

December 22, 2003

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555-0001

Subject: Reply to NRC Notice of Violation 99901351/20032-01-01

Dear Sirs:

This letter responds to your Notice of Violation issued on November 26, 2003. First, it provides a brief description of the service that our laboratory provides, then in light of this service, it presents a discussion of the violation, the corrective actions taken, the timing for corrective action implementation and the steps taken to assure no future occurrences.

Description of the Quality Product

The Advanced Thermal Hydraulic Research Laboratory (ATHRL) at Oregon State University is under contract with the U.S. Department of Energy (DOE) to obtain thermal hydraulic data using the reduced-scale APEX-1000 integral system test facility. This data is being used by Westinghouse to assess their AP1000 evaluation models as part of the AP1000 certification process. The APEX-1000 data is unique for two reasons. First, it can be demonstrated that the data is sufficiently robust to exercise important features of the AP1000 evaluation models. That is, for certain prescribed transients, the APEX-1000 reduced-scale data describes the same type of thermal hydraulic phenomena expected to arise in a corresponding AP1000 transient. As such the same predictive functions of the AP1000 evaluation models are challenged to predict the key thermal hydraulic phenomena of an APEX experiment. Second, using similarity arguments, insights into the overall system behavior of the AP1000 plant can be obtained for a range of transient conditions. Our quality product is reduced-scale data that can be used to assess AP1000 evaluation models.

1. Causes of Violation

While we fully support the mandate of 10 CFR 21.21 and applaud NRC's efforts to assure that substantial nuclear safety hazards are promptly reported to NRC and to affected parties, the need to initiate a 10 CFR 21.21 reporting program as part of the APEX-1000 test program was not readily apparent for the following reasons:

a. Applicability of 10 CFR 21.21 to Non-Licensees or Non-Applicants.

A 10 CFR 21.21 reporting process was not initially included in the APEX-1000 program because it is not clear to what extent these regulations are applicable to providers of data used to assess evaluation models. That is, OSU ATHRL does not produce hardware or software, nor any other component that will be directly used in the AP1000 plant. Furthermore, the reduced-scale APEX-1000 data is not being



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used in the design of the AP1000 plant. Therefore the impact of discovering a discrepancy in our APEX-1000 data is limited to an impact on the vendor's assessment of their AP1000 evaluation models. With regard to errors that arise in evaluation models, regardless of their cause, 10 CFR 50.46 (a) (3) provides very clear and specific guidance on error reporting. However, 10 CFR 50.46 is limited to applicants for or holders of an operating license or construction permit, of which OSU ATHRL is neither.

- b. Application of 10 CFR 21.21 to the APEX-1000 Testing Program is inconsistent with previous NRC practice regarding providers of Evaluation Model databases.

A 10 CFR 21.21 reporting process was not initially included in the APEX-1000 program because to do so was inconsistent with previous NRC practice under identical circumstances as documented in 10 CFR 50.46, titled *Acceptance criteria for ECCS for light-water nuclear power reactors*, and 10 CFR 50 Appendix K, titled *Evaluation Models*.

Appendix K presents the required and acceptable features of Emergency Core Cooling System (ECCS) evaluation models. NRC did not require Part 21.21 reporting programs for the organizations that generated the data bases used to assess the Appendix K evaluation model correlations. Furthermore, numerous databases are currently being used to assess the different functions of nuclear power plant evaluation models and specifically to quantify uncertainties as required by 10 CFR 50.46 (a) (1) (i) which states, "*Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated.*" To the best of our knowledge, the data sets being implemented in the best-estimate evaluation model uncertainty analyses are from providers, such as the open literature, that do not have 10 CFR 21.21 reporting programs.

- c. A 10 CFR 21.21 Reporting Program was not requested by Westinghouse nor required by the U.S. Department of Energy.

A 10 CFR 21.21 reporting process was not initially included in the APEX-1000 program because it was not required as part of the DOE contract nor did the Westinghouse and DOE quality assurance audits identify it as a program requirement.

2. Corrective Actions

It is the practice of ATHRL to notify its sponsors of all major discrepancies found in APEX-1000 data subsequent to the data's transmittal. As observed during the NRC inspection, documentation was available to demonstrate that this is the accepted practice of the laboratory. This standard practice has been formally incorporated into an OSU ATHRL Administrative Procedure titled, "*Advanced Thermal Hydraulic Research Laboratory, A-06, Reporting of Discrepancies in Test Data, Revision 0.*" The procedure indicates that because ATHRL staff do not have the capability of determining how a major discrepancy in test data would impact a data recipient's evaluation models, each data recipient will be notified within five (5) working days of the discovery of a major discrepancy, or the discovery of a failure to report a major discrepancy, so they can evaluate it pursuant to 10 CFR 21.21 (a). Minor discrepancies, such as typographical errors, that do not impact the content of the data, would not fall within the purview of this administrative procedure. This administrative procedure became effective on December 22, 2003.

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3. Preventing Future Violations

A Part 21.21 compliant Administrative Procedure, ATHRL, A-06, has been developed and is now in place, eliminating a repeat of this violation. With regard to implementation of the administrative procedure, all ATHRL staff have been informed of the new procedure requirements. In addition, a training session has been scheduled for no later than January 9, 2004. Training on A-06 will be provided for all personnel hired to work on the APEX-1000 test program subsequent to January 9, 2004.

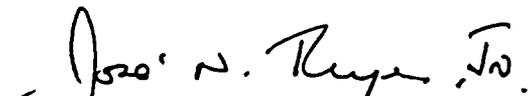
4. Date of Full Compliance

The date of full compliance is December 22, 2003.

In conclusion, the OSU Advanced Thermal Hydraulic Research Laboratory is committed to providing high quality data for the assessment of nuclear plant evaluation models in full compliance with NRC regulations. Therefore we have implemented a Part 21.21 reporting program in response to the NRC Notice of Violation.

It has been noted in Section 1 of this letter, titled *Causes for the Violation*, that the requirement to implement a Part 21.21 reporting process for the APEX-1000 testing program appears to be inconsistent with NRC's current practice with regard to providers of data for evaluation model assessment as observed in the implementation of 10 CFR 50.46 and 10 CFR 50 Appendix K. As such, this notice of violation raises the need for clarification from NRC as to the conditions under which Part 21.21 should be applied to providers of products or services that are not directly used in, or for the design of, a light water nuclear power reactor.

Sincerely,



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