

May 26, 2010

MEMORANDUM TO: Stephen Dingbaum
Assistant Inspector General for Audits

FROM: Bruce S. Mallett /**RA**/
Deputy Executive Director for Reactor
and Preparedness Programs
Office of the Executive Director for Operations

SUBJECT: UPDATE OF STAFF RESPONSE TO OFFICE OF THE
INSPECTOR GENERAL AUDIT OF THE U.S. NUCLEAR
REGULATORY COMMISSION'S QUALITY ASSURANCE
PLANNING FOR NEW REACTORS (OIG-10-A-02)

As you and I discussed on May 3, 2010, below is an update to our December 17, 2009, response to OIG-10-A-02, "Audit of NRC's Quality Assurance Planning for New Reactors," dated November 16, 2009, by the Office of the Inspector General (OIG). This update provides further discussion and additional actions we have taken in response to the findings and recommendations in the OIG audit.

OIG recommendations 1 and 2 ask us to clearly define the quality assurance (QA) review coordination requirements of the Standard Review Plan (SRP), NUREG-0800, and to develop a process for reviewers to coordinate QA reviews and a method to determine that the QA coordination has occurred for new reactor applications in the Office of New Reactors (NRO). We do not agree that it is necessary to further document a process for coordination between the two groups that actually perform QA reviews in NRO (i.e., Quality and Vendor Branches 1 and 2) beyond the routine, day-to-day coordination that is achieved because the two groups are under the direction of the same Division Director and use the same SRP and procedures.

There are other interfaces that may involve a question regarding QA from the other technical branches in NRO (i.e., those reviewing applications for Combined Licenses or Design Certifications and referred to as the "technical staff"). We do agree that we can clarify management's expectations regarding this type of coordination. With regard to these type review interfaces, our December 17, 2010, response described how information is shared between QA reviewers and technical staff if quality-related issues are identified. Our response also discussed the steps we are taking to modify the SRP to document this process to ensure coordination occurs. NRO has initiated the appropriate changes to the SRP to clarify the expected practice. As noted in the February 17, 2010, memorandum to the NRO's Rulemaking and Guidance Development Branch (Agencywide Documents Access and Management System Accession No. ML100190179), the SRP will be revised to state that "The organization responsible for quality assurance performs the reviews of design, construction, and operation

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phase quality assurance programs under SRP Chapter 17. In addition, while conducting regulatory audits in accordance with Office Instruction NRR-LIC-111 or NRO-REG-108, *Regulatory Audits*, the technical staff may identify quality-related issues. If this occurs, the technical staff should contact the organization responsible for quality assurance to determine if an inspection should be conducted.” The NRC staff issued the revised SRP sections on May 19, 2010.

OIG recommendations 3 and 4 relate to the quality of translated documents and associated impacts on licensing and inspection activities. We agree that proper translation of documents is important to both licensing and inspection decisions made by the regulator. We have reviewed what activities are conducted in NRO and Region II in these two areas and determined the actions needed to address this issue at this time. These activities are discussed further below.

For licensing, existing regulations require that applicants ensure the accuracy and completeness of the information submitted to the U.S. Nuclear Regulatory Commission (NRC) regardless of its genesis. The NRC bases its licensing decisions on this docketed information. Further, the staff reviews licensing submittals to ensure that the applicant's assumptions are technically correct and that the proposed activities provide reasonable assurance of the protection of the public health and safety and the environment. Accordingly, we decided that it is not necessary to take additional actions regarding the licensing process, since translations do not have any impact.

As for NRO vendor inspections, we agree that translators and/or interpreters may be needed to help assure the integrity of the information reviewed during inspections. To support inspections of foreign vendors and enhance communication during such inspections, we have allocated resources for the use of translators and interpreters, as necessary. It should be noted that the NRO used translators and/or interpreters during a vendor inspection in Japan last year and plans to do so again for an upcoming vendor inspection in Sweden. Accordingly, the staff revised Inspection Manual Chapter 2507, “Construction Inspection Program: Vendor Inspections,” on April 27, 2010, to include guidance on the use of translators and/or interpreters. In addition, NRO frequently coordinates its vendor inspections with its regulatory counterparts in the country where the vendor is located. Since the national regulator's inspectors are bilingual, they provide additional translation and interpretation support. This coordination facilitates communication in general and identification and resolution of potential translation concerns.

Furthermore, the NRC regulations require licensees to provide oversight of vendor activities. Specifically, Criterion VII of Appendix B to 10 CFR Part 50, “Control of Purchased Material, Equipment, and Services,” requires licensees who procure material, equipment, or services from contractors or subcontractors to perform evaluations of those suppliers. The purpose of this evaluation is to ensure the suppliers implement an effective quality assurance program, consistent with the requirements of Appendix B to 10 CFR Part 50 and the licensee's technical requirements for those items and services purchased by the licensee. In addition, 10 CFR 50.55a requires that components which are part of the reactor coolant pressure boundary meet the requirements for Class 1 components in Section III of the American Society of Mechanical Engineer (ASME) Boiler and Pressure Vessel Code. Under these requirements, the manufacturer must be an ASME certificate holder and employ an independent authorized nuclear inspector (ANI) to perform third party inspections to verify that components are constructed in accordance with ASME Section III requirements. The duties of the ANI include, but are not limited to, witnessing or verifying in-process fabrication, nondestructive examination, and various tests such as the hydrostatic and final pressure tests. Those requirements apply irrespective of the geographical location or native language of the vendor. We do not believe that it is necessary to take additional actions regarding the licensees' oversight of vendor activities.

Finally, as a general matter and consistent with our practice in other areas, if an issue associated with translation of documents is identified during the staff's reviews or inspections, we will take appropriate follow-up actions to ensure the issue is adequately addressed. We will evaluate and consider the need for additional reviews and/or inspections, on a sample basis, if we find issues. We will also consider additional communications (e.g., Generic Communications) to inform and share such matters with the nuclear industry if and when they occur.

Thank you again for our discussion on May 3, it aided us in providing a response that is better linked to the issues discussed in your report. If you have any question, please contact Mike Johnson or me.

cc. Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff

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 Commissioner Svinicki
 Commissioner Apostolakis
 Commissioner Magwood
 Commissioner Ostendorff

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(Ref G20090653, WITS201000109, WITS201000110, WITS201000111, WITS201000112)

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