July 31, 2013

MEMORANDUM TO:	Stephen D. Dingbaum Assistant Inspector General for Audits
FROM:	Glenn M. Tracy, Director/ <b>RA</b> / 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 believes that it remains responsive to OIG's recommendations. Enclosure 1 to this memorandum presents a history of correspondence for this audit.

## 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; and
- 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 26, 2013:

The proposed actions to issue a Regulatory Information Summary (RIS) and publish a Web site constitute the agency's proposed methodology to identify vendors that supply safety-related parts and services to the nuclear industry. These actions continue to meet the intent of OIG's

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recommendation. OIG will close this recommendation upon issuance and OIG review of the proposed RIS and review of the finalized framework of the NRO vendor Web site.

Status: Resolved.

#### NRC Staff Update:

Actions taken: The staff has drafted the RIS. The Office of Management and Budget requested additional information, including a draft of the RIS, to support the clearance. The staff provided this additional information and still anticipates issuing the RIS and posting the Web site by September 2013.

Target Completion Date: September 2013

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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 26, 2013:

This recommendation remains resolved. OIG notes that the development of the regulatory basis will occur concurrently with the development of the proposed rule, both to be completed in September 2013. OIG will close this recommendation upon review of the rule and 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 *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance." This progress includes clarifying acceptance methods for CGD.

The staff's intent remains consistent with its proposal in Commission paper SECY-11-0135, "Staff Plans To Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the *Code of Federal Regulations* Part 21, 'Reporting of Defects and Noncompliance.'" However, regarding schedule, the staff notes that SECY-11-0135 targeted September 2013, for publication of the proposed rule, concurrent with initial drafts of regulatory guides. The staff's updated schedule reflects issuance of Revision 1 to the draft regulatory basis in September 2013. This moves the projected dates for the proposed and final rules to September 2014, and September 2015, respectively.

This schedule shift is a result of extensive stakeholder participation and feedback. From the beginning of this 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.

The staff also notes that its 10 CFR Part 21 subscribers list has grown to over 2,000 subscribers. As previously noted, the staff posts progress updates regarding 10 CFR Part 21, including public meetings, and key documents, on the NRC's Web site at: <a href="http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/part-21-rulemaking.html">http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/part-21-rulemaking.html</a>.

In addition, the staff has participated in three Electric Power Research Institute (EPRI) Technical Advisory Group meetings on CGD. These meetings have focused on 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 via regulatory guide and will provide detailed guidelines for CGD.

<u>Target Completion Date</u>: Issue proposed rule and concurrent draft regulatory guides: September 2014

Contact: Victor Hall, NRO/DCIP

## **Recommendation 6**:

Issue regulatory guidance to clarify sampling expectations for CGD.

## OIG analysis dated March 26, 2013:

This recommendation remains resolved. As noted previously, this recommendation will be closed when OIG verifies that the next steps—to include implementation of the actions necessary to clarify sampling expectations for CGD—have been performed.

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 CGD. 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 will undertake regulatory guidance development in parallel with the development of the proposed rule.

<u>Target Completion Date</u>: Issue proposed rule and concurrent draft regulatory guides: September 2014

Contact: Victor Hall, NRO/DCIP

#### Recommendation 7:

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

#### OIG analysis dated March 26, 2013:

This recommendation remains resolved. As previously stated, this recommendation will be closed upon OIG review of the issuance of a regulatory basis, as well as 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. Sections 1 and A, "Lack of Regulatory Guidance," of the draft regulatory basis describe 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.

On May 30, 2013, the staff hosted a one-day meeting on evaluating and reporting (i.e., the 10 CFR Part 21 process). The results of that meeting, including stakeholder suggestions for improvement are summarized in the meeting minutes, Agencywide Document Access and Management System Accession No. ML13172A093, or on the 10 CFR Part 21 updates at: <a href="http://www.nrc.gov/reactors/new-reactors/oversight/guality-assurance/part-21-rulemaking.html">http://www.nrc.gov/reactors/new-reactors/oversight/guality-assurance/part-21-rulemaking.html</a>.

<u>Target Completion Date</u>: Issue proposed rule and concurrent draft regulatory guides: September 2014

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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 26, 2013:

The proposed actions continue to meet the intent of the recommendation. OIG notes with concern that the scheduled completion dates have slipped from 2013 to late 2014 in this response, and that the original completion date was September 2011. OIG requests that NRO provide updated scheduling dates as soon as possible. The recommendation will be closed after OIG reviews the proposed safety evaluation report (SER) and related generic communications to determine if they clarify the vendor requirements noted in the recommendation.

Status: Resolved.

## NRC Staff Update:

Actions taken and planned: The staff continues to work toward clarifying the requirements for licensees and vendors for how to approve accredited commercial-grade calibration laboratories for use in safety-related applications. The NRC staff plans to participate as observers in International Laboratory Accreditation Cooperation's (ILAC) evaluation of the Japan Accreditation Board (JAB) the week of November 11–15, 2013, in Tokyo, Japan. A team representing the Nuclear Utilities Procurement Issues Committee and the Nuclear Energy Institute (NEI) will also observe the evaluation of JAB's accreditation. After the observation of JAB's evaluation is completed, NEI is expected to submit for NRC review, an industry proposal to expand the NRC's current acceptance of third-party accreditation to include both domestic and international calibration and testing laboratories accredited under ILAC for purposes of CGD. NEI stated that it expects to submit this proposal by June 2014. After the review of NEI's proposal, the NRC staff plans to issue a generic communication to communicate and clarify to the nuclear industry the NRC's technical position on the use of the ILAC accreditation process. The staff still plans to issue a safety evaluation report and a generic communications document within 6 months of receiving an industry submittal. The staff continues to make presentations to stakeholders to clarify the topic.

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

Target Completion Date: 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.

Enclosure:

Correspondence History OIG-10-A-20, "Audit of NRC's Vendor Inspection Program"

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

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NAME		KKavanagh (PPrescott for)		ERoach (RMcIntyre for)	CHsu
DATE	07/17/2013	07/29/2013	07/29/2013	07/29/2013	07/26/2013
OFFICE	NRO/DCIP	OGC*	NRO		
NAME	LDudes		GTracy (G.Holahan for)		
DATE	07/30/2013	07/24/2013	07/31/2013		

# ADAMS Accession No: ML13211A005-pkg; ML13199A511-memo \*via e-mail NRO-002

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# Correspondence History OIG-10-A-20, "Audit of NRC's Vendor Inspection Program"

- <u>September, 28, 2010</u>—Audit Report: AUDIT OF NRC'S VENDOR INSPECTION PROGRAM (OIG-10-A-20)
  - Agencywide Documents Access & 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: STATUS OF RECCOMENDATIONS: AUDIT OF THE NUCLEAR REGULATORY COMMISSION'S VENDOR INSPECTION PROGRAM (OIG-A-20)
  ADAMS Accession No. ML110130015
- <u>May 26, 2011</u>—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. MI 111200142
  - 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. MI 120044064
  - ADAMS Accession No. ML12004A064
- <u>March 9, 2012</u>—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
- <u>August 3, 2012</u>—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
- <u>September 13, 2012</u>—Memo to the EDO: STATUS OF RECOMMENDATIONS: AUDIT OF THE NUCLEAR REGULATORY COMMISSION'S VENDOR INSPECTION PROGRAM (OIG-10-A-20)
  - o ADAMS Accession No. ML12257A180

Enclosure 1

- <u>February 4, 2013</u>—*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) o ADAMS Accession No. ML13028A364
- <u>March 23, 2013</u>— *Memo to the EDO:* STATUS OF RECOMMENDATIONS: NRC'S VENDOR INSPECTION PROGRAM (OIG 10-A-20) •
  - o ADAMS Accession No. ML13085A004

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