November 27, 2006

MEMORANDUM TO: Stephen D. Dingbaum
Assistant Inspector General for Audits

FROM: Martin J. Virgilio ***/RA/***
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

SUBJECT: EVALUATION OF THE NRC'S USE OF PROBABILISTIC RISK ASSESSMENT IN REGULATING THE COMMERCIAL NUCLEAR POWER INDUSTRY (OIG-06-A-24)

I am responding to your September 29, 2006, memorandum transmitting the subject audit report. I am pleased to note your comment that the U.S. Nuclear Regulatory Commission (NRC) is employing prevailing good practices in the evaluated areas. I submit the following responses to your specific recommendations to the agency's formal documented processes and associated configuration control for its probabilistic risk assessment (PRA) computer models and software.

Recommendation 1
Develop and implement a formal, written process for maintaining PRA models that are sufficiently representative of the as-built, as-operated plant to support model uses.

Response
Agree. The staff completed the Standardized Plant Analysis Risk (SPAR) Model Quality Assurance Plan, Revision 0, (SPAR Model QA Plan), and it became effective on September 15, 2006 (ML063070084) subsequent to the IG review. The agency established its formal quality assurance (QA) and configuration control plan using existing practices for SPAR model development. Section 7 of the SPAR Model QA Plan specifies that "each SPAR model will largely reflect actual plant design" and provides additional guidance to achieve that requirement. Use of the SPAR Model QA plan establishes a sufficient level of confidence in the SPAR models for the staff to support the agency's risk-informed regulatory activities (e.g., audit, review and screening tool). Currently, staff is reviewing the proposal to revise and update the SPAR models. The updates are based on recently identified Plant changes, which will be evaluated for risk significance. Note that SPAR models are not used as a basis for a licensee's licensing or design-bases activities.

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In conclusion, the SPAR Model QA Plan implements a formal, written process for maintaining PRA models that are sufficiently representative of the as-built, as-operated plant to support model uses.

Recommendation 2
Develop and implement a fully documented process to conduct and maintain configuration control of PRA software (i.e., SAPHIRE, GEM).

Response
Agree. Idaho National Laboratory (INL), NRC's contractor, documented this process in the Programers Workbench, SAPHIRE Development Manual (Enclosure 1), which was not provided to the Inspector General reviewers (Scientech). This document describes configuration management as—

> SAPHIRE software configuration is managed using a Revision Control System (RCS). An RCS allows developers to manage multiple revisions of files by keeping a complete history of the changes performed to the files. This allows the developer to see how and when a file was changed, or to quickly return to a previous revision of a file.

This configuration control approach is an acceptable practice commonly used by software developers.

In conclusion, the existing RCS satisfies the requirements for a fully documented process to conduct and maintain configuration control of PRA software (e.g., SAPHIRE, GEM).

Recommendation 3
Conduct a full verification and validation of SAPHIRE version 7.2 and GEM.

Response
Disagree. In the staff's judgment, SAPHIRE version 7 is sufficiently tested and benchmarked to support current use so that the staff may focus on implementing SAPHIRE version 8. Version 8 will satisfy the requirements described in the audit report for test documentation. The agency decided several years ago to perform limited validation and verification (V&V) on SAPHIRE version 7.2. It is impractical to "fully" test every feature and option under all different conditions in any complex system. INL compared the test, verification, and validation (TV&V) process for SAPHIRE version 7 to IEEE Standard 1012-1998, "IEEE Standard for Software Verification and Validation Plans," and documented its findings in "Comparison of the SAPHIRE TV&V to the IEEE V&V Process," dated May 20, 2003 (Enclosure 2). The staff did not provide this report to the Inspector General reviewers (Scientech). In the comparison, INL documented how the SAPHIRE TV&V does and does not satisfy the IEEE requirements. While extensive testing documentation exists related to each incremental release of SAPHIRE, not all parts of the IEEE Standard documentation are currently in place. One key reason the SAPHIRE TV&V does not satisfy the IEEE requirements is a lack of a formal definition of "software integrity levels" as defined in the Standard. INL has tested all vital features of SAPHIRE in the version 7 series. TV&V, as well as experience through the staff's use of SAPHIRE in conjunction with the SPAR models for risk-informed regulatory activities (e.g., Reactor Oversight Process (ROP),

Significance Determination Process (SDP), Management Directive (MD) 8.3, the Accident Sequence Precursor (ASP) program, and risk-informed license amendment reviews) has demonstrated that SAPHIRE does perform accurate probabilistic risk assessment (PRA) analysis calculations.

In summary, the staff performed a detailed review of the audit report and identified two important documents that should have been provided either during the audit or at the audit exit. I am providing these documents as Enclosures 1 and 2 to address Recommendations 2 and 3, respectively.

Enclosures:
One CD containing Enclosures 1 and 2 in
Adobe Acrobat format -

1. Programmers Workbench, SAPHIRE Development Manual, Idaho National Engineering and Environmental Laboratory, December 3, 2002 (ML06300629)
2. Comparison of the SAPHIRE TV&V to the IEEE V&V Process, Idaho National Engineering and Environmental Laboratory, May 20, 2003 (ML063100634)

cc w/o enclosure:
Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons

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