

April 13, 2018

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

FROM: Frederick D. Brown, Acting Director **/RA/ Vonna L. Ordaz for**
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 May 2, 2017:

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 resulting from DG-1291.

Status: Resolved

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

NRC Staff Update:

Actions taken and planned:

In April of 2018, the staff issued Regulatory Guide (RG) 1.234, Rev. 0, "Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17338A072). RG 1.234 was previously issued as Draft Guide (DG)-1291 dated July 2017 (ADAMS Accession No. ML16165A298). Regarding 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" (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).

In June of 2017, the staff issued RG 1.164, Rev. 0, "Dedication of Commercial-Grade Items for use in Nuclear Power Plants," (ADAMS Accession No. ML17041A206). RG 1.164 was previously issued as DG-1292, dated June 2016 (ADAMS Accession No. ML15313A425). Regarding the development of DG-1292, in June 2012, the 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 regulations. EPRI 3002002982 replaces the original commercial-grade dedication (CGD) guidance from 1988 to reflect lessons learned and address challenges that have been identified through expanded use of the original guidance. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in Volume 81 of the *Federal Register* (FR), page 44,670 (81 FR 44670), on July 8, 2016. The comment period ended on September 6, 2016. As finalized, RG 1.164 approves the use of EPRI 3002002982 with the exceptions or clarifications listed in Section C, "STAFF REGULATORY GUIDANCE," of RG 1.164. EPRI 3002002982 provides guidance and examples on how to use and/or develop a combination of acceptance methods as part of the CGD of items and services for use in nuclear power plants. Section 4.6, "Select Acceptance Methods and Develop and Document Acceptance Criteria," of EPRI 3002002982 provides the guidance to the industry of how to select and utilize one or more of the four dedication acceptance methods when performing CGD. Furthermore, Section 5, "COMMERCIAL-GRADE DEDICATION PROCESS," of EPRI 3002002982 provides more detailed information for each of the steps involved in the CGD process.

Target Completion Date: The staff issued the final RG 1.234 (previously DG-1291) in April 2018 and RG 1.164 (previously DG-1292) in June 2017.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-2
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 May 2, 2017:

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

Status: Resolved

NRC Staff Update:

Actions taken and planned:

As noted in Recommendation 1, in April 2018, staff issued RG 1.234 which provides new guidance for an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This new guide endorses NEI 14-09, Revision 1. The staff issued the final RG 1.164 in June 2017.

Target Completion Date: The staff issued the final RG 1.234 in April 2018 and RG 1.164 in June 2017.

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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 May 2, 2017:

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

Status: Resolved

NRC Staff Update:

Actions taken and planned:

As indicated in the staff's updates to Recommendations 1 and 2, in April of 2018, staff issued RG 1.234 which proposed new guidance for providing an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This new guide endorses NEI 14-09, Revision 1.

Target Completion Date: The staff issued the final RG 1.234 in April 2018.

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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-2
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), Dated April 13, 2018

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NRO-002

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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).

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).

Memorandum from V. Ordaz to Dr. B. Baker, "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)," April 7, 2017 (ADAMS Accession No. ML17059D029).

Memorandum from Dr. B. Baker 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)," May 2, 2017 (ADAMS Accession No. ML17122A238).

Memorandum from F. Brown to Dr. B. Baker, "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)," April 13, 2018 (ADAMS Accession No. ML18094A931).