

August 19, 2016

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

FROM: Jennifer Uhle, Director **/RA/**
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's) 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.

Status: Closed.

NRC Staff Update

The staff continues to implement our strategy to identify vendors that supply safety-related parts and services to the nuclear industry with Appendix B quality assurance programs.

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In our previous response to this recommendation, the staff proposed and has implemented an enhanced public outreach methodology to include a vendor registration form on the NRC public Web site and described the purpose and intended use of the information gathered through the registration process in regulatory issue summary (RIS) 14-07, "Enhancements to the Vendor Inspection Program-Vendor Information Request," on May 5, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13168A215). Public response to the registration was strongest during the first 6 months of implementation in 2014 with 54 respondents, almost all of whom were already in the Agency's existing vendor database. Since that time, use of the registration form has fallen to essentially no new valid registrations and has continued along that trend for approximately 2 years.

In addition to the Web registration, the vendor inspection database is maintained and updated based on several additional outreach activities, including regular interaction with industry organizations such as the Nuclear Procurement Issues Committee, as well as information gained through on-going routine vendor inspections, and interactions with licensees. Additionally, we routinely screen the participant lists from the biennial NRC vendor workshops to ensure that new vendors are identified and added to the vendor database. To date, the staff has held five vendor workshops, each with 400 to 600 participants.

The vendor registration Web site has not provided any recent vendor information. In order to continue the operation of the Web site, the staff would need to renew the Office of Management and Budget clearance (3150-0220), which expires on April 30, 2017. The justification and associated information collection tasks and paperwork are not cost beneficial. The staff's current outreach efforts provide an effective means for updating the vendor database. Therefore, the staff has concluded that the vendor registration Web site should no longer be continued.

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 7, 2016:

On the basis of the agency's ongoing actions, this recommendation remains resolved. OIG will close this recommendation upon review of the final version of the Regulatory Basis, DG-1292 and NEI 14-09. Specifically, 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 efforts to resolve issues related to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance." This progress includes specifying acceptance methods for CGD for both power and nonpower nuclear power plant applications. Accordingly, the staff continues working with stakeholders in a public process to support the development of industry guidance documents that will potentially be found acceptable by the NRC. The NRC's acceptability for use would be accomplished through two draft regulatory guides (DGs): DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants."

Regarding the development of DG-1292, Nuclear Energy Institute (NEI) submitted Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications (ADAMS Accession No. ML12213A608) for NRC review and approval. The staff completed its review of the EPRI document and concluded that it is an acceptable means of demonstrating compliance with the NRC's regulations. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in the *Federal Register* (FR DOC #2016-16422) on July 8, 2016. The comment period ends on September 6, 2016. The staff plans to address public comments and issue the final Regulatory Guide by the spring of 2017.

Target Completion Date: Completed.

Recommendation 6:

Issue regulatory guidance to clarify sampling expectations for CGD.

OIG analysis dated March 7, 2016:

This recommendation remains resolved and will be closed when OIG reviews the final versions of EPRI NP-5652, TR-102260, and DG-1292 to verify that actions taken are those deemed necessary to clarify sampling expectations for CGD.

Status: Resolved.

NRC Staff Update:

Actions taken and planned:

As noted in staff's update to Recommendation 5, the staff continues to make progress on its efforts to clarify 10 CFR Part 21. The staff's progress includes working with stakeholders in a public process to support the development of industry guidance documents that will potentially be found acceptable by the NRC. The NRC's acceptability for use would be accomplished

through two draft DGs: DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants."

Regarding the development of DG-1292, NEI submitted Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML12213A608) for NRC review and approval. The staff completed its review of the EPRI document and concluded that it is an acceptable means of demonstrating compliance with the NRC's regulations. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in the *Federal Register* (FR DOC #2016-16422) on July 8, 2016. The comment period ends on September 6, 2016. The staff plans to address public comments and issue the final Regulatory Guide by the spring of 2017.

Target Completion Date: Completed.

Recommendation 7:

Issue regulatory guidance describing a process that NRC considers acceptable for compliance with 10 CFR Part 21.

OIG analysis dated March 7, 2016:

This recommendation remains resolved. Per discussion with agency staff on February 8, 2016, OIG notes that NUREG-0302 will not be completed in light of agency staff's recommendation to the Commission to discontinue 10 CFR Part 21 rulemaking. OIG will, however, continue to review agency actions relating to DG-1291 and -1292 as they are completed. Closure will also be contingent upon OIG's final review of DG-1291 and -1292 when completed.

Status: Resolved.

NRC Staff Update:

Actions taken and planned:

As part of the Project AIM re-baselining effort, the NRC staff recommended termination of the 10 CFR Part 21 rulemaking effort in SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities," January 31, 2016 (ADAMS Accession No. ML16028A189). Specifically, Part 21 rulemaking was listed on the shed list of Enclosure 1, line item 2 (ADAMS Accession No. ML16028A212) to SECY-16-0009 (ADAMS Accession No. ML16028A208). That recommendation was accepted in the April 13, 2016, memo from the Commission to the Executive Director for Operations (ADAMS Accession No. ML16104A158). Therefore, the staff's efforts to revise Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," have ceased.

However, the staff continues working with stakeholders in a public process to support the development of industry guidance documents that will potentially be found acceptable by the NRC. The NRC's acceptability for use would be accomplished through two draft DGs:

DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants."

Regarding the development of DG-1291, NEI submitted guidance document NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance, Revision 1," in February 2, 2016 (ADAMS Accession No. ML16054A825) for NRC review and approval. The staff has completed its review of NEI 14-09 and determined that it was an acceptable means of demonstrating compliance with the NRC's regulations. This document will provide adequate guidance to implement the requirements of Part 21 and will supersede NUREG-0302. This approach is consistent with SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011 (ADAMS Accession No. ML110190027) and SECY-11-0135, "Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in 10 CFR Part 21, 'Reporting of Defects and Noncompliance,'" dated September 29, 2011 (ADAMS Accession No. ML112430138). DG-1291 is currently under review by staff in the Office of Nuclear Regulatory Research.

Regarding the development of DG-1292, NEI submitted EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" (ADAMS Accession No. ML12213A608) for NRC review and approval. The staff completed its review of the EPRI document and concluded that it is an acceptable means of demonstrating compliance with the NRC's regulations. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in the *Federal Register* (FR DOC #2016-16422) on July 8, 2016. The comment period ends on September 6, 2016. The staff plans to address public comments and issue the final Regulatory Guide by the spring of 2017.

Target Completion Date: Issue DG-1291, "Guidelines for Implementation of 10 CFR Part 21 Evaluating Deviations and Reporting of Defects and Noncompliance," by March 2017.

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 7, 2016

The proposed actions continue to meet the intent of the recommendation. OIG notes continued progress on completion of draft NEI 14-05 methodology as acceptable guidance for use in ILAC accreditation. The recommendation will be closed after OIG reviews NEI 14-05 and the draft RIS approving NEI 14-05 to determine if the new guidance clarifies vendor requirements as described in the recommendation.

Status: Resolved.

NRC Staff Update:

Actions taken and planned:

On March 16, 2016, the NRC staff published RIS 2016-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," (ADAMS Accession No. ML15323A346) to notify addressees of one method found acceptable by the NRC staff for procurement of calibration and testing services performed by domestic and international laboratories for use in safety-related applications. With the issuance of this RIS, the NRC staff has completed all actions associated with Recommendation 9.

Target Completion Date: Completed.

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"

accreditation. The recommendation will be closed after OIG reviews NEI 14-05 and the draft RIS approving NEI 14-05 to determine if the new guidance clarifies vendor requirements as described in the recommendation.

Status: Resolved.

NRC Staff Update:

Actions taken and planned:

On March 16, 2016, the NRC staff published RIS 2016-01, "Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," (ADAMS Accession No. ML15323A346) to notify addressees of one method found acceptable by the NRC staff for procurement of calibration and testing services performed by domestic and international laboratories for use in safety-related applications. With the issuance of this RIS, the NRC staff has completed all actions associated with Recommendation 9.

Target Completion Date: Completed.

Point of Contact: Yamir Diaz-Castillo, NRO/DCIP/QVIB-2
301-415-2228

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"

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*via email

NRO-002

OFC	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-2	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-3
NAME	ASakadales	YDiaz-Castillo (KKavanagh for)	PPrescott	KKavanagh
DATE	7/13/2016	7/15/2016	7/14/2016	7/15/2016
OFC	QTE*	NRO/DCIP	OGC/NLO*	NRO
NAME	Jay Dougherty	MCheok	AWilson	JUhle
OFC	7/06/2016	07/21/2016	08/04/2016	08/19/2016

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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-10-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
- 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*
- August 6, 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. ML14190B319*
- September 18, 2014 — *Memo to the EDO: Status of Recommendations: Audit of NRC’s Vendor Inspection Program (OIG 10-A-20), ADAMS Accession No. ML14261A414*
- January 14, 2015 —*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. ML14345A672*
- March 10, 2015— *Memo to the EDO: Status of Recommendations: Audit of NRC’s Vendor Inspection Program (OIG 10-A-20), ADAMS Accession No. ML15069A073*
- July 6, 2015—*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. ML15154B636*
- August 13, 2015— *Memo to the EDO: Status of Recommendations: Audit of NRC’s Vendor Inspection Program (OIG 10-A-20), ADAMS Accession No. ML15225A090*
- January 7, 2016—*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. ML15320A498*
- March 7, 2016— *Memo to the EDO: Status of Recommendations: Audit of NRC’s Vendor Inspection Program (OIG 10-A-20), ADAMS Accession No. ML16067A008*