

January 7, 2016

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

FROM: Jennifer Uhle, Director **/RA/ Gary Holahan 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'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.

**Recommendation 3:**

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

Status: Closed.

CONTACT: Antoinette Sakadales, NRO/DCIP  
301-415-6441

**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 August 13, 2015:**

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, "Dedication of Commercial Grade Items" and the Nuclear Energy Institute (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 non-power nuclear power plant applications. Accordingly, in March 2015, the staff issued Revision 1 of the Draft Regulatory Basis (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14135A207) to clarify 10 CFR Part 21 for public comment, and held a public meeting for interested stakeholder on April 28, 2015. The staff also issued the final regulatory basis to 10 CFR Part 21 in August 2015 (ADAMS Accession No. ML15152A457). In addition, the staff has been working with the nuclear industry in a public process to support the development of industry guidance documents that will potentially be found acceptable by the NRC. The NRC's approval for use would be accomplished through two regulatory guides. The staff has coordinated with the Office of Nuclear Regulatory Research to create two draft guides: Draft Regulatory Guide (DG) DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items."

Regarding the development of DG-1292, NEI submitted for staff review a Revision 1 to Electric Power Research Institute (EPRI) NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" (ADAMS Accession No. ML14265A198). Revision 1 to EPRI NP-5652 and TR-102260 is currently under an expedited review by staff in The Office of Nuclear Regulatory Research (RES). Once the draft regulatory guide has gone through internal review and concurrence, it will be sent out for public comment. If the staff concludes that the revision is an acceptable means of demonstrating compliance with the NRC's regulations, then the document will be found acceptable for use through DG-1292. The staff is scheduled to complete this review by the summer of 2016.

The table below outlines the staff's updated schedule and target completion dates.

<b>Milestones</b>	<b>Target Date</b>
Make Final NMSS Site Visit at Fuels Facilities ( <b>COMPLETE</b> )	September 27, 2013
Hold NMSS Public Meeting to Include Potential Solutions to Policy Issues ( <b>COMPLETE</b> )	March 6, 2014
Begin Concurrence of Draft Revision 1 of the Regulatory Basis ( <b>COMPLETE</b> )	March 31, 2014
Issue Draft Revision 1 of the Regulatory Basis ( <b>COMPLETE</b> )	March 31, 2015
Hold Public Meetings to Discuss Draft Revision 1 of the Regulatory Basis ( <b>COMPLETE</b> )	April 28, 2015
Issue Regulatory Basis ( <b>COMPLETED</b> )	August 31, 2015
Issue DG-1292	Summer 2016

Target Completion Date: Issue DG-1292, "Dedication of Commercial Grade Items" by summer of 2016.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB  
301-415-6441

#### **Recommendation 6:**

Issue regulatory guidance to clarify sampling expectations for CGD.

OIG analysis dated August 13, 2015:

This recommendation remains resolved and will be closed when OIG reviews the final versions of EPRI NP-5652 and TR-102260, and DG-1292 to determine if they contain the updated actions 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 the nuclear industry in a public process to support the development of guidance documents that will potentially be found acceptable by the NRC. The NRC's approval would be accomplished through two regulatory guides. The staff has coordinated with RES to create two draft guides: DG-1291 and DG-1292.

Regarding the development of DG-1292, NEI submitted for staff review a Revision 1 to Electric Power Research Institute (EPRI) NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" (ADAMS Accession No. ML14265A198). Revision 1 to EPRI NP-5652 and TR-102260 is currently under an expedited review by staff in RES. Once it has gone through internal review and

concurrence, it will be sent out for public comment. If the staff concludes that the revision is an acceptable means of demonstrating compliance with the NRC's regulations, then the document will be found acceptable for use through DG-1292. The staff is scheduled to complete this review by the summer of 2016.

Target Completion Date: Issue DG-1292, "Dedication of Commercial Grade Items" by summer of 2016.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB  
301-415-6441

### **Recommendation 7:**

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

OIG analysis dated August 13, 2015:

This recommendation remains resolved. OIG will continue to review agency actions as they are completed. Closure will also be contingent upon OIG's final review of implemented actions NRC considers acceptable for compliance with Part 21, including DG-1291, DG-1292, and the final rulemaking.

Status: Resolved.

NRC Staff Update:

Actions taken and planned:

The staff continues to make progress on its efforts to resolve problems with implementing the existing regulatory language. Accordingly, in March 2015, the staff issued Revision 1 of the Draft Regulatory Basis (ADAMS) Accession No. ML14135A207) to clarify 10 CFR Part 21 for public comment, and held a public meeting for interested stakeholders on April 28, 2015. The staff issued the final regulatory basis to 10 CFR Part 21 in August 2015 (ADAMS Accession No. ML15152A457). In addition, the staff has been working with the nuclear industry in a public process to support the development of industry guidance documents that will potentially be found acceptable by the NRC. The NRC's approval for use would be accomplished through two regulatory guides. The staff has coordinated with the Office of Nuclear Regulatory Research to create two draft guides: Draft DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items."

Regarding the development of DG-1291, the NEI submitted for staff review a guidance document NEI 14-09, Revision 0, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," in August 2014 (ADAMS Accession No. ML14245A415) for NRC review and approval. In October and November 2015, the staff facilitated public meetings (summaries can be found in ADAMS Accession No. ML15306A450 and ML15329A202), with stakeholders to discuss the contents of NEI 14-09. Specifically, the staff discussed the document's sole focus on licensees, the definition of 'failure to comply,' when a basic component is considered delivered for use, criteria for distinguishing between the discovery and evaluation phases, and the distinction between notification and reporting. NEI discussed

several proposed changes and a revised draft NEI 14-09 is anticipated in January 2016. If the staff concludes that NEI 14-09 is an acceptable means of demonstrating compliance with NRC's regulations, this document would provide proper clarification of Part 21 and replace NUREG-0302. This approach is consistent with SECY-11-0032 and SECY-11-0135. In addition, the staff has formed an agency-wide Part 21 working group to address Part 21 issues. The first meeting of the working group occurred on November 24, 2015.

Regarding the development of DG-1292, NEI submitted for staff review Revision 1 to Electric Power Research Institute (EPRI) NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" (ADAMS Accession No. ML14265A198) for NRC review and approval. DG-1292 is currently under an expedited review by staff in RES. Once it has gone through internal review and concurrence, it will be sent out for public comment. If the staff concludes that the revision is an acceptable means of demonstrating compliance with the NRC's regulations, then the document will be found acceptable for use through DG-1292. The staff is scheduled to complete this review by the summer of 2016.

Regarding the Part 21 proposed rule, the Part 21 rulemaking has been prioritized as a low priority as part of the Project AIM 2020 baselining effort. As such, the staff will focus its efforts on the development and endorsement of guidance, (i.e., DG-1291 and DG-1292), until final direction on the staff's Part 21 rulemaking efforts is provided by the Commission.

Target Completion Date: Issue DG-1292, "Dedication of Commercial Grade Items" by summer of 2016. Issue proposed rule and DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," on a schedule which will be consistent with the rulemaking priority established by the Commission.

Point of Contact:       Antoinette Sakadales, NRO/DCIP/QVIB  
                                  301-415-6441

### **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 August 13, 2015**

The proposed actions continue to meet the intent of the recommendation. OIG notes the staff's acceptance of NEI draft 14-05 as an acceptable methodology 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:

By letter dated February 9, 2015 (ADAMS Accession No. ML14322A535), the NRC staff transmitted its safety evaluation of the guidelines developed by the NEI and contained in NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1. The NRC found this document presents an acceptable methodology for licensees and suppliers of basic components to use the accreditation provided by International Laboratory Accreditation Cooperation in lieu of performing a commercial-grade survey when procuring calibration and testing services from domestic and international laboratories.

The NRC staff also completed the Regulatory Issue Summary (RIS) that will be used to notify licensees and suppliers of basic components of the NRC's endorsement of NEI 14-05. A notice of opportunity for public comment on the RIS was published on the Federal Register (80 FR 30095) on August 10, 2015, for a 60-day comment period. One member of the public and one organization provided a total of eight comments. The NRC staff is currently in the process of addressing the public comments.

Target Completion Date: The NRC staff expects to issue the RIS in January 2016.

Point of Contact: Yamir Diaz-Castillo, NRO/DCIP/MVIB  
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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## Enclosure:

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

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\*via email

NRO-002

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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

- 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