August 14, 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 June 23, 2003. According to this report, OTI's first response to the NRC's findings is not sufficient and requires further clarification.

After careful review of the NRC's report, and based on your described requirements we are providing a more comprehensive response that is submitted with this letter.

We extend our appreciation to Mr. Joseph J. Petrosino, and Mr. Michael E. Waterman for their valuable time in assisting us with clarification of open issues.

In closing, we would like to assure you that OTI is always forthright and candid with ETAP users, inspectors and auditors. Over 52% of the nuclear plants in the United States have standardized on the ETAP program. We contribute this broad acceptance of ETAP as high impact software to the superior quality of the program and OTI's conduct that is known for accuracy and frankness.

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 Roshdieh, PE

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

IE09

Item 99901350/2003-201-01

NRC: "As of January 8, 2003, OTI has 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."

OTI: The following OTI's quality assurance procedure is established for verification & validation of ETAP library data.

Verification & Validation (V&V) of ETAP Library Data

The library data provided by ETAP shall be based on the Original Equipment Manufacturer's (OEM's) technical data, applicable standards, or calculated values. The accuracy, correctness, and completeness of the data entered shall be ensured by plans and procedures that are established to validate the source of data, provide guidelines for data entry, verify the entered data, audit of the V&V process, and retention of the quality records.

1. Validation of Library Data References

The following plans are established to ensure that the sources for the library data are accurate, correct, and complete and proper authorities are assigned to this task.

a. Library data shall be obtained from the OEM's technical data, applicable standards, or calculated values.

b. Any data, which is obtained from entities other than the applicable OEM or published standards, is not acceptable as a Library Data Reference.

c. An appointed authority or authorities, designated by the OTI's VP engineering, shall validate Library Data References. Library Data Reference validation shall ensure accuracy, correctness, and completeness of the library data.

d. The Library Data References shall be specified for the usage of the validated data references. For example the usage may be for short-circuit values only.

e. Library Data References shall be stamped, signed, and dated by the OTI's approved authority or authorities.

f. Library Data References may be in hard copy or electronic format.

2. Guidelines for Entering Library Data

A guideline for entering library data shall be provided for each library type. Guidelines shall have OTI's review and approval signatures.

3. V&V of the ETAP Library Data

The following plans are established to ensure that the approved Library Data References are entered in the ETAP libraries per approved guidelines.

a. V&V of ETAP library data shall be carried out using OTI's Incident Report (IR) forms.

b. The library data entered shall be based on the validated Library Data References. A copy of the reference material or information regarding the reference material and its location shall be attached to each IR.

c. Library data shall be entered per requirements of the approved guidelines for entering library data.

d. The verification of the entered library data shall be based on the validated Library Data References and approved guidelines for entering library data. Per requirements of OTI's IR form, evidence of the verification activities shall be maintained as attachments to the IR forms.

4. Audit of V&V of Library Data

The V&V process for library data shall be audited prior to each software release. The scope of this audit shall cover the entire V&V activities.

5. Quality Records

Validated Library Data References, guidelines for library data entries, Incident Reports generated for library data V&V, and audit records are considered quality records and shall be maintained permanently.

(1) Corrective Action

New procedures are established as explained above. For corrective action please refer to the **Verification & Validation (V&V) of ETAP Library Data** procedures, Section 1.

(2) Preventive Action

New procedures are established as explained above. For preventive action please refer to the **Verification & Validation (V&V) of ETAP Library Data** procedures, Section 4.

(3) Implementation

The above corrective and preventive actions are currently in place and will be reflected in the ETAP 5.0 release, which is scheduled for release by the end of 2003.

Item 99901350/2003-201-02

NRC: "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 accuracy, correctness and completeness before putting 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 manufacturer's technical data that OTI obtained from other entities included:

(1) 3M Firewrap® Values
(2) TSI Thermo-Lag® Values
(3) Westinghouse Overload Heater Values"

OTI: Please refer to Verification & Validation (V&V) of ETAP Library Data procedures, which is included in OTI's response to NRC's 99901350/2003-201-01.

(1) Corrective Action
ETAP nuclear users have been informed that the OEM's technical data for the above libraries were provided to OTI by TVA. This information was transmitted to users with the 4.7.4N release package.

New procedures are established as explained in item 99901350/2003-201-01. For corrective action please refer to the **Verification & Validation (V&V) of ETAP Library Data** procedures, Section 1.

(2) Preventive Action
New procedures are established as explained in item 99901350/2003-201-01. For preventive action please refer to the **Verification & Validation (V&V) of ETAP Library Data** procedures, Section 4.

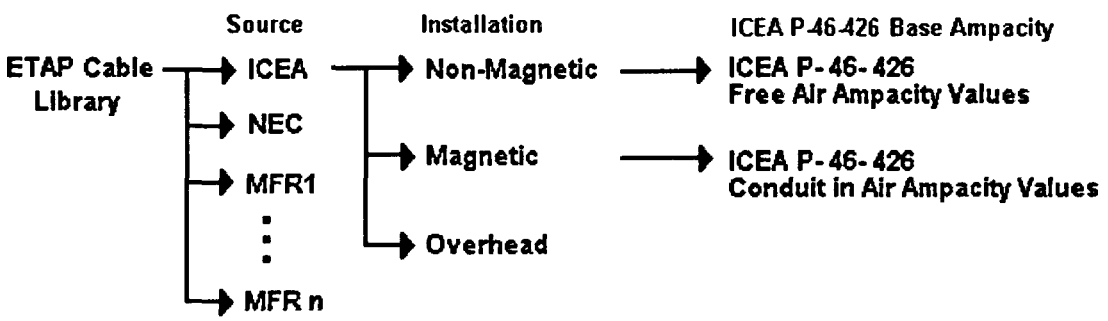
(3) Implementation
The above corrective and preventive actions are currently in place and will be reflected in the ETAP 5.0 release, which is scheduled for release by the end of 2003.

Item 99901350/2003-201-03

NRC: "As of January 8, 2003, 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."

OTI: The ICEA cable Base Ampacity values for "free air" applications were re-evaluated against the data provided in the Insulated Cable Engineers Association ICEA P-46-426. This re-evaluation has confirmed that ETAP library data based on ICEA P-46-426 is correct and no-errors were found.

The structure of the ETAP Cable library is shown in the following figure:



ICEA P-46-426 only extends to free air Base Ampacities for non-magnetically installed cables. Therefore, if the free air Base Ampacities are to be compared against the ETAP library values, then the non-magnetic library subdivision must be selected. The Etap library shows the more conservative conduit in free air Base Ampacities for magnetic installations (trays that provide circulating currents).

The NRC inspectors identified certain ETAP library Base Ampacities for free air that might have discrepancies with the corresponding data in ICEA P-46-426. These cable samples are shown in tables 1-3. These tables show comparisons of Base Ampacities for both "magnetic" and "non-magnetic" applications for 1/C & 3/C, 600 Volt cables.

	Base Ampacity for **Non-Magnetic Installation**			
	Duct Bank	Buried	Free Air	Conduit in Free Air
ETAP	429	531	487	425
ICEA P-46-426	429	531	487	425
	Base Ampacity for **Magnetic Installation**			
	Duct Bank	Buried	Free Air	Conduit in Free Air
ETAP	429	531	425 **	425
ICEA P-46-426	429	531	N/A *	425

Table 1: 600V, 3/C, 500 kcmil, Copper Conductor Cables

	Base Ampacity for **Non-Magnetic Installation**			
	Duct Bank	Buried	Free Air	Conduit in Free Air
ETAP	133	178	138	123
ICEA P-46-426	133	178	138	123
	Base Ampacity for **Magnetic Installation**			
	Duct Bank	Buried	Free Air	Conduit in Free Air
ETAP	133	178	123**	123
ICEA P-46-426	133	178	N/A*	123

Table 2: 600V, 3/C, #2 AWG, Copper Conductor Cables

	Base Ampacity for **Non-Magnetic Installation**			
	Duct Bank	Buried	Free Air	Conduit in Free Air
ETAP	176	231	192	N/A**
ICEA P-46-426	176	231	192	N/A**
	Base Ampacity for **Magnetic Installation**			
	Duct Bank	Buried	Free Air	Conduit in Free Air
ETAP	176	231	130***	N/A**
ICEA P-46-426	176	231	N/A*	N/A**

Table 3: 600V, 1/C, #2 AWG, Copper Conductor Cables

* Not Available, ICEA P-46-426 does not provide Base Ampacity values for magnetically installed cables in free air (cable trays).

** ETAP library provides the conduit in free air Ampacities for cables with magnetic installation. ETAP considers cable raceways in free air (such as cable trays) that allow circulating current around the cable, to have the same Base Ampacities as that in conduit in air. Magnetically installed cables imply that there is a continuous raceway (conduit) around the cables with circulating current due to the magnetic field of the cables. This circulating current will prevent heat flow as well as generate heat due to I^2R losses. This is part of the reason why ETAP uses the more conservative (conduit in free air) Base Ampacity values for magnetically installed cables in cable trays.

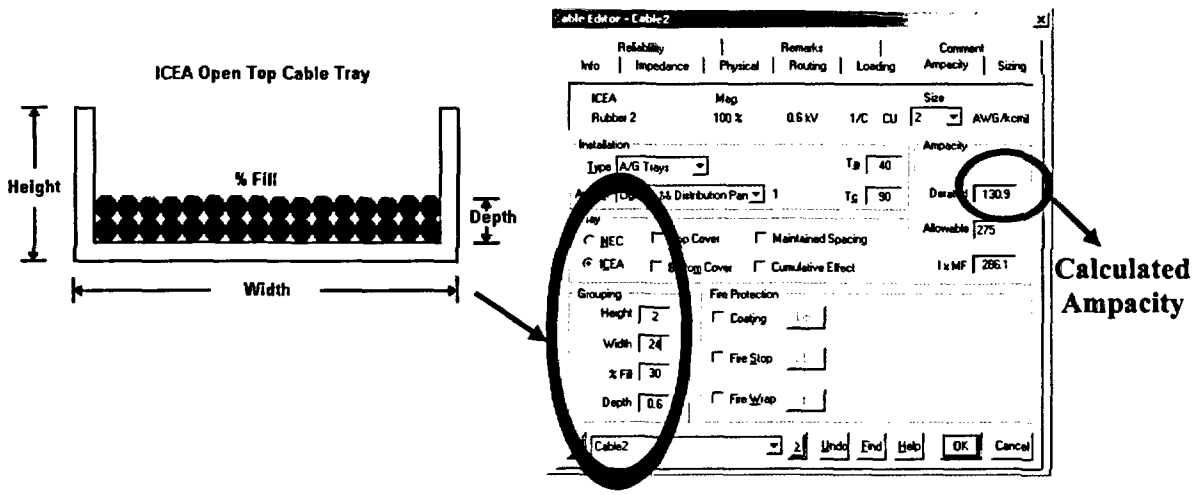
*** The ICEA P-46-426 conduit in free air Base Ampacities for triplexed cables are utilized for this application. 1/C cables (low voltage) cannot be placed in isolated trays. If 1/C cables are placed in a tray, ETAP considers all 3-phases are placed in the same tray, and utilizes the worst-case condition, which consists of the three 1/C cables bundled together in a triplex configuration. This is the reason why ETAP utilizes the ICEA triplexed cable Base Ampacities for this application, which is 130 Amps.

Note that 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.

Operation Technology, Inc. etap.com
17 Goodyear Irvine, CA 92618 Tel: 949-462-0100 Fax: 949-462-0200 oti@etap.com

ICEA Cable Tray Ampacity Calculations in ETAP

The following figure illustrates the definition of the cable tray used for the ICEA Ampacity calculations in cable trays. ETAP will use the width, height, %fill and other parameters to determine the Ampacity for cables based on a configuration similar to what is shown in the figure. The calculated Ampacity is displayed on the Cable Editor Ampacity Page.



(1) 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.

(2) 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).

(3) Implementation:

These changes will be implemented in ETAP 5.0.

Item 99901350/2003-201-04

NRC: "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."

OTI: OTI can provide adequate objective evidence, which indicates verification and validation tests have verified the adequacy of ETAP 4.0.0N or other versions.

Regarding the documents under inspection related to the cable editor's cable-sizing calculations based on ICEA Standards, OTI can provide adequate objective evidence that V&V of ICEA method was included and performed in the test plan for the 4.0.0N release. Per OTI's V&V procedures, adequacy of the test cases generated for the cable sizing program were approved by the Test Manager, the Technical Test Manager, and the Test Engineer.

The V&V documents maintained for 4.0.0N release (TCS-CAB-013) shows that the ICEA method of calculations for cable sizing were tested for 42 different scenarios and compared with the values provided in the ICEA Standard. The comparison results were satisfactory and the test cases passed. After release of 4.0.0N, and based on internal test activities, an error was detected regarding the ICEA calculations (TIR-Cable-190) and subsequently reported to all ETAP nuclear users (ERCA-PS-02-004). Correction of this error was included in 4.7.0N release. Test case TCS-CAB-016 was then added to the test plan to validate the correction.

For each ETAP release, a listing of all program features, possible calculations paths, different program options, limitations, etc. are provided. This list is then reviewed and approved by designated authorities to determine the adequacy of the regression tests for each module, element, etc. The listing of all required tests and their results are summarized in the Test Summary Reports that are signed and approved by testing authorities. See corrective and preventive actions section for details.

(1) Corrective Action

For the purpose of continuous improvement, the following review shall be added to the existing V&V reviews. Note that the VP Engineering presently conducts a similar review titled Software Verification & Validation Plan Review. However, due to growth and complexity of the program, a second review for completeness of the V&V test cases will be valuable.

Test Design Specification Review (TDSR)

Test Design Specification (TDS) forms consist of a listing of the program features to be tested for a particular ETAP module. This document is compiled by the Technical Test Manager, Test Manager, and Test Engineer with sufficient feedback from the designers of the module. The Technical Test Manager, who has expert technical knowledge of the assigned module(s), must conduct a review of the assigned TDS prior to each release of ETAP. By signing this document, the Technical Test Manager declares that all available features for the specified module are verified & validated. The Technical Test Manager shall consider various possibilities that each feature maybe utilized by the program users. TDSR report shall include the finalized TDS and a listing of the review objectives. Review objectives may vary for different modules.

TDSR report is considered a quality record and shall be maintained permanently with the release V&V package.

Also note that Test Engineers are required to provide evidence of test case results for all test cases in form of tables of comparisons or appropriate attachments. This requirement facilitates the review process of individual test cases and the Test Design Specifications.

(2) Preventive Action
OTI's Software Verification & Validation Plan Review (SVVPR), which is conducted by VP Engineering, evaluates the adequacy and completeness of SVVP. The following item shall be added to the objectives of SVVPR:

- Review of the TDSR for adequacy of the review objectives and completeness.

(3) Implementation
The above corrective and preventive actions are currently in place and will be reflected in the ETAP 5.0 release.

Item 99901350/2003-201-05

NRC: "As of January 8, 2003, OTI had failed to ensure that adequate records were developed and maintain 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."

OTI: The following response was accepted in the NRC's, June 23, 2003 report. Based on this report, "this issue is considered closed and no further action is warrant for Non conformance 99901350/2003-201-05".

TIR-CABLE-190 is a Test Incident Report document and includes adequate and complete documentation and evidence of test verification. For detail information refer to the reply to Item 99901350/2003-201-04.

According to OTI's V&V procedures evidence of test cases are reported in form of tables of comparisons in SVVR (Software Verification and Validation Report) and/or attachments to the printed TDS (Test Design Specification), TCS (Test Case Specification), TPS (Test Procedure Specification), and TCB (Test Case Benchmark). Note that SVVR is one of the documents that are distributed as part of the V&V package to our nuclear users.

For ETAP 4.7.0N, verification attachments to TDS, TCS, TPS, and TCB documents are several thousands of pages. The evidence to support the test plan includes over 100,000 pages. Due to simplicity of some cases, less than 2 % of test cases do not require supporting evidence since they are documented in the test log and can be duplicated very simply.

In the case of TCS-CAB-016 test case, the test procedure is very simple and the pass/fail criterion is very clear. The test engineer passed the test case and logged it as "Passed". Since duplication of this test case is simple no attachments were included. This procedure was considered acceptable for the purpose of further review and quality assurance.

(1) Corrective Action:
Test engineers are required to provide evidence of test case results for all test cases in form of tables of comparisons or appropriate attachments regardless of how simple the test case maybe.

(2) Preventive Action:
The following item will be added to the functional audit list, which is conducted prior to each release.
- Verify that each test case is furnished with evidence of test results.

(3) Implementation:
The above corrective and preventive actions are currently in place and will be reflected in the ETAP 5.0 release.

Enclosure 2, Section 3.1, 10 CFR Part 21 Program

NRC: "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 are generally acceptable with only minor procedural clarifications that were 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 10 CFR Part 21."

OTI: 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.

Enclosure 2, Section 3.2.1, Westinghouse Model FH Overload Heater 3.2.1 of 99901350/201

NRC: "Although the overload heater resistance values in the ETAP-PS library were found to be within the maximum and minimum values provided by the manufacturer, it was expected that voltage drop calculations would be slightly non-conservative using the ETAP-PS library data because its library values for heaters did not contain both maximum (for voltage drop calculation) and minimum (for short-circuit calculation) values, in all cases. Therefore, the inspectors concluded that OTI has not adequately verified all of the manufacturer's technical specifications used in its software."

OTI: The issue concerning verification of the manufacturer's technical specifications is addressed in OTI's response to NRC's Item 99901350/2003-201-01.

ETAP currently uses one single value for the overload heater resistance for Load Flow and Short-Circuit type analysis. The value used is the average overload heater resistance, which is obtained from the library.

The use of the average values instead of maximum resistance values for load flow calculations can yield slightly non-conservative results. The voltage drop due to an overload heater is usually a small percentage of the overall voltage drop, which is mostly due to cable impedance. Use of the maximum values instead of the average values for the overload heater resistance can increase the overall voltage drop by a relatively small percentage, e.g., 1.76% vs. 1.75% voltage drops. Note that this difference depends on the length and size of the cable as well as the size of the overload heater.

(1) 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.

(2) 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.

(3) Implementation:
The additional fields that will account for the maximum and minimum overload heater resistance values will be included in ETAP 5.0.

Enclosure 2, Section 3.2.4, Device Time Current Characteristic Curves (TCCs) 3.2.4.1b of 99901350/201

NRC: "...The inspectors revealed that OTI engineers could accept up to 13% deviation between the vendor between the vendor information and dada in the ETAP-PS library. The inspectors consider 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."

OTI: The Verification and Validation procedures for ETAP libraries allow for the following:

1. OTI's acceptance criteria for library data derived from published manufacturer and/or standard data provided in tabulated or equation forms is zero percent (0%) deviation. Examples of such library data are cables, protective device ratings, etc.

2. OTI's acceptance criteria for library data collected graphically, (Time Current Characteristics or TCCs) is 10% deviation for any single derived point. In the case of solid-state trip device curves, a 13% deviation is allowed. In most cases, the average percent deviation is less than 4%.

3. For the graphical library data, errors due to the digitalization and curve fitting a nonlinear curve between input points are unavoidable, taking into consideration the process used to generate the TCC curves. This process involves the following steps:

    a. Compilation of the manufacturer TCC curve data through digitization of the points from manufacturer TCC plots
    b. Extrapolation / Interpolation of the missing points
    c. Use of curve-fitting algorithms to generate the curves
    d. Logarithmic scale of the TCC curves

(1) 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.

(2) 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.

(3) Implementation:
ETAP 5.0 will include ETAP STAR.

Enclosure 2, Section 3.2.4.3, Bussmann® Fusetron FRN-R Fuse

NRC: "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. Since some sections of the TCC matched and others did not, 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 10 CFR Part 21 program."

OTI: 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.

Enclosure 2, Section 3.2.6, Battery Load Profile 3.2.6.b of 99901350/201

NRC: "The inspectors concluded that it is possible that higher non-conservative battery voltages can be obtained by end users when using fixed current (Fixed amp=1) method. Conversely, the inspector 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."

OTI: For Battery discharge calculations, ETAP provides two different methods to calculate the battery voltage from the library characteristic curves. These are Fixed Amp (FA) and Fixed Amp-Hour (FAH) methods. The main difference between these methods is their interpolation/extrapolation procedure.

The accuracy of the FA and FAH methods highly depends on the availability of enough battery curves to cover the load profile points. When the battery discharge points are located in the region in-between the battery characteristic curves, the FA & FAH methods use interpolation of the curves and yield almost identical calculated battery voltage. When the battery load profile points are located outside the covered region, extrapolation must be used to calculate the battery voltage. Under such situation, the FA and FAH methods may calculate different battery voltage values. This is mainly due to the highly non-linear shape of the fan curves and the fact that battery manufacturers do not provide enough data that covers low discharge rates at higher Vpc.

Either method can yield conservative or non-conservative results. This depends on the location of the load profile, the shape of the characteristic curves and the availability of battery curve points provided by the manufacturers.

The FAH method is prone to irregularities and tends to produce unrealistic behavior under low battery discharge conditions, i.e., battery voltage increases under a constant load current. Under similar conditions, the FA method yields realistic results that can appear less conservative when compared to the FAH results. The ETAP FAH method gives results similar to those obtained with other programs that use the same method.

(1) 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.

(2) 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.

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