



**UNITED STATES**  
**NUCLEAR REGULATORY COMMISSION**  
WASHINGTON, D.C. 20555-0001

**OFFICE OF THE  
INSPECTOR GENERAL**

August 17, 2010

**MEMORANDUM TO:** R. William Borchardt  
Executive Director for Operations

**FROM:** Stephen D. Dingbaum */RA/*  
Assistant Inspector General for Audits

**SUBJECT:** STATUS OF RECOMMENDATIONS: AUDIT OF NRC'S  
QUALITY ASSURANCE PLANNING FOR NEW  
REACTORS (OIG-10-A-02)

**REFERENCES:** DEPUTY EXECUTIVE DIRECTOR FOR REACTOR AND  
PREPAREDNESS PROGRAMS MEMORANDUM DATED  
DECEMBER 17, 2009

DEPUTY EXECUTIVE DIRECTOR FOR REACTOR AND  
PREPAREDNESS PROGRAMS MEMORANDUM DATED  
MAY 26, 2010

Attached is the Office of the Inspector General's (OIG) analysis and status of recommendations as discussed in the agency's response memoranda dated December 17, 2009, and May 26, 2010. Based on these responses, recommendations 1 and 2 are closed and recommendations 3 and 4 are resolved. Please provide an update for these recommendations by December 15, 2010.

If you have questions or concerns, please call me at 415-5915, or RK Wild, Team Leader, at 415-5948.

Attachment: As stated

cc: N. Mamish, OEDO  
J. Andersen, OEDO  
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C. Jaegers, OEDO

**Audit Report**  
**Audit of NRC's Quality Assurance Planning for New Reactors**  
**OIG-10-A-02**

**Status of Recommendations**

Recommendation 1: Clearly define the QA [Quality Assurance] review coordination requirements of the standard review plan.

Agency Response Dated  
December 17, 2009:

NRO acknowledges that NUREG-0800, "Standard Review Plan," (SRP) states in some chapters that the technical reviewers will coordinate their review with the QA reviewers. However, NRO believes that all QA requirements that need to be verified during the licensing process are contained in Chapter 17, "Quality Assurance," of the SRP and that there are no QA portions of the technical chapters of the SRP outside of Chapter 17. NRO staff has completed its review of NUREG-0800 and has identified all SRP sections and chapters that refer to QA coordination. The NRO staff plans to initiate changes to the identified sections and chapters of NUREG-0800 to state that "the organization responsible for QA performs the reviews of design, construction, and operations phase quality assurance programs under SRP Section 17.5, 'Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants.'" In addition, the SRP will be revised to state that "while conducting regulatory audits in accordance to Office Instruction 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 staff expects to provide the SRP mark-ups to the responsible organization by March 2010 for incorporation into the next revision of the SRP.

Agency Response Dated  
May 26, 2010:

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

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**Status of Recommendations**

Recommendation 1 (continued):

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 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

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Recommendation 1 (continued):

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 Analysis:

NRC stated that the QA review coordination portions of the technical chapters of the Standard Review Plan are not needed. Thus, NRO took steps to cleanse the document of any mention of QA review coordination in the technical chapters of the Standard Review Plan. As part of this effort, NRO determined that these changes were administrative in nature and could be made unilaterally. Given the agency's de-emphasis of coordination language in the now-revised Standard Review Plan, the original recommendation has been made obsolete. Thus, recommendation 1 is closed.

**Status:**

Closed.

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**Status of Recommendations**

Recommendation 2: Develop a process for reviewers to coordinate QA reviews and a method to determine that the QA coordination has occurred.

Agency Response Dated  
December 17, 2009: As stated in response to recommendation 1, the NRO staff initiated changes to the identified sections and chapters of the SRP to state that the review of quality assurance is performed in accordance with SRP Chapter 17 consistent with the remaining SRP chapters.

Agency Response Dated  
May 26, 2010: NRC reiterated that it agrees that it could clarify management's expectations for coordination between QA reviewers and technical staff. NRC explained that it has initiated changes to the SRP as outlined in a February 17, 2010 memorandum to the NRO Rulemaking and Guidance Development Branch. NRC stated that NRC issued the revised SRP sections on May 19, 2010.

OIG Analysis: NRC's response to recommendation 1 indicated that the QA review coordination language in some of the technical chapters of the Standard Review Plan is not needed and, thus, NRO has eliminated those requirements. As such, the need to develop a process to assure that QA reviews are coordinated in accordance with the Standard Review Plan is moot. Therefore, recommendation 2 is closed.

**Status:** Closed.

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**Status of Recommendations**

Recommendation 3: Determine how the quality of translated documents impacts:

- a). NRC and industry ability to assess the quality of foreign-supplied safety-related parts and services to new nuclear power plants.
- b). NRC and industry QA oversight, including licensing and inspection activities.

Agency Response Dated  
December 17, 2009:

The quality of translated documents impacts the level of NRC resources needed to assess the quality of foreign-supplied components and services to new nuclear power plants since translators and/or interpreters may be needed to help assure the integrity of information reviewed during inspections. In Fiscal Year (FY) 2009, NRO has taken steps to allocate resources for the use of translators and/or interpreters to support NRO foreign vendor inspections. In addition, an inspector from the national regulator of the country of the inspected organization often participates in our vendor inspections. This is done as part of the Multinational Design Evaluation Program. Since the national regulator's inspectors are bilingual, they provide additional translation and interpretation support.

The regulations require that the applicant ensure the accuracy and completeness of submitted information, regardless of its genesis. During its review, the NRC bases its licensing determinations on this docketed information. Therefore, whether any translation was involved prior to submittal is not germane to the NRC conclusions. As for NRO vendor inspections, NRO has incorporated the use of translators and/or interpreters into its vendor inspections at foreign suppliers, as needed. In FY 2009, NRO has taken steps to allocate resources for the use of translators and/or interpreters to support NRO foreign vendor inspections. In addition, an inspector from the national regulator of the

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Recommendation 3 (continued):

country of the inspected organization often participates in our vendor inspections. This is done as part of the Multinational Design Evaluation Program. Since the national regulator's inspectors are bilingual, they provide additional translation and interpretation support.

Agency Response Dated  
May 26, 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

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Recommendation 3 (continued):

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

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Recommendation 3 (continued):

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.

OIG Analysis:

NRC's response to recommendation 3 indicates steps the agency has taken to meet the intent of the recommendation, but additional action is needed to fully address the recommendation. OIG's recommendation requested NRC to make a determination of the impact of translated documents on two separate areas related to (a) assessing the quality of parts and services, and (b) QA oversight.

With regard to part (a), NRC did not offer any determination of the impact of translated documents on the ability of both NRC and industry to assess the quality of parts and services. Rather, the agency stated that the quality of translated documents impacts the level of NRC resources needed to assess the quality of parts and services during inspections. Part (a) of the recommendation is requesting the agency to consider the totality of impacts from translated

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Recommendation 3 (continued):

documents on the entire industry, and not only on the resource requirements of NRC. Outside of the potential cost impacts to the agency, NRC did not evaluate all of the potential uses of foreign translated documents that directly and indirectly impact the quality of foreign-supplied parts and services. For example, NRC would not likely need language translators to inspect a U.S.-based vendor. Nonetheless, that same U.S.-based vendor may be procuring parts from a foreign sub-vendor that provides accompanying technical documentation in a translated document.

With regard to part (b), NRC provided responses regarding how the quality of translated documents impacts three oversight areas; specifically, licensing, vendor inspections, and licensee oversight of vendor activities. NRC's response in these areas does not fully address the recommendation, as follows:

1. For licensing, NRC stated that applicants must ensure the accuracy and completeness of submitted, docketed information. Thus, NRC has determined that translations conducted prior to submission are not germane to NRC conclusions. Although licensees are required to provide accurate information, inaccurate information may be inadvertently submitted. Licensees typically employ various means to increase the assurance that information provided to NRC is accurate; however, NRC has not assessed if licensees check translated documents in a similar manner.

As part of any such analysis of impacts of translated documents, NRC should also consider all of the purposes for which foreign language documents may be translated in the new reactor construction environment. Based on the OIG's audit fieldwork, documents related to the QA of new nuclear power

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Recommendation 3 (continued):

plant parts and services may be translated for at least four distinct purposes.

- First, documents from foreign-based design certification applicants which are translated into English prior to submission to the NRC.
- Second, documents which are translated into English by foreign vendors for review by NRC inspectors during NRC vendor inspections.
- Third, documents which are translated by foreign-based nuclear vendors for U.S. based licensees or vendors for Appendix B supplier audits or commercial grade dedication.
- Fourth, technical manuals and other documents that are delivered along with components would have to be translated into English if they were manufactured by a foreign supplier.

Many of these documents would not be routinely submitted to NRC, yet the impact of these documents on the quality of industry activities, including submissions to NRC and in industry's own oversight activities, may be profound.

2. For vendor inspections, NRO determined that translators and/or interpreters may be needed to assure the integrity of the information reviewed during the inspections, and has allocated resources for the use of translators and interpreters and updated Inspection Manual Chapter 2507. However, Inspection Manual Chapter 2507 does not establish expectations that translators and interpreters will be used as necessary to ensure that the utilization of foreign language documents or communication with

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Recommendation 3 (continued):

foreign language speakers does not degrade the quality of the inspection. The response states that foreign inspectors are bilingual and that this ensures foreign language interpretation assistance will be available on inspections, but such assistance is not mandated and may not always be available when needed to ensure inspection quality is maintained.

3. For licensee oversight of vendor activities, NRC stated that current regulations require licensees to provide oversight of vendor activities. Furthermore, for Class 1 reactor coolant vessel boundary components, NRC stated that manufacturers must employ independent nuclear inspectors to verify that components are constructed in accordance with ASME requirements irrespective of the native language of the manufacturer. NRO determined that no additional actions were required. However, ASME Class 1 components represent a small part of the plant. There are many other safety-significant components that are manufactured at vendors that are not subject to independent nuclear inspectors.

On the basis that NRC has taken some initial steps to meet the intent of the recommendation, this recommendation is resolved. It will be closed when the agency provides determinations for both parts of the recommendation. For part (a) of the recommendation, it will be closed when NRC provides documentation of its determination of the impacts of translated documents on both the NRC's and the industry's ability to assess the quality of foreign-supplied safety-related parts and services to new nuclear power plants. Part (b) of the recommendation will be closed when NRC provides documentation of its determination of the impacts of translated documents on both the NRC's and the industry's oversight.

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Recommendation 3 (continued):

**Status:** Resolved.

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**Status of Recommendations**

Recommendation 4: Incorporate results of the assessments into NRC's QA oversight activities.

Agency Response Dated  
December 17, 2009:

As stated in response to recommendation 3.b, NRO has incorporated the use of translators and/or interpreters into its vendor inspections at foreign suppliers, as needed. The use of translators and/or interpreters to support NRO foreign vendor inspections was effective as of FY 2009. NRO will continue to evaluate necessary improvements into its QA oversight activities.

Agency Response Dated  
May 26, 2010:

As described above and in NRC's response to the previous recommendation, the agency concluded that it does not need to take any action with respect to document translation in licensing since NRC regulations require that applicants ensure the accuracy and completeness of the information submitted to the NRC. Further, NRC concluded that it does not believe that it is necessary to take additional actions regarding the licensees' oversight of vendor activities in the context of document translation. NRC has determined that translators and/or interpreters may be needed to help assure the integrity of the information reviewed during inspections. As such, NRO has allocated resources for the use of translators and interpreters and revised IMC 2507 to include guidance on the use of translators and/or interpreters.

OIG Analysis:

On the basis that the agency has taken some steps to implement program changes as a result of some initial determinations under recommendation 3, this recommendation is resolved. It will be closed when the agency provides determinations for both parts of recommendation 3, and incorporates the results of the determinations into NRC's QA oversight activities.

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**Status of Recommendations**

Recommendation 4 (continued):

**Status:** Resolved.