

October 31, 2003

Mr. Farrokh Shokooh
President and CEO
Operation Technology, Incorporated
17 Goodyear
Irvine, California 92618-1812

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 99901350/2003-201,
NOTICE OF NONCONFORMANCE AND JUNE 23, 2003, NRC LETTER

Dear Mr. Shokooh:

Thank you for your August 14, 2003, letter in response to the Notice of Nonconformance (NON) that was discussed in the subject U.S. Nuclear Regulatory Commission (NRC) Inspection Report and our subsequent letter, dated June 23, 2003. We have reviewed your letter and find that your August 14, 2003, reply partially addressed the NRC concerns regarding the Operation Technology, Incorporated (OTI) electrical transient analyzer program ETAP® PowerStation® (ETAP-PS) software program control. As discussed in the enclosure to this letter, NRC staff concerns have not been resolved for every issue. Therefore, we look forward to your prompt response to resolve the remaining concerns that are discussed in this letter and enclosure.

Our June 23, 2003, letter repeated our request that OTI evaluate the results of the OTI review of the 10 CFR Part 50, Appendix B concerns identified during the NRC inspection in accordance with 10 CFR Part 21. However, your August 14, 2003, response did not specifically state or respond, for each issue, whether or not OTI performed a 10 CFR Part 21 *evaluation*, nor did OTI state that it did not have the capability to perform the required *evaluation* and informed its end users so that end users could cause an *evaluation* to be performed in accordance with the provisions of 10 CFR Part 21. Therefore, we request that OTI state, for each issue, whether or not OTI performed a 10 CFR Part 21 *evaluation*, as defined in §21.3 of 10 CFR Part 21, or informed the applicable NRC licensees of this *deviation*, in accordance with the provisions of 10 CFR Part 21.

You are requested to respond to the identified concerns and requests within 30 days of the date of this letter. This information is necessary for the NRC to determine if OTI was, or currently is, in violation of 10 CFR Part 21 regulations. After receipt and review of your response to this letter we may decide to review the implementation of your corrective action during a future NRC staff inspection to determine that full compliance has been achieved and will be maintained or may consider other regulatory action.

NRC inspectors have identified that nuclear industry vendors do not fully understand the meaning of "*evaluation*," as defined in §21.3 of 10 CFR Part 21. Part 21 states that an ***evaluation*** means "the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard." The NRC inspectors find that most vendors are usually not aware of the

specific application of their products or services at NRC licensed nuclear power facilities and, therefore, usually do not have the capability to "evaluate" deviations pursuant to Part 21. Although individual vendors are well aware of their product design, materials, and services, the NRC staff has found that most vendors do not appropriately evaluate identified deviations or failures to comply, as they could relate to the specific licensee applications, system interactions, technical specification requirements, exceeding safety limits or other NRC license requirements.

Further, §21.21(b) states, in part, that if the deviation or failure to comply is discovered by a supplier of basic components, or services 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. Please note that failure to perform required/adequate *evaluations* of identified deviations or failure to inform end users of deviations, if an entity does not have the capability to perform the required *evaluation*, are violations of 10 CFR Part 21.

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). If you or your staff has any questions regarding this matter, we will be pleased to discuss them with you. Please contact Mr. Gregory Cwalina at (301) 415-2983, if you have any questions or need assistance regarding this matter.

Sincerely,

/RA/

Theodore R. Quay, Chief
Emergency Preparedness and Plant Support Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosure: As stated.

specific application of their products or services at NRC licensed nuclear power facilities and, therefore, usually do not have the capability to "evaluate" deviations pursuant to Part 21. Although individual vendors are well aware of their product design, materials, and services, the NRC staff has found that most vendors do not appropriately evaluate identified deviations or failures to comply, as they could relate to the specific licensee applications, system interactions, technical specification requirements, exceeding safety limits or other NRC license requirements.

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Sincerely,

Original signed by:

Theodore R. Quay, Chief
Emergency Preparedness and Plant Support Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosure: As stated.

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STATUS OF NONCONFORMANCE ISSUES REGARDING OTI's RESPONSE TO IR99901350/2003-201

A. Nonconformance 99901350/2003-201-01 OPEN

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. The OTI response states library data shall be obtained from the OEM's technical data, applicable standards, or calculated values. Please respond to the following:

- 1) Does OTI intend to obtain ETAP library values from its own calculations?
- 2) Where/how are the calculated values derived from and will they form part of the basis for the library data?
- 3) Does OTI intend to verify the calculated data values in accordance with 10 CFR Part 50, Appendix B, quality assurance controls?

OTI indicated that it established new procedures for its corrective and preventive action and those actions that were established for verification and validation of ETAP library data will be reflected in your ETAP 5.0 release. However, it appears that the adequacy of the library data prior to OTI's corrective action could be indeterminate in some cases; therefore:

- 4) Has OTI performed a 10 CFR Part 21 "*evaluation*," as defined in §21.3 of 10 CFR Part 21, of a potentially indeterminate condition for the adequacy of the library data prior to OTI's corrective action, or has OTI informed its end users if OTI determined that it does not have the capability to perform the *evaluation* to determine if a defect exists?

B. Nonconformance 99901350/201-02: OPEN

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue.

- 1) Has OTI performed a 10 CFR Part 21 *evaluation*, as explained to OTI in our June 23, 2003, letter or informed its end users of this *deviation*, in accordance with the provisions of 10 CFR Part 21, if OTI determined that it does not have the capability to perform the *evaluation* to determine if a defect exists?

C. Nonconformance 99901350/2003-201-03: OPEN

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. The August 14, 2003, OTI corrective action, preventive action, and implementation stated:

Corrective Action: To avoid any possible confusion for 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 trays), which assumes that the cable tray is continuously surrounding the cable and is creating circulating currents.

Preventive Action: ETAP 5.0 will include the information that describes the application of ICEA P-54-440 Cable Base Ampacities. Including all the details that inform the users about the application of magnetically installed cables in free air (cable trays).

Implementation: These changes will be implemented in ETAP 5.0.

OTI's corrective and preventive actions describe steps that OTI has taken to correct **future** problems and **to prevent recurrence**. However, it does not appear that OTI has taken steps to correct **existing/past** problems at licensee facilities that may have used the wrong table for the ETAP-PS library base ampacity values for "free air" applications.

- 1) Has OTI performed a 10 CFR Part 21 *evaluation*, of this matter, as explained to OTI in our June 23, 2003, letter or informed its end users of the **existing/past** potential library base ampacity *deviation*, in accordance with the provisions of 10 CFR Part 21, if OTI determined that it does not have the capability to perform the required *evaluation* to determine if a defect exists?

D. **Nonconformance 99901350/2003-201-04:** **OPEN**

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue.

- 1) Has OTI performed a 10 CFR Part 21 *evaluation*, as explained to OTI in our June 23, 2003, letter or informed its end users of this *deviation* regarding **existing/past** problems, in accordance with 10 CFR Part 21, if OTI determined that it does not have the capability to perform the *evaluation* to determine if a defect exists?

E. **Nonconformance 99901350/2003-201-05:** **CLOSED**

**ADDITIONAL QUESTIONS/COMMENTS REGARDING
OTI's RESPONSE TO IR9901350/2003/201 IDENTIFIED CONCERNS**

F. 3.1 of 99901350/2003-201:

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. NRC's June 23, 2003, response to OTI stated:

The NRC inspectors concluded that the OTI Part 21 program and procedures that it has adopted to implement the provisions of 10 CFR Part 21 were generally acceptable with only minor procedural clarification that was noted to OTI. No violations of 10 CFR Part 21 were characterized in this area. However, it was noted to OTI that they are required to evaluate the results of their review of the 10 CFR Part 50, Appendix B concerns identified during this inspection in accordance with the provisions of 10 CFR Part 21.

OTI's August 14, 2003 response to the June 23, 2003, letter stated:

The above-specified changes for the procedures are implemented at this time. The modifications and clarifications will be included in the next revision of the OTI QA Manual that will be issued and distributed to all nuclear users in the near future.

Although it was stated to OTI "that they are required to evaluate the results of their review of the 10 CFR Part 50, Appendix B concerns identified during this inspection in accordance with 10 CFR Part 21," OTI did not specifically state or address, for every issue, whether or not OTI performed a 10 CFR Part 21 *evaluation*, as explained to OTI in our June 23, 2003, letter or if OTI determined that it did not have the capability to perform the required *evaluation*, that it inform its end users so that they may cause an *evaluation* to be performed in accordance with the provisions of 10 CFR Part 21.

Please note that failure to perform required/adequate *evaluations* of identified deviations or failure to inform end users of deviations, if an entity does not have the capability to perform the required *evaluation*, are violations of 10 CFR Part 21.

Please state, for each issue indicated, whether or not OTI performed an "*evaluation*," as defined in §21.3 of 10 CFR Part 21, or informed the applicable NRC licensees of any deviations, in accordance with the provisions of 10 CFR Part 21.

G. 3.2.1 of 99901350/2003-201:

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. OTI's corrective and preventive actions, stated:

Corrective Action: An informative report (INFR-03-008) has been distributed to all ETAP Nuclear Users to inform them about the current way that ETAP handles overload heater resistance values for load flow calculations [emphasis added].

Preventive Action: Additional fields will be added to the program to account for the maximum and minimum values of the overload heater resistance. The load flow and short circuit type analysis will use the resistance value that yields the most conservative results [emphasis added].

- 1) Did OTI's informative report (INFR) 03-008, address to the end users that past applications of the program may require an *evaluation*, as defined in §21.3 of 10 CFR Part 21, for past/existing applications at licensee facilities?
- 2) Was the issuance of INFR-03-008, performed, in part, as a result of OTI's compliance with the provisions of 10 CFR Part 21?
- 3) Please provide a copy of INFR-03-008 with your reply to this letter.

H. 3.2.4.1.b of 99901350/2003-201:

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. OTI's corrective and preventive actions, stated:

Corrective Action: An informative report (INFR-03-009) has been distributed to all ETAP Nuclear Users to inform them about the verification and validation procedures for ETAP libraries and the circumstances surrounding the allowed % deviations.

Preventive Action: ETAP STAR is a new protective device coordination program. For this new version, the entire library data have been recreated for the Time Current Curve libraries with improved techniques for collecting and entering the data. The re-evaluation along with improved techniques will reduce the % deviation from OEM data.

- 1) Did OTI's informative report (INFR) 03-009, address to the end users that past verification and validation procedures for ETAP libraries and the circumstances surrounding the allowed percentage *deviations* may require an *evaluation*, for past/existing applications at licensee facilities, pursuant to the provisions of 10 CFR Part 21?
- 2) Was the issuance of INFR-03-009, performed, in part, as a result of OTI's compliance with the provisions of 10 CFR Part 21?
- 3) Please provide a copy of INFR-03-009 with your reply to this letter.

I. **3.2.4.3 of 99901350/2003-201**

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. As stated in Section 3.2.4.3 of NRC Inspection Report 99901350/2003-201:

The inspectors concluded that Bussmann® Fusetron FRN-R fuse curves obtained from the ETAP-PS library **did not match** the published **vendor curves at each point**. **“The inspectors** characterized this as a weakness and **requested** OTI to **review its library fuse data obtained from other vendors** to determine whether this is an **isolated case or other examples exist** such that OTI needs to inform its end users of discrepancies in accordance with the provisions of 10 CFR Part 21. [The NRC Report stated]: A comparison of TCCs identified that the curves did not match as identified in Point Beach CAP029824. However, further review showed that correlation existed between Power Plot curves and manufacturers’ curves at several particular points (i.e., 0.01, 0.1, 1.0, 10, 100, and 1000 seconds). That is, although **some sections of the TCCs matched, others did not**. It was noted that some of the readings appeared to be non-conservative and this was discussed with the OTI personnel. The inspectors did not attempt to perform any verification for the intermediate points (e.g., 2 seconds to 8 seconds). As a result of the finding regarding the TCCs, the inspectors informed OTI that it should perform a review of the discrepancies relating to the manufacturers’ fuse curves in accordance with its 10 CFR Part 21 program requirements [emphasis added].

OTI’s August 14, 2003, response stated:

The curves for Bussmann® Fusetron FRN-R type fuses have been re-evaluated and it has been determined that they are correct when compared to the original equipment manufacturer’s TCCs. OTI provides a list of the FRN-R sizes that have been verified and validated.

OTI did not state whether its library fuse data obtained from **other vendors** exhibited the same problems which the NRC inspectors identified or whether the Fusetron example was isolated, nor did OTI state whether end users were informed of the deviations so end users could cause a deviation of **past/previous** applications to be performed. Since the NRC staff specifically verified that the **Fusetron FRN-R fuse curves** obtained **from** the ETAP-PS **library did not match** the Bussmann® published curves **at each point (some sections of the TCCs matched and others did not)**, it is not clear how OTI’s re-evaluation determined that the ETAP-PS library data was correct and OTI’s conclusions were different from the NRC conclusion.

- 1) Please explain how OTI’s re-evaluation for the Bussmann’s **entire fuse curves** determined that the ETAP-PS library data was correct when compared to the same vendor’s TCCs.
- 2) Please state what was identified as a result of OTI’s verification effort for **other** vendor’s **entire fuse curves** pertaining to the ETAP-PS library data.

- 3) Has OTI performed a 10 CFR Part 21 *evaluation*, as explained to OTI in our June 23, 2003, letter or informed its end users of this *deviation* regarding **existing/past** problems, in accordance with 10 CFR Part 21, if OTI determined that it does not have the capability to perform the *evaluation* to determine if a defect exists?

J. **3.2.6.b of 99901350/2003-201:**

The OTI corrective and preventive actions for this issue appear to be only partially responsive. The NRC staff requests additional information regarding this issue. OTI's corrective action, stated:

Corrective Action: An informative report (INFR-03-010) has been distributed to all ETAP Nuclear Users to inform them about the differences between the two methods. The technical notes explain the methodology used and the advantages/disadvantages of either method. This will help the engineers to select the most appropriate ETAP battery discharge method for the simulation of their particular battery load profile.

Preventive Action: The option for selecting either interpolation method will be placed directly on the Battery Discharge Study Case. Users should check critical results that are close to acceptance criteria values with both methods to ensure that the worst case is covered.

Implementation: ETAP 5.0 will have the options for selecting the interpolation method directly from the Battery Discharge Study Case.

- 1) Did OTI's informative report INFR-03-010, address to the end users that **past** licensees use of the ETAP battery discharge calculation could have inadvertently provided non-conservative values that may require an *evaluation* for **past/existing** applications at licensee facilities, in accordance with the provisions of 10 CFR Part 21?
- 2) Was the issuance of INFR-03-010, performed, in part, as a result of OTI's compliance with the provisions of 10 CFR Part 21?
- 3) Please provide a copy of INFR-03-010 with your reply to this letter.