

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 FROM "AUDIT OF THE
U.S. NUCLEAR REGULATORY COMMISSION'S
IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF
DEFECTS AND NONCOMPLIANCE" (OIG-11-A-08)

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-11-A-08, "Audit of the U.S. Nuclear Regulatory Commission's Implementation of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, Reporting of Defects and Noncompliance," dated June 2011. The staff continues to implement actions in response to OIG's audit and remains responsive to OIG's recommendations.

Recommendation 1:

Revise 10 CFR Part 21 for full conformity with the *Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance.*

OIG Analysis dated March 7, 2016:

OIG notes the ongoing staff efforts and agrees the proposed actions support the intent of the recommendation. OIG will continue to assess agency progress on DG-1292 under other open recommendations. Based on OIG's review of the February 8, 2016 SECY-09-0016 "Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities," January 31, 2016 (ML16028A189), OIG notes that staff has recommended termination of Part 21 activities. This recommendation will therefore remain in resolved status until the Commission makes a formal decision regarding the staff's proposed actions to discontinue Part 21 rulemaking.

Status: Resolved

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

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. The staff described the Project AIM re-baselining effort in SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities," January 31, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16028A189). Specifically, Enclosure 1 (line item 2) to SECY-16-0009 shows 10 CFR Part 21 rulemaking on the shed list (ADAMS Accession No. ML16028A212). The Commission accepted the staff's recommendation in a memo to the Executive Director for Operations dated April 13, 2016 (ADAMS Accession No. ML16104A158). Therefore, the staff has ceased efforts to revise 10 CFR Part 21.

However, the staff continues working with stakeholders in a public process to support the development of industry guidance documents that can 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-1291, in February 2016, the Nuclear Energy Institute (NEI) submitted for NRC staff review and approval NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1, (ADAMS Accession No. ML16054A825). The staff has completed its review and determined that it describes an acceptable means of demonstrating compliance with the NRC's regulations. This document will provide adequate guidance to implement the requirements of 10 CFR 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 Title 10 of the *Code of Federal Regulations 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 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:

Issue DG-1291, "Guidelines for Implementation of 10 CFR Part 21, 'Reporting of Defects and Noncompliance,'" by March, 2017.

Recommendation 2:

Expedite publication of interim guidance that specifies requirements for Part 21 reporting in accordance with the *Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance*.

OIG Analysis dated March 7, 2016:

Based on OIG's review of the February 8, 2016 SECY-09-0016 "Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities," January 31, 2016 (ML16028A189), and discussions with agency staff on February 8, 2016, OIG notes that staff has recommended termination of Part 21 rulemaking. Pending a Commission decision, OIG concurs with staff's continued refinement of NEI 14-09 as appropriate guidance to support 10 CFR Part 21. OIG concurs with agency actions based on the agency's response of January 7, 2016. This recommendation will be closed upon completion of OIG review of NEI 14-09 that specifies Part 21 reporting requirements.

Status: Resolved

NRC Staff Update:**Actions taken and planned:**

As indicated in the staff's update to Recommendation 1, the staff has been working with internal and external stakeholders to develop guidance that can potentially be found acceptable through regulatory guides. Regarding the development of DG-1291, NEI submitted for NRC staff review and approval the guidance document NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," (ADAMS Accession No. ML16054A825). The staff has completed its review of NEI 14-09 and determined that it describes an acceptable means of demonstrating compliance with the NRC's regulations. This document will provide adequate guidance to implement the requirements of 10 CFR Part 21 and will supersede NUREG-0302. This approach is consistent with SECY-11-0032 and SECY-11-0135.

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" (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.

Regarding the 10 CFR Part 21 proposed rule, the NRC has terminated the 10 CFR Part 21 rulemaking as a result of the Project AIM re-baselining effort. As such, the staff will focus its efforts on the development and endorsement of the guidance in DG-1291.

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

Recommendation 3:

Correct the sections of NUREG-1022, *Event Reporting Guidelines 10 CFR 50.72 and 50.73, October 2000*, that are in conflict with the *Energy Reorganization Act of 1974, as Amended, Section 206, Noncompliance* and 10 CFR Part 21.

(See ADAMS Accession No. ML12353A311)

Status: Closed

Recommendation 4:

Review, revise as applicable, and reissue NUREG-0302, *Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance, July 12-26, 1977*.

OIG Analysis dated March 7, 2016:

The agency's proposed action continues to meet the intent of the recommendation. OIG continues to follow agency progress with the review of NEI 04-19 and continued work on DG-1291. This recommendation will be closed upon completion and OIG review and approval of the updated guidance in the form of NEI 14-09 and DG-1291.

Status: Resolved

NRC Staff Update:

Actions taken and planned:

As indicated in the staff's updates to Recommendations 1 and 2, regarding the development of DG-1291, the staff has completed its review of NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," (ADAMS Accession No. ML16054A825) and determined that it describes an acceptable means of demonstrating compliance with the NRC's regulations. The document provides adequate guidance to implement the requirements of 10 CFR Part 21 and will supersede NUREG-0302. This approach is consistent with SECY-11-0032 and SECY-11-0135.

Regarding the 10 CFR Part 21 proposed rule, the NRC has terminated the 10 CFR Part 21 rulemaking as a result of the Project AIM re-baselining effort.

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

Recommendation 5:

Incorporate Inspection Procedure 36100, *Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance* into the NRC Baseline Inspection Program.

(See ADAMS Accession No. ML112590026)

Status: Closed

Enclosure:

Correspondence History Reference OIG-11-A-08,
“Audit of NRC’s Vendor Inspection Program”

Recommendation 5:

Incorporate Inspection Procedure 36100, *Inspection of 10 CFR Part 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance* into the NRC Baseline Inspection Program.

(See ADAMS Accession No. ML112590026)

Status: Closed

Enclosure:

Correspondence History Reference OIG-11-A-08,
“Audit of NRC’s Vendor Inspection Program”

DISTRIBUTION: OEDO-16-00136

JGordon, OIG
SDingbaum, OIG
SZane, OIG
RidsEdoMailCenter
RidsNroMailCenter
RidsOgcMailCenter
RidsNrrOd
RidsNrrDirs

ADAMS ACCESSION NO.: ML16194A166

*via e-mail

NRO-002

OFFICE	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-3	QTE*
NAME	ASakadales	PPrescott	KKavanagh	CHsu
DATE	7/13/2016	7/14/2016	7/15/2016	7/12/2016
OFC	NRO/DCIP	OGC/NLO*	NRO	
NAME	MCheck	AWilson	JUhle	
DATE	7/21/2016	08/04/2016	08/19/2016	

OFFICIAL RECORD COPY

Correspondence Reference
OIG-11-A-08, “Audit of NRC’s Vendor Inspection Program”

- NUREG-0302, “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance,” dated October 1977 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML062080399).
- Office of the Inspector General (OIG) Audit OIG-11-A-08, “Audit of NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance,” dated March 23, 2011 (ADAMS Accession No. ML110820426).
- Memorandum from S. Dingbaum to R.W. Borchardt, “Status of Recommendations: Audit of NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08),” dated June 10, 2011 (ADAMS Accession No. ML111610150).
- Memorandum from E. Leeds to S. Dingbaum, “Status of Recommendations from Audit of NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08),” dated August 18, 2011 (ADAMS Accession No. ML112150597).
- Memorandum from S. Dingbaum to R. W. Borchardt, “Status of Recommendations: Audit of NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08),” dated September 16, 2011 (ADAMS Accession No. ML112590026).
- 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’,” dated September 29, 2011 (ADAMS Accession No. ML112430138).
- Draft NUREG-1022, Revision 3, “Event Report Guidelines 10 CFR 50.72 and 50.73,” issued for public comment October 13, 2011 (ADAMS Accession No. ML11273A065).
- Memorandum from G. Tracy to S. Dingbaum, “Status of Recommendations from ‘Audit of the NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance’ (OIG-11-A-08), dated November 13, 2012 (ADAMS Accession No. ML12293A210).
- Memorandum from S. Dingbaum to R. W. Borchardt “Status of Recommendations: Audit of NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08),” dated December 20, 2012 (ADAMS Accession No. ML13007A030).
- Memorandum from E. Leeds to S. Dingbaum, “Status of Recommendation 3 from Audit of ‘U.S. NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance’ (OIG-11-A-08),” dated December 27, 2012 (ADAMS Accession No. ML12353A311).

- Memorandum from S. Dingbaum to G. Tracy, "Status of Recommendation from Audit of 'The U.S. Nuclear Regulatory Commission's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance' (OIG-11-A-08)," dated April 23, 2013 (ADAMS Accession No. ML13093A471).
- Memorandum from S. Dingbaum to R. W. Borchardt, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated July 23, 2013 (ADAMS Accession No. ML13203A015).
- Memorandum from G. Tracy to S. Dingbaum, "Status of Recommendations from "Audit of the NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" (OIG-11-A-08), dated November 21, 2013 (ADAMS Accession No. ML13254A284).
- Memorandum from S. Dingbaum to M.A. Satorius, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated February 19, 2014 (ADAMS Accession No. ML14050A461).
- Memorandum from G. Tracy to S. Dingbaum, "Status of Recommendations from "Audit of the NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" (OIG-11-A-08), dated June 20, 2014 (ADAMS Accession No. ML14141A518).
- Memorandum from S. Dingbaum to M.A. Satorius, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated August 7, 2014 (ADAMS Accession No. ML14219A694).
- Memorandum from G. Tracy to S. Dingbaum, "Status of Recommendations from "Audit of the NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" (OIG-11-A-08), dated January 14, 2015 (ADAMS Accession No. ML14345A985).
- Memorandum from S. Dingbaum to M.A. Satorius, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated March 30, 2015 (ADAMS Accession No. ML15089A311).
- Memorandum from G. Tracy to S. Dingbaum, "Status of Recommendations from "Audit of the NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" (OIG-11-A-08), dated July 6, 2015 (ADAMS Accession No. ML15154B583).
- Memorandum from S. Dingbaum to M.A. Satorius, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated August 13, 2015 (ADAMS Accession No. ML15225A134).
- Memorandum from J. Uhle to S. Dingbaum, "Status of Recommendations from "Audit of the NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" (OIG-11-A-08), dated January 7, 2016 (ADAMS Accession No. ML15323A233).
- Memorandum from S. Dingbaum to V. McCree, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated March 7, 2016 (ADAMS Accession No. ML16067A010).