April 25, 2007

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

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: SUPPLEMENTARY RESPONSE TO RECOMMENDATIONS IN OIG-06-A-24, "EVALUATION OF THE NRC'S USE OF PROBABILISTIC RISK ASSESSMENT IN REGULATING THE COMMERCIAL NUCLEAR POWER INDUSTRY"

My memorandum to you dated November 27, 2006, responded to the recommendations of OIG-06-A-24. The information below supplements my responses to Recommendations 1, 2, and 3 as requested by your staff and discussed at the meetings between your staff and Office of Nuclear Regulatory Research (RES) staff on February 23, 2007, and March 23, 2007.

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

Supplementary Response
The initial response to this recommendation in my November 27, 2006 memorandum discussed and provided documentation on the Standardized Plant Analysis Risk (SPAR) model Quality Assurance (QA) plan and its implementation. The SPAR model QA plan provides reasonable assurance that the SPAR models used by NRC risk analysts and senior reactor analysts (SRAs) represent the as-built, as-operated plants to the extent intended within the scope of the SPAR models.

In the meetings between RES and Office of the Inspector General (OIG) staffs to discuss the response, the OIG staff raised a question about how the SPAR models are kept current to represent the plants and whether the processes for doing so were documented. The RES staff

CONTACT: Peter Appignani, RES/DRASP
301-415-6857

explained that the models are kept current via the supplemental verification activities that are routinely carried out as part of the analytic process associated with NRC risk applications, such as incident investigation (under Management Directive 8.3, “NRC Incident Investigation Program”), the Significance Determination Process (SDP), and Accident Sequence Precursor (ASP) evaluations. Regional inspectors and engineers who are knowledgeable of the as-built, as-operated plant are normally involved by the analyst to ensure that the SPAR model represents the current plant for the application.

Guidance is provided to SPAR model users in the Risk Assessment of Operating Events Handbook to ensure analytic results are sufficiently representative of the as-built, as-operated plant. Specifically, the handbook provides guidance where SPAR models are used in incident investigations, SDP, and ASP evaluations. The use of the handbook for SDP Phase 3 risk assessments is recommended in Inspection Manual Chapter 0609, “Significance Determination Process.”

Over the years, the NRC staff has developed processes that ensure that risk-based regulatory decisions are based on the as-built and as-operated plant. These processes include:

- The use of the draft Risk Assessment of Operating Events Handbook (more commonly referred to as the Risk Assessment Standardization Project or RASP Handbook) that provides guidance on basic principles of risk assessment, appropriate methodology (i.e., tool box of techniques), and documentation standards.

- An internal review of the risk evaluations by experienced analysts.

- A consensus review for major decisions and high-risk events, which ensures that both the licensee and the NRC are using state-of-the-art approaches and complete plant information.

Other means are also used to ensure that decisions made are based on the as-built and as-operated plant. These include:

- The use of well-trained and experienced risk analysts with years of NRC or external PRA experience and who have taken NRC training courses (SRAs have been through a formal qualification program). Their backgrounds ensure that they know how to use and interpret PRA results in light of the current plant design and the event being analyzed. These analysts are also knowledgeable about potential PRA and SPAR model limitations, boundary conditions, and uncertainties in results.

- The expert support from our contractor Idaho National Laboratory (INL) as part of the RES-funded “help desk” for SPAR and Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE) technology.

More specific details about the above processes are provided in Enclosure 1, "Additional Information on NRC Processes for Ensuring Risk-Based Decisions are Based on the As-Built and As-Operated Plant."

In summary, as discussed with the OIG, the revised RASP Handbook will provide a formal, written process for maintaining PRA models that are sufficiently representative of the as-built, as-operated plant to support model use. Revision 1 of the RASP Handbook will be completed during Calendar Year 2007.

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

Supplementary Response
At a meeting with the staff on February 23, 2007, the OIG requested additional documentation with respect to Recommendation 2. Additional documents were provided to the OIG as listed in Enclosure 2. At a subsequent meeting, the staff explained to the OIG that at the time the OIG was performing the audit, the INL was developing a new software quality assurance program as a result of the split of Idaho National Engineering and Environmental (INEEL) into INL and the Idaho Cleanup Project.

On April 2, 2007, the new INL software quality assurance program was implemented. On April 5, 2007, the staff provided the OIG with confirmation of this action (by email and follow-up call) and with the following INL documents: INL Report PDD-13610, Rev. 2, "Software Quality Assurance Program," Effective Date April 2, 2007 and INL Report LWP-13620, Rev. 3, "Software Quality Assurance," Effective Date April 2, 2007. The INL's SAPHIRE development project will now make use of this new software quality assurance program. These documents will be incorporated into NRC statements of work to ensure continued use. Thus, a fully documented process to conduct and maintain configuration control of PRA software (i.e., SAPHIRE, GEM) has been developed and implemented.

We consider actions to address this recommendation to be completed.

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

Supplementary Response
At a meeting with the staff on February 23, 2007, the OIG acknowledged that performing a full verification and validation (V&V) of SAPHIRE Version 7 would not be justified at this time due to the development schedule for SAPHIRE Version 8. The INL recommended the implementation of four recommendations from INEEL Report No. CCN 42566, "Submittal of Final Report under Job Code Number (JCN) Y6394, Task 8," dated May 30, 2003, for the SAPHIRE Project verification and validation. These recommendations are consistent with the Institute of Electrical and Electronics Engineers Standard for Software Verification and Validation 1012-1998. Subsequent discussions with the OIG staff indicated that the addition of these four recommendations, combined with code testing, would satisfy full verification and validation of SAPHIRE Version 8. The INL will implement these recommendations as requested by the NRC statement of work for JCN N6423 (SAPHIRE Version 8). Beta testing is anticipated to take 1 to

2 years. No general release date for SAPHIRE Version 8 has been set at this time, although it is anticipated in CY 2009. Because V&V efforts will continue throughout the software development process, this recommendation will remain open until Version 8 is released.

Enclosures:
1. Additional Information on NRC Processes For Ensuring Risk-Based Decisions Are Based on the As-Built and As-Operated Plant
2. Supplemental Documents List

cc: Chairman Klein
Commissioner McGaffigan
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Commissioner Jaczko
Commissioner Lyons
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NAME	FEltawila	L-A Culp	MBaily	BSheron	MVirgilio	
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Additional Information on NRC Processes For Ensuring Risk-Based Decisions Are Based on the As-Built and As-Operated Plant

Over the years, the NRC staff has developed processes for ensuring NRC risk-based regulatory decisions are based on the as-built and as-operated plant. These processes include:

1. Risk Assessment Standardization Project (RASP) Handbook

   The RASP Handbook provides instructions for the staff on how to apply appropriate procedures and methods for risk assessment of inspection findings and reactor incidents. Developed in response to an Office of Nuclear Reactor Regulation (NRR) user need request, the handbook provides a structured approach to performing a quantitative risk assessment of events related to internal event initiators and external event initiators. Both volumes of the handbook have been released for trial use by the staff and are routinely used to assess inspection findings and reactor incidents. Although much of the handbook focuses on how to perform the analysis, Section A in Volume 1, "Boundary Condition for Analysis," describes means to ensure that analyses use Standardized Plant Analysis Risk (SPAR) models that are sufficiently representative of the as-built, as-operated plant to support model uses. These include emphasizing that (a) the NRC staff who apply probabilistic risk assessment (PRA) methods have training and experience commensurate with the particular use of analysis being undertaken, (b) methods reflect the current PRA state of technology, plant design, and operational features, and (c) analyses should identify key uncertainties and sensitivities and their significance, and be sufficiently complete and comprehensible to permit a quality assurance review. The Office of Nuclear Regulatory Research (RES) plans to issue Revision 1 of the handbook to NRR by late in calendar year 2007. Revision 1 will incorporate comments from NRC risk analysts and senior reactor analysts (SRAs) based on field use and training.

2. Internal Reviews

   Both the Accident Sequence Precursor (ASP) and Significance Determination Process (SDP) evaluations have procedures that require a thorough, structured review and sign-off by a second experienced and qualified reviewer. Additional staff reviews are performed commensurate with the risk significance and the complexity of the analysis. NRR reviews all Phase 3 SDPs completed by the regions. The NRR-originated SDP Phase 3 risk assessments typically involve a site-visit to (a) provide for direct feedback from the licensee and (b) review plant-specific procedures, operator training, and equipment relevant to the risk assessment. NRR-originated SDP Phase 3 risk assessments receive peer reviews by a senior-level advisor for PRA or a senior reliability and risk analyst, as well as specify the assigned regional senior reactor analyst for the case.

3. Licensee Reviews

   Staff requirements from the ASP program and SDP make it necessary for the NRC risk analyst to interact with the licensee to identify and resolve any issues with the SPAR model

when they perform a quantitative risk evaluation. The technology of risk analysis of operating events at nuclear power plants was developed and evolved with the ASP program. Initiated in 1979, ASP has a formal, written internal review process to ensure the quality of analyses. Historically, ASP analyses were transmitted to staff and licensees for comment to ensure that the analyses properly reflected the design and operation of the affected plants. Over the past year, changes were made to streamline the review process and to make it more efficient by not requiring licensee review for the less-risk significant events. However, risk-significant events will still be reviewed by the licensee.

The SDP requirements in Inspection Manual Chapter (IMC) 0609, "Significance Determination Process," require NRC staff to obtain a licensee's perspectives on the initial characterization of significance of an inspection finding. The licensee is given the choice of presenting further information or perspectives or accepting the staff's decision. If the licensee provides further information, usually in a regulatory conference, the staff will make a final significance determination after careful consideration of the licensee's additional information. If the licensee disagrees with the staff's final determination of significance, the licensee may appeal the decision if actual (verifiable) plant hardware, procedures, or equipment configuration were inadvertently not considered by the staff. Thus, the SDP process provides ample opportunities for the licensee to review the SDP analyses to assure the decision made reflects the as-built, as-operated plant configuration. Guidance in IMC 0609A, "Determining the Significance of Reactor Inspection Findings for At-Power Situations," has recently been revised to direct SDP analysts to use the RASP Handbook in conducting Phase 3 SDP risk assessments of inspection findings.

4. Qualified Analysts

The SRA qualification program requires the qualifying SRA to have an acceptable level of knowledge and experience in PRA technology and SDP methodology before becoming certified as an SRA. The SRA qualification program assures that SRAs are uniquely trained to perform complex SDP analyses, as well as to conduct peer reviews of completed SDP analyses. The ASP program requires its contractor to provide personnel with at least 10 years of risk analysis experience in the nuclear industry. In NRR, SRAs and PRA practitioners are required to be qualified technical reviewers in accordance with the NRR Office Procedure ADM 504, "Qualification Program." Newly hired PRA practitioners in NRR also receive training (classroom, individual study activities, and on-the-job training in accordance with the NRR Division of Risk Assessment, Branch-Specific Training Plans.

NRC risk analysts go through an extensive series of courses taught at NRC's Professional Development Center. These courses have comprehensive tests. SRAs and PRA practitioners involved with the Reactor Oversight Process SDP receive periodic SPAR model and Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE) training regarding significant changes to models and software during the bi-annual SRA counterpart meetings. Formal classroom refresher training for risk assessment is offered through a new course, P501, "Advanced Topics in Risk Assessment." In addition, the NRR, RES, regional SRAs, and Idaho National Laboratory (INL) staff participate in SRA counterpart meetings.

5. INL Support

INL technical staff accompanied NRR staff during the SDP Phase 2 Plant-Specific Notebook site visits between 2001 and 2004. During these site visits, they collected information and discussed technical issues with the licensees. Subsequent to these site visits, the NRR conducted a second round of benchmarking (see SDP Phase 2 Notebooks, Rev. 2) and received plant-specific information and PRA model information from each licensee. The NRR staff has provided the most current version of the SDP notebooks, notebook supporting information, and licensee information to RES to further enhance SPAR model accuracy, and they regularly contact the licensee for clarification during SPAR model development and revision efforts. The INL also provides technical support services for model users to answer questions and investigate issues that arise from the use of the revised Revision 3 SPAR models by staff analysts. This includes resolution of modeling issues or plant specific issues identified by model users during the performance of a risk assessment of an operational event or inspection finding. Technical support services also include investigating and resolving research issues that require answers before the modeling of a given operational event, condition, or a technical issue can proceed.

SUPPLEMENTAL DOCUMENTS LIST

Filename	Description
ChangeFormDataLog.xls	Excel file of changes
Event Evaluations GEM 2005.pdf	User Manual
fixes.doc	Version 7.26 changes through October 2005
howto_risk_dlls.doc	How to build the sage risk dlls for the SAPHIRE 8 software project
NUREG-CR-6688.pdf	Testing, Verifying, and Validating SAPHIRE Versions 6.0 and 7.0, INEEL/EXT-99-00876
Programmers_Workbench.pdf	SAPHIRE Development Manual
Project Setup Guide.doc	Saphire Project Environment Development Guide
RCS Reports Subdirectory	Revision Control System (RCP) (39 SAPHIRE 7.26 Release Notes Fix files - files not listed)
SAPHIRE 6-7 NUREG Vol-1 - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Summary Manual, INL/EXT-05-00248
SAPHIRE 6-7 NUREG Vol-1 - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Summary Manual, INL/EXT-05-00248
SAPHIRE 6-7 NUREG Vol-2 - 2006 Final.doc,	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Technical Reference, INL/EXT-05-00327
SAPHIRE 6-7 NUREG Vol-2 - 2006 Final.pdf,	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Technical Reference, INL/EXT-05-00327
SAPHIRE 6-7 NUREG Vol-3a - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Code Reference Manual – Part A, INL/EXT-05-00644
SAPHIRE 6-7 NUREG Vol-3a - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Code Reference Manual – Part A, INL/EXT-05-00644
SAPHIRE 6-7 NUREG Vol-3b - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Code Reference Manual – Part B, INL/EXT-05-00644
SAPHIRE 6-7 NUREG Vol-3b - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Code Reference Manual – Part B, INL/EXT-05-00644
SAPHIRE 6-7 NUREG Vol-4 - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Tutorial, INL/EXT-05-00654
SAPHIRE 6-7 NUREG Vol-4 - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Tutorial, INL/EXT-05-00654
SAPHIRE 6-7 NUREG Vol-5 - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), GEM Manual, INL/EXT-05-00682
SAPHIRE 6-7 NUREG Vol-5 - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), GEM Manual, INL/EXT-05-00682
SAPHIRE 6-7 NUREG Vol-6 - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Quality Assurance Manual, INL/EXT-05-00655
SAPHIRE 6-7 NUREG Vol-6 - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Quality Assurance Manual, INL/EXT-05-00655
SAPHIRE 6-7 NUREG Vol-7 - 2006 Final.doc	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Data Loading Manual, INL/EXT-05-00643
SAPHIRE 6-7 NUREG Vol-7 - 2006 Final.pdf	Draft NUREG, Systems Analysis Programs for Hands-on Integrated Reliability Evaluations (SAPHIRE), Data Loading Manual, INL/EXT-05-00643
SAPHIRE Advanced 2005.pdf	User Manual
SAPHIRE Basics 2005.pdf	User Manual
SAPHIRE Change Design and Testing Procedure.doc	The SAPHIRE Change Design and Testing Procedure
SAPHIRE_8_Project_Plan.doc	Project plan
SAPHIRE_8_SVVP_REV_2_Prelimn.pdf	SAPHIRE Version 8 Software Verification and Validation Plan, INL/EXT-05-00821
SAPHIRE_Quality_Assurance_Methodology.pdf	A variety of techniques used to assure the quality of SAPHIRE software
Software Development Resources.pdf	Software Development Resources, INEEL Identifier: GDE-7066 (software development guide)
Software Quality Assurance.pdf	19.1 Software Quality Assurance, Idaho Cleanup Project, Identifier: PRD-5092
Sofware Management.pdf	Management Control Procedure, Software Management, Idaho Cleanup Project, Identifier: MCP-550
Web Site Change Log Forms.doc	SAPHIRE web site change log