



December 9, 2003

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

SUBJECT: REPLY TO A NOTICE OF NONCONFORMANCE - 99901350/2003-201

Dear Mr. Quay:

Thank you for your report dated October 31, 2003. According to this report, you have required further clarifications to OTI's responses. After careful review of the NRC's report, we are presenting the enclosed responses to your inquiries.

Based on the requirements of 10 CFR Part 21 and OTI's Quality Assurance programs, OTI's responsible authorities continually perform 10 CFR Part 21 deviation assessment for all concerns, which are reported, based on internal tests or incidents received from ETAP users.

The scope of the deviation assessment performed by OTI includes the effect of the deviation in the calculation results and/or accuracy of library data. In the event that the deviation assessment determines that the severity of the problem and/or deficiency could cause minor or substantial effect on the ETAP basic results, OTI notifies all ETAP nuclear users, in writing, and within five working days of OTI's determination that a deviation exists.

In a letter accompanied with an Error Report we request ETAP nuclear users to evaluate the reported error in accordance with §21.21 of 10 CFR Part 21. Therefore, by generating error reports, OTI informs its nuclear users so that nuclear users could cause an evaluation to be performed in accordance with the provisions of 10 CFR Part 21. We also request that if a nuclear users have used the module and/or capabilities specified in the Error Report, and have determine that it requires 10 CFR Part 21 reporting, contact us immediately. If we do not hear from nuclear users, the classification of the reported error will remain as reported. Nuclear users are requested to acknowledge the receipt of the Error Reports.

In closing, we would like to thank Mr. Joseph J. Petrosino, and Mr. Gregory Cwalina for their assistance in clarification of the open issues.

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Should you have further questions or require additional information please contact me at (949) 462-0100 or send your e-mail to qa@etap.com.

Sincerely,
Nazan Roshdich, PE

A handwritten signature in black ink that reads "Nazan Roshdich".

Quality Assurance Manager
OPERATION TECHNOLOGY, INC.

CC: Chief, Equipment and Human Performance Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation
Washington, D.C. 20555



RESPONSE TO IR99901350/2003-201

For further clarification of our responses to NRC issues, we would like to describe the purpose of OTI's Informative Reports.

Informative Reports

As a result of OTI's 10 CFR Part 21 deviation assessment, OTI may issue Informative Reports. Informative Reports are not categorized as error reports by OTI. Informative Reports describe program operations, applications, enhancements, and/or limitations and they serve as an extension of the ETAP User Guide and ETAP Help. It is our intention to use this report to communicate any helpful information or clarifications to ETAP nuclear users. Informative Reports are distributed to all applicable nuclear users. In the letter accompanied with the Informative Reports, nuclear users are requested to evaluate the Informative Reports in the same manner as error reports. Nuclear users are requested to acknowledge the receipt of the Informative Reports similar to the response for error reports.

Please note the following responses for the NRC concerns.

Nonconformance 99901350/2003-201-01

NRC: A. "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 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: Calculated values in the ETAP libraries are based on OEM technical data or applicable standards. Calculations are mainly for the purpose of conversion and are based on approved industry standards. For example, if a library requires data for Power Factor (PF) and the manufacturer documents provide kVA and kW values, then PF is calculated by the following equation: $PF = kW/kVA$. Note that the bases for the calculated values are included in the *Guidelines for Entering Library Data* documents, which are reviewed and approved. All ETAP calculations, including library data, are verified & validated in accordance with 10 CFR 50, Appendix B, quality assurance controls.

NRC: "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 capability to perform the *evaluation* to determine if a defect exists?"

OTI: All library data entered in the ETAP program have been verified & validated prior to each release. For all ETAP library data, original manufacturer data are directly obtained from the manufacturer or standards as source of the data. OTI's quality assurance program has always required an independent verification of the library data entered in the program.

In the case of the Fire Coating and Fire Wrap libraries, OTI has informed its nuclear users that the original manufacturer data has been provided by Tennessee Valley Authorities (TVA). This information was conveyed to nuclear users with the ETAP 4.7.4N documents and issuance of an Informative Report (INFR-03-012).

The newly added quality assurance procedure titled "Verification & Validation of ETAP Library Data", which was described in OTI's response dated August 14, 2003, was based on NRC's audit and recommendations and is considered as an enhancement to our current quality assurance procedures.

OTI has performed a 10 CFR Part 21 deviation assessment of this issue. Based on the adequacy of OTI's methods for library data verification, in the past and present, we assert that all known errors in the ETAP library data have been reported in accordance 10 CFR Part 21 requirements at this time.

Nonconformance 99901350/2003-201-02

NRC: B. "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 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?"

OTI: OTI has performed a 10 CFR Part 21 deviation assessment of this issue. As a result of this assessment, OTI has informed ETAP nuclear users that the original manufacturer data for Fire Coating and Fire Wrap libraries were provided to OTI by Tennessee Valley Authorities (TVA). This information was conveyed to nuclear users with the ETAP 4.7.4N package and issuance of an Informative Report (INFR-03-012). Informative Reports include information regarding the effected ETAP revisions.

Per OTI's phone discussion with Mr. Joe Petrosino and Mr. Gregory Cwalina, on December 1, 2003, attachment of INFR-03-012 report is not required.



Nonconformance 99901350/2003-201-03

NRC: C. "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 provision 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?"

OTI: As described in the OTI's response dated August 14, 2003, there are no errors in the cable ampacity data. Our approach to add more information in the ETAP User Guide is simply providing more engineering background to our users. Note that the purpose of ETAP User Guide is providing instruction for the use of the ETAP program.

In addition, as described in August 14, 2003 response "...ETAP does not use the library Base Ampacities (free air) to perform the ICEA Ampacity calculations in cable trays. For trays, ETAP calculates the cable Ampacities based on the methodology described in ICEA P-54-440. This calculation is based on the physical parameters that describe the configuration of the cable tray. The Base Ampacities (for free air) provided in the ICEA P-46-426 are not useful for these Ampacity calculations and are not used."

Therefore, there is no possibility of the wrong calculation results based on an engineer's confusion in the usage of this library.

OTI has performed a 10 CFR Part 21 deviation assessment of this issue. As a result of this assessment OTI has concluded that there are/were no errors in the ETAP cable ampacity library data and its usage, and error reporting, per provisions of 10 CFR Part 21, were not required in this matter.



Nonconformance 99901350/2003-201-04

NRC: D. "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?"

OTI: OTI has performed a 10 CFR Part 21 deviation assessment of this issue. OTI has concluded that since objective evidence are available for Verification & Validation of ETAP releases and the added review procedure (TDSR) is an enhancement to the existing V&V procedures, error reporting, per provisions of 10 CFR Part 21, were not required in this matter.

Nonconformance 99901350/2003-201-05 CLOSED



**ADDITIONAL QUESTIONS/COMMENTS REGARDING
OTI'S RESPONSE TOIR99901350/2003/201 IDENTIFIED CONCERNS**

3.1 of 99901350/2003-201

NRC: F. "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 clarifications 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 provision 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 CDF 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 provision 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 any 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."

OTI: Based on the requirements of 10 CFR Part 21 and OTI's Quality Assurance programs, OTI's responsible authorities continually perform 10 CFR Part 21 deviation assessment for all concerns, which are reported, based on internal tests or incidents received from ETAP users.

The scope of the deviation assessment performed by OTI includes the effect of the deviation in the calculation results and/or accuracy of library data. In the event that the deviation assessment determines that the severity of the problem and/or deficiency could cause minor or substantial effect on the ETAP basic results, OTI notifies all ETAP nuclear users, in writing, and within five working days of OTI's determination that a deviation exists.



In a letter accompanied with an Error Report we request ETAP nuclear users to evaluate the reported error in accordance with §21.21 of 10 CFR Part 21. Therefore, by generating error reports, OTI informs its nuclear users so that nuclear users could cause an evaluation to be performed in accordance with the provisions of 10 CFR Part 21. We also request that if a nuclear users have used the module and/or capabilities specified in the Error Report, and have determine that it requires 10 CFR Part 21 reporting, contact us immediately. If we do not hear from nuclear users, the classification of the reported error will remain as reported. Nuclear users are requested to acknowledge the receipt of the Error Reports.

3.2.1 of 99901350/2003-201

NRC: G. "The OTI corrective and preventive actions for this issue appear to be 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.

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.

- 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 the INFR-03-008 with your reply to this letter."

OTI: OTI has performed a 10 CFR Part 21 deviation assessment of this issue. As a result of this assessment, OTI issued an Informative Report (INFR-03-008), which explains the application of the program. Nuclear users were informed that average (nominal) overload heater resistance values are used in the libraries. ETAP users have the option to add and use their own libraries for overload heaters with maximum resistance values or select another library data. Informative Reports include information regarding the effected ETAP revisions.

Per OTI's phone discussion with Mr. Joe Petrosino and Mr. Gregory Cwalina, on December 1, 2003, attachment of INFR-03-008 report is not required.



3.2.4.1.b of 99901350/2003-201

NRC: H. "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 fro 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."

OTI: OTI has performed a 10 CFR Part 21 deviation assessment of this issue. As a result of this assessment, OTI issued an Informative Report (INFR-03-009), which describes the acceptance criteria and explains the basis for acceptance criteria for verification & validation of the PowerPlot curves. Informative Reports include information regarding the effected ETAP & PowerPlot revisions.

OTI is presently developing new libraries for graphic curves (Time Current Characteristic Curves), which is expected to reduce the deviations to less than $\pm 2\%$.

Per OTI's phone discussion with Mr. Joe Petrosino and Mr. Gregory Cwalina, on December 1, 2003, attachment of INFR-03-009 report is not required.



Item 3.2.4.3 of 99901350/2003-201

NRC: I. "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 PowerPlot 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 appears 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 9 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 curve 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 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 ETAP-PS library data was correct and OTI's conclusions were different from the NRC conclusion.

- 1) Please explain how OTI's re-evaluation of 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 determined that it does not have the capability to perform the capability to perform the *evaluation* to determine if a defect exists?"

OTI: OTI has performed a 10 CFR Part 21 deviation assessment of this issue.

The inspection of the Bussmann® fuse curves was performed by audit of the V&V procedures, manufacturer data and documents for Bussmann® fuse curve libraries. The results showed that validated fuse curves are within the acceptance criteria.

The NRC report indicates that for a specific Bussmann® fuse, some sections of the TCC matched and others did not match the manufacture curve. Review of validation of this Bussmann® fuse shows that this deviation is within the acceptance criteria and Part 21 reporting is not required.

OTI is currently in process of review of the entire fuse curves. This is an on going task that requires inspection of thousands of curves. Review activities are scheduled to be completed by the end of March 2004. Any deviations found as a result of this review will be reported in accordance with provisions of 10 CFR Part 21.

Item 3.2.6.b of 99901350/2003-201

NRC: J. "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 provide non-conservative values that may require an evaluation for past/existing applications at licensee facilities, in accordance with provisions of 10 CF 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.”

OTI: OTI has performed a 10 CFR Part 21 deviation assessment of this issue. As a result of this assessment, OTI issued an Informative Report (INFR-03-010), which describes the use 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. Informative Reports include information regarding the effected ETAP revisions.

Per OTI's phone discussion with Mr. Joe Petrosino and Mr. Gregory Cwalina, on December 1, 2003, attachment of INFR-03-010 report is not required.