

August 6, 2014

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

FROM: Glenn M. Tracy, Director /**RA Gary Holahan Acting for**/
Office of New Reactors

SUBJECT: STATUS OF RECOMMENDATIONS AND STAFF RESPONSE TO
THE OFFICE OF THE INSPECTOR GENERAL'S AUDIT OF THE
U.S. NUCLEAR REGULATORY COMMISSION'S VENDOR
INSPECTION PROGRAM (OIG-10-A-20)

This memorandum provides the U.S. Nuclear Regulatory Commission (NRC) staff's updates for the remaining open recommendations from the Office of the Inspector General's (OIG) audit OIG-10-A-20, "Audit of NRC's Vendor Inspection Program," dated September 28, 2010. The staff continues to implement actions in response to OIG's audit and remains responsive to OIG's recommendations.

Recommendation 1:

Develop an Office of New Reactors (NRO) Vendor Inspection Program planning document that:

- a. Articulates a clear purpose for the Vendor Inspection Program
- b. Establishes metrics to evaluate the success of the Vendor Inspection Program

Status: Closed.

Recommendation 2:

Develop and document a methodology to identify vendors that supply safety related parts and services to the nuclear industry with Appendix B quality assurance programs.

OIG analysis dated March 12, 2014:

The proposed actions to issue a Regulatory Issue Summary (RIS) and publish a Web site by March 2014 constitute the agency's proposed methodology to identify vendors that supply safety-related parts and services to the nuclear industry. These actions continue to

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meet the intent of OIG's recommendation. OIG notes that the Office of Management and Budget's queries regarding FOIA have delayed RIS and Web site publication from the original September 2013, completion date to March 2014. OIG will close this recommendation upon issuance and OIG review of the RIS and review of the finalized framework of the NRO vendor Web site upon final completion.

Status: Resolved.

NRC Staff Update:

The staff issued RIS 2014-07, "Enhancements to the Vendor Inspection Program-Vendor Information Request," on May 5, 2014. It is available on the agency's public Web site at:

<http://nrcweb.nrc.gov:400/reactors/new-reactors/oversight/quality-assurance/vendor-insp/reg-info-summaries.html>.

RIS 2014-07 provides licensees and vendors with the option of completing an electronic Vendor Registration Form, also found on the public Web site. The staff is continuing to update the vendor information in an internal use only database that provides the NRC with the vendor's contact information for outreach and communication purposes. As a result of the RIS 2014-07, approximately 47 vendors have completed the Vendor Registration Form and have been added to the internal database. Enclosure 3 to this memorandum provides a copy of the issued RIS.

Target Completion Date: Completed - May 5, 2014.

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Recommendation 3:

Develop and document a risk-informed methodology to select vendors for inspection.

Status: Closed.

Recommendation 4:

Develop and use a vendor outreach/communications plan.

Status: Closed.

Recommendation 5:

Align NRC guidance and regulations to clarify acceptance methods for commercial-grade dedication (CGD).

OIG analysis dated March 12, 2014:

This recommendation remains resolved. OIG will close this recommendation upon review of (1) Revision 1 to the draft regulatory basis, which was to be completed in September 2013, and (2)

the proposed and final rules in 2015 and 2016, respectively. OIG notes the change in due dates, discussed with NRO staff on January 27, 2014, because of changes to the 10 *Code of Federal Regulations* (CFR) Part 21 rulemaking schedule as well as incorporation of Office of Nuclear Materials Safety and Safeguards (NMSS) and external stakeholder comments. Closure will be contingent upon OIG review of the steps taken by NRO to implement those actions necessary to align the guidance and the regulation to clarify acceptance methods for CGD.

Status: Resolved.

NRC Staff Update:

Actions taken and planned: The staff continues to make progress on its rulemaking efforts to clarify Title 10 of the 10 CFR Part 21, "Reporting of Defects and Noncompliance." This progress includes clarifying acceptance methods for CGD.

The staff continues to participate in the Electric Power Research Institute (EPRI) Technical Advisory Group meetings on CGD. These meetings have focused on the industry's proposals to issue a revision to EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)." If the staff agrees the revision is an acceptable means of demonstrating compliance with the NRC's regulations, the document will be endorsed through a regulatory guide and will provide detailed guidelines for CGD. The staff has coordinated with the Office of Nuclear Regulatory Research to create draft regulatory guide (DG)-1292, "Dedication of Commercial Grade Items." EPRI plans to finalize its guidance in late summer 2014.

From the beginning of this rulemaking project, the staff has emphasized its commitment to keeping its stakeholders informed and involved. Comments received during the public meetings have provided excellent insights for improving the regulatory basis. This extensive stakeholder participation and feedback has led to a revision of the schedule. In addition, the staff has been developing solutions to many of the complex issues associated with the rulemaking. One example of this has been the staff's work on defining basic components for nonreactor facilities. Staff from NRO and NMSS has been coordinating this effort to develop a common solution that avoids potential detrimental effects. The staff performed four site visits in the summer of 2013, at different fuel cycle facilities, to gauge the differences in interpretation of the current definition and inform a path forward. The staff's updated schedule is included in the table below. The latest schedule reflects a targeted issuance of Revision 1 to the draft regulatory basis in August 2014. Revision 1 of the draft regulatory basis is currently in concurrence. The staff recently presented concepts from this latest revision at the 2014 Workshop on Vendor Oversight. That presentation is publicly available in the Agencywide Documents Access and Management System under Accession No. ML14153A121.

Milestones	Target Date
Conduct Internal Collaboration on Draft Regulatory Basis	Ongoing
Make Final NMSS Site Visit at Fuels Facilities (COMPLETE)	September 27, 2013
Hold NMSS Public Meeting to Include Potential Solutions to Policy Issues (COMPLETE)	March 6, 2014

Milestones	Target Date
Begin Concurrence of Revision 1 to the Draft Regulatory Basis (COMPLETE)	March 31, 2014
Release Revision 1 to the Draft Regulatory Basis	August 2014
Hold Public Meetings to Discuss Regulatory Basis	Fall 2014
Finalize Regulatory Basis	December 2014
Issue Proposed Rule with draft guides	September 2015
Issue Final Rule	December 2016

Target Completion Date: Issue proposed rule and draft guides, DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items"- September 2015. Issue final rule: December 2016.

CONTACT: Victor Hall, NRO/DCIP/QVIB
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Recommendation 6:

Issue regulatory guidance to clarify sampling expectations for CGD.

OIG analysis dated March 12, 2014:

This recommendation remains resolved and will be closed when OIG reviews the updated actions deemed necessary to clarify sampling expectations for CGD.

Status: Resolved.

NRC Staff Update:

Actions taken and planned: As noted above for Recommendation 5, the staff continues to make progress on its rulemaking efforts to clarify 10 CFR Part 21, which includes sampling expectations for commercial grade dedication. Section G, "Sampling Requirements," of Chapter 3, "Commercial Grade Dedication," of the draft regulatory basis describes the staff's technical analysis of sampling. The staff is discussing development of an updated industry sampling guidance document with stakeholders and will undertake regulatory guidance development in parallel with the development of the proposed rule.

Target Completion Date: Issue proposed rule and draft guides, DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items" September 2015. Issue final rule: December 2016.

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Recommendation 7:

Issue regulatory guidance describing a process that NRC considers acceptable for compliance with Part 21.

OIG analysis dated March 12, 2014:

This recommendation remains resolved. OIG will continue to review agency actions as provided above, to include work being done on completing the regulatory basis, revisions to the current rulemaking schedule, and ultimately the issuance of a final rule and final regulatory guides. Closure will also be contingent upon OIG's final review of implemented actions NRC considers acceptable for compliance with Part 21 as previously indicated.

Status: Resolved.

NRC Staff Update:

Actions taken and planned: As noted above for Recommendation 5, the staff continues to make progress on its rulemaking efforts to clarify 10 CFR Part 21, which includes describing a process that the NRC considers acceptable for compliance to the regulations. Section 1 and Section A, each entitled, "Lack of Regulatory Guidance," of the draft regulatory basis describes the staff's technical analysis of regulatory guidance for 10 CFR Part 21. The staff will undertake regulatory guidance development in parallel with the development of the proposed rule.

During the May 30, 2013, public meeting on evaluating and reporting (i.e., the 10 CFR Part 21 process), the Nuclear Energy Institute (NEI) agreed to author a guidance document on the evaluating and reporting process. Development is expected to be similar to EPRI's efforts to revise guidance on CGD. This may be useful guidance that could be endorsed through the planned NRC regulatory guide. The staff attended an NEI Part 21 Guidance Team meeting on April 23, 2014, and noted that NEI is making progress on development of its guidance. NEI plans to complete a first draft of the guide in the late summer of 2014.

Target Completion Date: Issue proposed rule and draft guides, DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items"- September 2015. Issue final rule: December 2016.

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Recommendation 8:

Clearly indicate via the NRC public Web site how and when Part 21 has changed.

Status: Closed.

Recommendation 9:

Develop guidance that clarifies the requirements for vendors on how to approve accredited commercial-grade calibration laboratories for safety-related applications.

OIG analysis dated March 12, 2014:

The proposed actions continue to meet the intent of the recommendation. OIG notes the staff's progress, including participation in International Laboratory Accreditation Cooperation (ILAC) meetings as well as the NEI proposals expected in June 2014. The recommendation will be closed after OIG reviews the proposed safety evaluation report (SER) and related generic communications prior to final publication in December, 2014 to determine if the new guidance clarifies vendor requirements as described in the recommendation.

Status: Resolved.

NRC Staff Update:

The staff continues to work toward clarifying the requirements for licensees and vendors for how to approve accredited commercial grade calibration and testing laboratories for use in safety-related applications. On April 29, 2014, NEI submitted for the NRC's review and endorsement NEI 14-05, Revision 0, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services." This guidance provides an approach to utilize accreditation by signatories to the ILAC Mutual Recognition Arrangement as part of a purchaser's commercial grade dedication of laboratory services. The NRC staff is currently reviewing NEI 14-05 and is preparing to issue a request for additional information (RAI) to get clarification on some areas of NEI 14-05. Once NEI's response to the RAI has been reviewed and accepted, the NRC staff plans to issue a SER followed by a RIS. In addition, the NRC staff recently completed a presentation at the NRC's Workshop on Vendor Oversight titled "NRC's Expectations when using the International Laboratory Accreditation Cooperation Process."

Based on NEI's updated schedule, the staff expects to complete the SER and issue a generic communication in December 2014.

Target Completion Date: Complete SER and issue generic communications by December 2014.

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Recommendation 10:

Develop and implement a formal agencywide strategy and plan to monitor and evaluate counterfeit, fraudulent, and suspect items.

Status: Closed.

Enclosures:

1. Correspondence History OIG-10-A-20, "Audit of NRC's Vendor Inspection Program"
2. NRC Regulatory Issue Summary 2014-07

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Magwood
Commissioner Ostendorff
SECY
EDO

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 Commissioner Ostendorff
 SECY
 EDO

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ADAMS Accession No: ML14074A025

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NRO-002

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DATE	7/21/14	7/22/14	7/14/14	7/30/14	8/6/14	

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Correspondence History
OIG-10-A-20, “Audit of NRC’s Vendor Inspection Program”

- September, 28, 2010—*Audit Report*: Audit of NRC’s Vendor Inspection Program (OIG-10-A-20)
 - Agencywide Documents Access and Management System (ADAMS) Accession No. ML102730627
- October 30, 2010—*Memo to the Assistant Inspector General for Audits*: Staff Response to the Office of the Inspector General’s Audit of the Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML102950601
- January 11, 2011—*Memo to the EDO [Executive Director for Operations]*: Status of Recommendations: Audit of the Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-A-20)
 - ADAMS Accession No. ML110130015
- May 26, 2011—*Memo to the Assistant Inspector General for Audits*: Status of Recommendations and Staff Response to the Office of the Inspector General’s Audit of the U.S. Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML111290142
- July 27, 2011—*Memo to the EDO*: Status of Recommendations: Audit of the Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML11209C350
- January 6, 2012—*Memo to the Assistant Inspector General for Audits*: Status of Recommendations and Staff Response to the Office of the Inspector General’s Audit of the U.S. Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML12004A064
- March 9, 2012—*Memo to the EDO*: Status of Recommendations: Audit of the Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML120690007
- August 3, 2012—*Memo to the Assistant Inspector General for Audits*: Status of Recommendations and Staff Response to the Office of the Inspector General’s Audit of the U.S. Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML12207A607
- September 13, 2012—*Memo to the EDO*: Status of Recommendations: Audit of the Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML12257A180
- February 4, 2013—*Memo to the Assistant Inspector General for Audits*: Status of Recommendations and Staff Response to the Office of the Inspector General’s Audit of the U.S. Nuclear Regulatory Commission’s Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML13028A364

Enclosure 1

- March 26, 2013— *Memo to the EDO*: Status of Recommendations: NRC's Vendor Inspection Program (OIG 10-A-20)
 - ADAMS Accession No. ML13085A004
- July 31, 2013—*Memo to the Assistant Inspector General for Audits*: Status of Recommendations and Staff Response to the Office of the Inspector General's Audit of the U.S. Nuclear Regulatory Commission's Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML13199A511
- October 17, 2013— *Memo to the EDO*: Status of Recommendations: Audit of NRC's Vendor Inspection Program (OIG 10-A-20)
 - ADAMS Accession No. ML13290A366
- February 3, 2014 —*Memo to the Assistant Inspector General for Audits*: Status of Recommendations and Staff Response to the Office of the Inspector General's Audit of the U.S. Nuclear Regulatory Commission's Vendor Inspection Program (OIG-10-A-20)
 - ADAMS Accession No. ML14029A069
- March 12, 2014— *Memo to the EDO*: Status of Recommendations: Audit of NRC's Vendor Inspection Program (OIG 10-A-20)
 - ADAMS Accession No. ML14071A050