



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

April 22, 2004

Dr. Jose N. Reyes, Jr., Director  
Advanced Thermal Hydraulic Research Laboratory  
Oregon State University  
116 Radiation Center  
Corvallis, OR 97331-5902

**SUBJECT: NRC INSPECTION REPORT NO. 99901351/03-01, NOTICE OF VIOLATION AND  
NOTICE OF NONCONFORMANCE**

Dear Dr. Reyes:

Thank you for your letters of December 22 and 23, 2003, and January 29, 2004, in response to the Notice of Violation (NOV) and Notice of Nonconformance (NON) issued as a result of an NRC inspection at your facility. As noted in NRC Inspection Report 99901351/03-01, dated November 26, 2003, the NRC inspectors identified several issues related to the conduct of testing activities at the Oregon State University (OSU) Advanced Thermal Hydraulic Research Laboratory (ATHRL) in support of certification of the Westinghouse AP1000 design. The NOV documented that the OSU ATHRL did not have a documented process or procedure to address "Notification of Failure to Comply or Existence of a Defect and its Evaluation," as described in 10 CFR 21.21 for scaling and testing activities performed at your facility. The NON documented that the OSU ATHRL: (1) did not adequately address 10 CFR Part 50, Appendix B, requirements for corrective action and record retention in the ATHRL Quality Plan; and, (2) did not comply with the ATHRL Quality Plan and procedures for certain APEX-1000 testing activities in the areas of quality document control, control of measuring and test equipment; and computer software control.

We have reviewed your reply and found it responsive to the concerns raised in the NOV and NON. The NRC may review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Your letter also requested clarification as to the conditions under which 10 CFR 21.21 should be applied to vendors of products or services that are not directly used in, or for the design of, a light water reactor plant. The regulations of 10 CFR 21 apply to each individual, corporation, partnership, or other entity that supplies basic components for a facility. As defined in 10 CFR 21.3, the term basic component includes safety-related design, analysis, testing, or consulting services. Although your December 22, 2003, letter stated that the reduced scale APEX-1000 data is not being used in the design of the AP1000 plant, the staff has determined that the scaling analyses and testing performed by the OSU ATHRL is needed to demonstrate that certain accident analysis evaluation models were appropriately applied to the AP1000 design. The staff considers that analysis, testing, and consulting services used to demonstrate the applicability of specific safety-related evaluation methods to a particular design are basic components as defined in 10 CFR 21. Therefore, although the analysis and testing performed by the OSU ATHRL may not have been directly used in the design of the AP1000 plant, this

information was used to demonstrate the applicability of certain design methods and evaluation models to the AP1000 design. As such, the staff considers the OSU ATHRL to be a supplier of a basic component under 10 CFR Part 21.

The staff does not believe that this position is inconsistent with past practices. For example, 10 CFR 50.46(c)(2), states, in part, that an evaluation model includes one or more computer programs and all other information necessary for the application of the calculational framework to a specified loss of coolant accident. The staff considers that "all other information necessary for the application of the calculational framework" includes analysis and testing used to demonstrate that specific computer programs are applicable to the AP1000 design. Furthermore, 10 CFR 50.46 establishes additional requirements related to emergency core cooling system acceptance criteria and was not intended supplant or obviate the need to comply with other NRC regulations, such as 10 CFR Part 21. In summary, the staff concludes that the requirements of 10 CFR Part 21 apply not only to suppliers of basic components used to directly develop specific accident analysis evaluation models, but also to suppliers of basic components used to demonstrate that existing evaluation models are appropriately utilized for a specific application.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

***/RA/***

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

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Sincerely,

*/RA/*

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

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