

April 7, 2017

MEMORANDUM TO: Dr. Brett M. Baker
Assistant Inspector General for Audits

FROM: Vonna L. Ordaz, Acting 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 NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance," dated June 10, 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 September 7, 2016:

OIG acknowledges that staff will discontinue the Part 21 rulemaking based on the April 13, 2016, memo to the Commission. OIG recognizes the ongoing staff efforts and agrees the proposed actions support the intent of the recommendation. OIG will close the recommendation upon review of the final Regulatory Guide.

Status: Resolved

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

NRC Staff Update:

Actions taken and planned:

The staff continues to work with stakeholders through a public process to support the development of industry guidance documents that the NRC will potentially find acceptable for use in demonstrating compliance with NRC regulations. The NRC's acceptance of the documents for this purpose would be accomplished through draft regulatory guides DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants."

In regard to the development of DG-1291, in February 2016, the Nuclear Energy Institute (NEI) submitted NEI 14-09, Revision 1, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16054A825), to the NRC for review and approval. 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and will supersede NUREG-0302, Revision 1, "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," issued October 1977. 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). The Office of Nuclear Reactor Regulation (NRR) staff is currently reviewing DG-1291. The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

In regard to the development of DG-1292, in June 2012, NEI submitted Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications" (ADAMS Accession No. ML12213A608), to the NRC for 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 Volume 81 of the *Federal Register*, page 44,670 (81 FR 44670), on July 8, 2016. The comment period ended on September 6, 2016. The staff addressed public comments and sent them to the Office of Nuclear Regulatory Research (RES) in December 2016. The staff plans to issue the final regulatory guide (RG 1.164) in the spring of 2017.

Target Completion Date: The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

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

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 September 7, 2016:

OIG acknowledges the Commission's acceptance of staff recommendation to discontinue Part 21 rulemaking. OIG will close this recommendation once staff have issued DG-1291 and OIG verifies that it specifies requirements for Part 21 reporting.

Status: Resolved

NRC Staff Update:

Actions taken and planned:

As noted in the NRC staff's update to Recommendation 1, the staff has been working with internal and external stakeholders to develop guidance that the NRC can potentially find acceptable in associated regulatory guides. In regard to the development of DG-1291, NEI submitted NEI 14-09 to the NRC for review and approval. 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.

In regard to the development of DG-1292, NEI submitted EPRI 3002002982 to the NRC for 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* (81 FR 44670) on July 8, 2016. The comment period ended on September 6, 2016. The staff addressed public comments and sent them to RES in December 2016. The staff plans to issue the final regulatory guide (RG 1.164) in 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 2020 rebaselining effort. For this reason, the staff will focus its efforts on the development and endorsement of the guidance in DG-1291. The NRR staff is currently reviewing DG-1291. The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

Target Completion Date: The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-3
301-415-6441

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 September 7, 2016:

The agency's proposed action continues to meet the intent of the recommendation. OIG continues to follow agency progress on DG-1292, DG-1292, and NE 14-09. This recommendation will be closed upon completion and OIG review and approval of the updated guidance in the form of the final version of NEI 14-09, DG-1291, and 1292.

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 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. The NRR staff is currently reviewing DG-1291. The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

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 2020 rebaselining effort.

Target Completion Date: The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-3
301-415-6441

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

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-3
 301-415-6441

Enclosure:
Correspondence History Reference
OIG-11-A-08, "Audit of NRC's Implementation
of 10 CFR Part 21, Reporting of Defects
and Noncompliance"

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), DATE APRIL 7, 2017

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ADAMS ACCESSION NO.: ML17059D029 *via e-mail NRO-002

OFFICE	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-3	NRO/DCIP/QVIB-3	QTE*
NAME	ASakadales	PPrescott	KKavanagh	JDougherty
DATE	3/7/2017	3/7/2017	03/09/2017	2/24/2017
OFC	NRO/DCIP	OGC/NLO*	NRO	
NAME	TMcGinty	AWilson	VOrdaz	
DATE	03/11/2017	03/21/2017	04/07/2017	

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Correspondence Reference
OIG-11-A-08, "Audit of NRC's Implementation
of 10 CFR Part 21, Reporting of Defects and Noncompliance,"

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," 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," March 23, 2011 (ADAMS Accession No. ML110820426).

Memorandum from S.D. 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)," June 10, 2011 (ADAMS Accession No. ML111610150).

Memorandum from E.J. Leeds to S.D. Dingbaum, "Status of Recommendations from Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," August 18, 2011 (ADAMS Accession No. ML112150597).

Memorandum from S.D. 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)," 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,'" September 29, 2011 (ADAMS Accession No. ML112430138).

NUREG-1022, Revision 3, "Event Report Guidelines 10 CFR 50.72 and 50.73: Draft Report for Comment," September 2011 (ADAMS Accession No. ML11273A065).

Memorandum from G.M. Tracy to S.D. Dingbaum, "Status of Recommendations from '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 (OIG-11-A-08)," November 13, 2012 (ADAMS Accession No. ML12293A210).

Memorandum from S.D. 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)," December 20, 2012 (ADAMS Accession No. ML13007A030).

Memorandum from E.J. Leeds to S.D. Dingbaum, "Status of Recommendation 3 from Audit of 'U.S. Nuclear Regulatory Commission's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance' (OIG-11-A-08)," December 27, 2012 (ADAMS Accession No. ML12353A311).

Enclosure

Memorandum from S.D. Dingbaum to G.M. 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)," April 23, 2013 (ADAMS Accession No. ML13093A471).

Memorandum from S.D. 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)," July 23, 2013 (ADAMS Accession No. ML13203A015).

Memorandum from G.M. Tracy to S.D. Dingbaum, "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)," November 21, 2013 (ADAMS Accession No. ML13254A284).

Memorandum from S.D. 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)," February 19, 2014 (ADAMS Accession No. ML14050A461).

Memorandum from G.M. Tracy to S.D. Dingbaum, "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)," June 20, 2014 (ADAMS Accession No. ML14141A518).

Memorandum from S.D. 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)," August 7, 2014 (ADAMS Accession No. ML14219A694).

Memorandum from G.M. Tracy to S.D. Dingbaum, "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)," January 14, 2015 (ADAMS Accession No. ML14345A985).

Memorandum from S.D. 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)," March 30, 2015 (ADAMS Accession No. ML15089A311).

Memorandum from G.M. Tracy to S.D. Dingbaum, "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)," July 6, 2015 (ADAMS Accession No. ML15154B583).

Memorandum from S.D. 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.D. Dingbaum, "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)," January 7, 2016 (ADAMS Accession No. ML15323A233).

Memorandum from S.D. Dingbaum to V.M. McCree, "Status of Recommendations: Audit of U.S. Nuclear Regulatory Commission's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," March 7, 2016 (ADAMS Accession No. ML16067A010).

Memorandum from J. Uhle to S.D. Dingbaum, "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)," August 19, 2016 (ADAMS Accession No. ML16194A166).

Memorandum from S.E. Zane to V.M. McCree, "Status of Recommendations: Audit of U.S. Nuclear Regulatory Commission's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," September 7, 2016 (ADAMS Accession No. ML16251A303).