subject NON. The circumstances surrounding them were described in the NRC Inspection Report and are repeated in the enclosure to this letter.

Therefore, you are again requested to respond specifically to the identified nonconformances that were delineated in the NON in conjunction with the associated narrative contained in the Inspection Report and the attached enclosure when preparing your response.

Section 21.21, "Notification of a failure to comply or existence of a defect and its evaluation," requires each applicable entity to evaluate, as defined in §21.3 of 10 CFR Part 21, deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards in order to identify a reportable defect or substantial safety hazard, were it to remain uncorrected, and if the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to §21.21(a) of 10 CFR Part 21.

Therefore, you are again requested to determine whether any of the NRC inspector identified nonconformances or concerns are required to be evaluated pursuant to 10 CFR Part 21. For example, we found that OTI did not adequately address or respond to the inspectors findings that: (1) Bussmann® Fusetron FRN-R fuse curves obtained from the ETAP-PS library did not match the published vendor curves at each point as identified in Point Beach corrective action program document CAP029824; and (2) an OTI record review indicated that OTI engineers could accept slightly less than a 13% deviation between the vendor's information and data in the ETAP-PS library in a certain trip device curve but neither the appropriateness of, nor the circumstances surrounding the 13% deviation were reviewed by the NRC, the matter was referred to OTI. Therefore, each of the examples identified to OTI needs to be evaluated in accordance with the provisions of 10 CFR Part 21.

We are concerned that OTI did not adequately respond to the issues that were identified and stated in the NRC Report. Further, we are also concerned that we have identified some OTI responses to our Inspection Report that can be misleading, as discussed in the enclosure. The NRC's expectation in its dealings with NRC licensees and vendors is for candid and accurate discussions to be conducted in a straightforward manner. We presume that OTI will abide by that expectation and provide an adequate response to the issues that are stated in the previous and current NRC correspondence.

After receipt and review of your response to this letter and our inspection findings, we may decide to review the implementation of your corrective action during a future U.S. Nuclear Regulatory Commission staff inspection to determine that full compliance has been achieved and will be maintained or consider other regulatory action. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter will be placed in the NRC's Public Document Room (PDR).

Mr. F. Shokooh

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If you or your staff have any questions regarding this matter, we will be pleased to discuss them with you. Please contact Mr. Joseph Petrosino at (301) 415-2979, if you have any questions or need assistance regarding this matter.

Sincerely,

/RA/

Theodore R. Quay, Chief
Equipment and Human Performance Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosure: As stated.

Mr. F. Shokooh

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Enclosure: As stated.

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NRC DISCUSSION ADDRESSING OTI ATTACHMENT A RESPONSE TO IR 99901350/201

Nonconformance 99901350/2003-201-01:

The NRC staff has determined that OTI's reply to Nonconformance 99901350/2003-201-01 (nonconformance 201-01) did not adequately address the stated issue.

The staff also noted that OTI omitted an important portion of the stated nonconformance in its attachment that could be misleading in understanding the essence of the issue.

The NRC issue identified inadequately established quality assurance program controls/procedures. That is, nonconformance 201-01 stated:

As of January 8, 2003, OTI had not established 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 its ETAP® PowerStation® (ETAP-PS) software library design bases [emphasis added].

* The NRC Inspection report narrative (highlighted above) was omitted by OTI from its April 8, 2003, letter and can be misleading to the average reader because it removes an important aspect of the technical issue.

The essence of the NRC identified concern was that OTI's established program did not ensure that OEM's technical data, obtained from entities other than OEMs, was verified by OTI to assure its accuracy, correctness and completeness before inputting into its ETAP-PS software library design bases.

The OTI response stated "the present OTI QA program does require that original manufacturer data be used for library data. OTI's QA program also requires an independent verification of the library data entered in the program." However, this response misses the point of the issue.

The NRC inspectors found that OTI's QA program does not ensure that technical data, which it obtained from entities other than applicable OEMs, was verified to assure its accuracy, correctness and completeness before inputting the data into its ETAP-PS software library design bases. Section 3.2 of the NRC Inspection Report documented that OTI's 10 CFR Part 50 Appendix B quality program allowed OTI to accept data for use in its ETAP-PS library, from someone other than the OEM without OTI conducting any actions to verify that the obtained data was accurate, correct and complete.

The inspectors were informed by OTI staff that OTI obtained different vendor technical information from Tennessee Valley Authority (TVA) and that OTI did not have objective evidence indicating that its design basis library data for certain vendor components had been verified by OTI to ensure data accuracy, correctness and completeness. For example, the NRC Report states in part, that:

The inspectors verified that OTI received the Westinghouse overload heater, model FH, resistance data from TVA, as stated in Point Beach CAP029824, instead of obtaining it directly from the OEM, Westinghouse. The inspectors asked OTI what actions it had performed and what objective evidence they could

offer showing OTI's verification of the OEM data. Specifically, the inspectors asked whether OTI performed any quality assurance program actions such as, source evaluation, verifying/checking the adequacy and completeness of OEM data, engineering reviews or comparisons, auditing or other activities that would provide objective evidence of the acceptability of OEM's technical specifications from second and third party entities. This area was considered important because the OEM's technical data is used in ETAP-PS software, which is used in design basis calculations at NRC licensed facilities. If incorrect, it could affect the adequacy of plant design bases.

The inspectors found that the TVA supplied overload heater resistance data only contained a nominal value as compared with the minimum and maximum values that were supplied directly by the Cutler Hammer overload heater division (formerly a division of Westinghouse). Discussions with the OTI quality assurance manager determined that OTI did not perform or establish any measures to ensure that it performed independent verification of OEM data obtained from entities other than the OEM, such as TVA. The OTI staff stated that since the OEM's technical data came from TVA, an NRC licensee, they did not believe that any action was necessary to verify the accuracy, correctness or completeness of the TVA supplied data. As a result, OTI did not take any action to assess the effectiveness of the TVA quality assurance program controls that were used to control and supply the OEM technical data to OTI. As a result, the NRC inspectors were concerned about the effectiveness of OTI's quality assurance program control used to ensure the accuracy, completeness, and correctness of OEM technical information in its ETAP-PS library.

The NRC staff determined that OTI's corrective action, preventative action and implementation provided to the NRC was not responsive to Nonconformance 201-01. OTI is requested to respond specifically to Nonconformance 201-01. The staff expects that OTI's response will specifically address the aspects requested in the NRC's Notice of Nonconformance, for example: (1) provide a description of steps that have been or will be taken to correct the inadequately established QA program controls/procedures; (2) provide a description of steps that have been or will be taken to prevent recurrence of accepting OEM data from second party entities without verifying the accuracy, correctness and completeness before inputting into your library, and (3) provide the dates your corrective actions and preventive measures were or will be completed.

Nonconformance 99901350/201-02:

The NRC staff has determined that OTI's reply to Nonconformance 201-02 did not adequately address or respond to the stated details of Nonconformance 201-02. Instead, OTI's reply states: "refer to the reply to Item 99901350/2003-201-01." Nonconformance 201-02 stated:

As of January 8, 2003, OTI had failed to ensure that original equipment manufacturer's (OEM's) technical data, that it obtained from entities other than applicable OEMs, was verified in accordance with [its own] 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. Examples of manufacturers' technical data that OTI obtained from other entities included:

- 3M Firewrap® Values
- TSI Thermo-Lag® Values
- Westinghouse Overload Heater Values

This issue is discussed in detail within Section 3.2 of the NRC Report. The inspectors determined that OTI failed to take any recognized quality assurance program measures to provide reasonable assurance that technical data from entities other than the applicable OEM was verified in accordance with OTI documented procedures to assure its accuracy, correctness and completeness before inputting the data into its ETAP-PS software library design bases.

The inspectors also determined that OTI failed to ensure that sufficient QA records were maintained for objective evidence of activities affecting quality. OTI did not have objective evidence indicating that its design basis library data for certain vendor components had been verified by OTI to ensure data accuracy, correctness and completeness because OTI staff stated that they did not take any action regarding verification activities. For example, the NRC Report states:

The inspectors determined that the ETAP-PS library contains only two fire protection encapsulation type components, 3M type 20A Firewrap® and Thermal Science, Incorporated Thermo-Lag®. However, it was noted during discussions with OTI staff that both fire resistant products technical specification data was also obtained from TVA instead of the applicable OEMs. Although neither Firewrap® nor Thermo-Lag® is used at Point Beach, the inspectors performed a review of this area relevant to the source and control of the OEM data by OTI.

The inspectors conducted discussions with OTI to assess OTI's control of the technical data from TVA. OTI stated that it did not take any action to verify the accuracy, correctness, nor completeness of the Thermo-Lag® or Firewrap® technical data directly either through a verification process of the supplying entity or by obtaining the data from the OEM.

The inspector's review of OTI's library data source for the firewrap material determined that OTI did not take any steps to verify the incoming OEM's product data. This was characterized as an example of safety-related component design parameters that OTI assumed was correct, complete and accurate for use in its ETAP-PS software without performing verification activities.

Since OTI has not responded to the specific concerns identified in Nonconformance 201-02, OTI is requested to review the identified concerns and reply accordingly. OTI is also requested to respond to the following NON requests: (1) provide a description of steps that have been or will be taken to correct these items (e.g., verify that OEM data received from non-OEMs is verified in accordance with OTI documented procedures to assure the data was accurate, correct and complete prior to entering into ETAP-PS design bases); (2) provide a description of steps that have been or will be taken to prevent recurrence (e.g., ensuring that OTI's procedures have adequate controls to ensure that recurrence is prevented through better QA controls); and (3) provide the dates your corrective actions and preventive measures were or will be completed.

Therefore, OTI is requested to respond to the stated concern that is identified in Nonconformance 201-02 and its associated NRC Report details.

Nonconformance 99901350/2003-201-03:

OTI's reply to Nonconformance 201-03 disagrees with the finding and states that the NRC inspectors did not compare the correct ETAP cable library data with the data selected from the ICEA-P-46-426.

The NRC inspectors determined that OTI did not address the essence of the issue which was "the **base ampacity values** obtained from the ETAP-PS library **corresponded with ICEA** ampacity values for all values sampled **except for some free air applications** [emphasis added]." As a result of that finding, Nonconformance 201-03 was identified. The finding was that:

OTI failed to ensure that its ETAP-PS library base ampacity values 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.

The NRC inspectors worked in conjunction with OTI staff to compare the ETAP cable library data and the inspector's conclusions were based upon direct interaction with the OTI staff during the January 6-8, 2003, inspection at OTI. For example, the NRC Report stated:

The inspectors conducted discussions with OTI engineering staff, reviewed cable ampacity values, and compared the ETAP-PS library values to the ICEA Standards ampacity values. The inspectors reviewed library data for the cable ampacity values for different size cables and applications, such as values for: Duct Bank, Buried cable, Free Air, and Conduit in free air.

The inspectors determined that the base ampacity values obtained from the ETAP-PS library corresponded with ICEA ampacity values for all values sampled except for some free air applications. [As a result,] the inspectors informed OTI that it should review its library data for the free air application to determine whether they need to take action applicable to 10 CFR Part 21.

The inspectors informed OTI that it needed to verify the correctness of its ampacity values for free air applications against the ICEA Standard. The incorrect value is considered as an example of a QA process control implementation weakness in the OTI design control area.

This aspect was documented in Section 3.2.2 of the Inspection Report. Additionally, OTI stated in its April 8, 2003, letter, that:

The [NRC] Inspector did not compare the correct ETAP cable library data with the data selected from the ICEA P-46-426 Standard. The Inspector must select non-magnetic installed cables for comparison of the free air ampacities.

The OTI staff provided only magnetic installation examples to the NRC inspectors for its review of the ampacity issues. No non-magnetic installation examples were offered or provided to the NRC inspectors. As documented in the Inspection Report, the NRC inspectors worked with OTI staff throughout the inspection to gain their understanding of the matters being reviewed and worked with them to navigate through the ETAP program software issues. For this issue, it was explained to OTI staff what was needed to be verified or reviewed. As a result, the OTI staff demonstrated what was required and provided the NRC inspectors with four cable ampacity library examples, two 600 volt, magnetic installation, and two 5,000 volt, magnetic installation.

It is expected that OTI has taken, or will take, action in regard to its library data for the free air application to determine whether any deviations are, or were existing, to cause an evaluation, as defined in §21.3 of 10 CFR Part 21, to be performed and to inform end users if applicable. Additionally, OTI has not addressed or proposed actions to prevent recurrence and its “future enhancement” statement appears to need additional clarification.

Therefore, the NRC staff requests OTI to specifically address the items discussed above that are still of concern to the NRC regarding OTI’s compliance with NRC regulations.

Nonconformance 99901350/2003-201-04:

OTI disagrees with Nonconformance 201-04. The finding was:

As of January 8, 2003, OTI could not provide adequate objective evidence which indicated their regression test verified the adequacy of ETAP-PS version 4.0.0N even though it was corrected by TCS-CAB-016.

The NRC report indicated that:

OTI stated that it conducts a complete set of regression tests for each new version of ETAP-PS. These tests are intended to address all functions of ETAP-PS, and are verified by the appropriate vendors’ product development organizations. The inspectors were provided with a listing of the regression test cases. The extensive number of ETAP-PS functional requirements and corresponding test cases was such that, over the inspection period, the inspectors could not conclude that all software requirements are tested per the OTI’s software quality assurance procedures. However, given the error that was to be corrected by task TCS-CAB-016, which should have been detected by testing prior to the release of ETAP-PS version 4.0.0N, the inspectors could not conclude that all functions are validated for each new version of ETAP-PS.

The inspectors reviewed TIR-CABLE-190, dated April 22, 2002, applicable to ETAP-PS version 4.0.4; and Task TCS-CAB-016 and its associated test plan, TPS-CAB-016, which consisted of a listing of the affected software Requirements, consisting of Section 3.1.70, Cable-Sizing, requirements’ 1.10, 1.13-1.23, and a description of the test procedure. On the basis of the documentation provided in the test results report, the inspectors could not verify that all options of the program were tested for the Cable Sizing Modifications in ETAP-PS version 4.0.0N, and could not verify the test results for the ETAP-PS version 4.7.0N, “Cable Sizing Modifications,” because these results were not included in the modification package. The inspectors identified that even though the cable sizing modification results were not included in the modification packages in both versions of ETAP-PS, the packages were approved by the appropriate managers.

The Software Verification and Validation Report (SVVR) documentation was not included in the TIR package, as required by the vendor’s quality assurance program. The objective evidence of V&V results that was included in the TIR package for the temporary change consisted of test results documentation that verified the function had been disabled. The test results for the temporary correction consisted of several pages of ETAP-PS screen images from a computer display depicting the results of the test using the corrected program.

The temporary correction was checked as "Passed" by A.M. on April 23, 2002. The Tester ID was AM-187. This task was assigned Modification Request (MR) 1131.

Appendix B Criterion III requires that, where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the test program shall include suitable qualifications testing of a prototype unit under the most adverse design conditions. The inspectors concluded that OTI was not in conformance with Criterion III of Appendix B, in that the set of regression tests used to verify the adequacy of design did not detect the failure in ETAP-PS version 4.0.0N that was corrected by TCS-CAB-016.

Therefore, the NRC staff requests OTI to specifically address the concern that is documented regarding OTI's compliance with NRC regulations.

Nonconformance 99901350/2003-201-05:

OTI disagrees with Nonconformance 201-05. The finding was:

As of January 8, 2003, OTI failed to ensure that adequate records were developed and maintained **to provide objective evidence of test results.** [*] Specifically, test results for two tests, TIR-CABLE-190 and TCS-CAB-016 (TPS-CAB-016), did not contain adequate documentation in their applicable test packages to provide evidence of satisfactory test performance to assure that test requirements had been satisfied [emphasis added].

* The NRC Inspection report narrative (highlighted above) was omitted by OTI from its April 8, 2003, letter and can be misleading to a reader because it removes an important aspect of the technical issue.

Even though OTI disagrees with the NRC nonconformance and even though OTI has omitted a portion of the narrative that identified the crux of the issue, "to provide objective evidence of test results," OTI's stated corrective action in its response appears to address the NRC concern for this issue. Elements of the concern as stated in the NRC Inspection report are:

The inspectors identified that the test procedure documentation was not consistent with the test procedure documentation in OTI's test procedure library, which controlled the testing of other ETAP-PS functional requirements. As a result, the inspectors could not verify that the vendor had appropriately verified the test procedure before performing the validation testing for this functional requirement. Further, even though OTI has procedures for coordinating among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces, as required by 10 CFR Part 50 Appendix B Criterion III, "Design Control," and Criterion XI, "Test Control," the inspectors did not find any objective evidence to show the activities were satisfactorily accomplished in accordance with the requirements.

Additionally, since the test results were not recorded in one test documentation package, and a test procedure was not documented in another test package, the inspectors concluded that the two tests that were reviewed by the inspectors were not controlled in accordance with Appendix B, Criterion XI, "Test Control."

Criterion XI requires that test results be documented and evaluated to assure that test requirements have been satisfied. Since OTI did not record the test results in the test documentation package, the inspectors could not verify that OTI had independently verified the test results for those two tests, as required.

Therefore, this issue is considered closed and no further action is warranted for Nonconformance 99901350/2003-201-05.

NRC DISCUSSION ADDRESSING OTI ATTACHMENT B STATEMENTS

3.2.1 of 99901350/201:

That section of the NRC IR stated:

Although it was determined that overload heater resistance values in the ETAP-PS library are within the maximum and minimum values provided by the manufacturer, it was determined that, for voltage drop calculations, slightly non-conservative results will be obtained using ETAP-PS library data. Therefore, it was noted to OTI that its library values for heaters did not contain both maximum (for voltage drop calculation) and minimum (for short circuit calculation) values, in all cases.

OTI concluded that they have added an option to include a tolerance for the overload heater resistance to their "wish list" for the ETAP 5.0.0 release.

This appears to be an appropriate response to address any recurrence of the non-conservative results. However, as discussed in the cover page of this letter, OTI is still required to evaluate or inform end users pursuant to the provisions of 10 CFR Part 21.

3.2.4.1.b of 99901350/201:

That section of the NRC IR stated:

The inspectors reviewed records associated with Amptector 1A and conducted discussions with OTI personnel. The inspectors determined that ETAP-PS Power Plot version 2.5, Release 056 did not include all of the manufacturer's field settings. It was determined that a subsequent version, ETAP-PS 4.0.4 Release 076 dated May 16, 2002, was enhanced to include additional settings. The Amptector 1A TCCs, obtained from Westinghouse, matched the ETAP-PS TCC values with some deviation noted. Although the issue in the CAP was confirmed by the inspectors, this represented an ETAP-PS capability function limitation; not a nonconformance.

However, [during this review] a different concern was identified by the inspectors. The inspectors identified that **OTI engineers could accept up to a 13% deviation** [emphasis added] between the vendor's information and data in the ETAP-PS library. The inspectors considered this to be an excessive amount of deviation but did not review the appropriateness of the 13% deviation nor the circumstances surrounding the acceptability during this inspection. Therefore,

the issue of the 13% allowable deviation in this area needs to be reviewed by OTI in accordance with §21.21 of 10 CFR Part 21 to determine whether end users need to be informed of this matter.

However, OTI's April 8, 2003, response expressed that:

The above statement [in section 3.2.4.1.b] regarding ETAP libraries is incorrect... In the case of solid-state trip device curves the deviation of less than 13% is allowed.

OTI was informed that the NRC inspector's did not review the appropriateness of the 13% deviation nor the circumstances surrounding the acceptability during this inspection. The issue should therefore, not be whether the allowable deviation is either **up to a 13% deviation** [as stated by the NRC], or **less than a 13% deviation** [as stated by OTI]. Instead, the NRC staff stresses to OTI that the issue is compliance with the provisions of 10 CFR Part 21 and OTI's 10 CFR Part 50, Appendix B quality assurance program.

OTI's statement is misleading the focus of the issue. The NRC has requested OTI to evaluate or inform end users, as discussed in this letter, of the 13% deviation policy to determine the appropriateness of the matter and whether end users need to be informed.

The NRC's expectation in its dealings with NRC licensees and nuclear industry vendors is for candid and accurate discussions in a straightforward manner. We anticipate that OTI will abide by that expectation and provide an adequate response to this issue.

3.2.6.b of 99901350/201:

The justification that OTI has provided for the relevant observation does not address what was requested by the NRC to ensure that the intent of 10 CFR Part 21 is met. The NRC Report stated that this area needs to be reviewed in accordance with §21.21 of 10 CFR Part 21 to determine whether customers need to be informed of this matter.

That section of the NRC IR stated:

[As a result of the observations of, and discussions with, the OTI personnel] the inspectors concluded that it is possible that higher non-conservative battery voltages can be obtained by end users when using the fixed current (fixed amp =1) method. Conversely, the inspectors noted that acceptable results can be obtained in ETAP-PS when using the fixed ampere-hour method (fixed amp = 0). This area needs to be reviewed in accordance with §21.21 of 10 CFR Part 21 to determine whether customers need to be informed of this matter.

The NRC expects that OTI will address this observation as requested to ensure compliance with its 10 CFR Part 50, Appendix B quality assurance program.