

July 6, 2015

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

FROM: Glenn M. Tracy, Director */RA/* Gary M. Holahan 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 the U.S. Nuclear Regulatory Commission's Implementation of 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 30, 2015:

OIG agrees with the agency's proposed actions based on the expectation that Revision 1 of the draft Regulatory Basis will be finalized in June 2015. OIG notes that staff has provided a revised schedule, and will assess the progress of completing the actions to address this recommendation in revised milestones to OIG in future audit follow-up submissions.

This recommendation will be closed upon completion and OIG review of the relevant, completed staff actions per the schedule provided above.

Status: Resolved

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

S. Dingbaum

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Status: Resolved

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NRC Staff Update:

Actions taken and planned:

As previously noted, the U.S. Nuclear Regulatory Commission (NRC) staff revised and issued NUREG-1022, Revision 3, "Event Reporting Guidelines: 10 CFR 50.72 and 50.73," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13032A220), in a *Federal Register* notice published February 11, 2013. The staff removed the discussion related to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance." The NRC published Revision 3 of NUREG-1022 in January 2013, and it took effect July 1, 2013. In addition, the staff issued a Commissioners' Assistants (CA) note, "Clarification of Staff Position on Part 21 Reporting Requirements," dated September 19, 2011. The CA note communicated the staff's position to ensure full conformity with the Energy Reorganization Act.

The staff continues making progress on its rulemaking efforts to revise 10 CFR Part 21, 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 plans to issue the final regulatory basis to 10 CFR Part 21 in July 2015. 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-1291, the Nuclear Energy Institute (NEI) submitted for staff review a guidance document on the evaluation and reporting of defects and noncompliance 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). The staff is currently reviewing NEI 14-09 and plans on meeting with stakeholders in the near future to discuss amending certain language found in this document. Specifically, issues that need to be resolved include the point of discovery as it relates to the identification of deviations and evaluating of defects for operating reactors in licensee event reports (LERs). Since the staff believes that Part 21 rule language changes are necessary prior to finding NEI 14-09 as an acceptable means of demonstrating compliance with the NRC's regulations, staff will be working in parallel on the development of DG-1291 and the proposed rule. This approach is consistent with SECY-11-0032 and SECY-11-0135.

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. 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 prior to issuance of the rule. The staff is scheduled to complete this review by the summer of 2016.

The table below outlines the staff’s updated schedule.

Milestones	Target Date
Make Final NMSS Site Visit to Fuels Facilities (COMPLETE)	September 27, 2013
Hold NMSS Public Meeting to Discuss Potential Solutions to Policy Issues (COMPLETE)	March 6, 2014
Begin Concurrence of Draft Revision 1 of the Regulatory Basis (COMPLETE)	March 31, 2014
Issue Draft Revision 1 of the Regulatory Basis (COMPLETE)	March 2015
Hold Public Meetings to Discuss Draft Revision 1 of the Regulatory Basis (COMPLETE)	April 28, 2015
Issue Final Regulatory Basis	July 2015
Issue DG-1292	Summer 2016
Issue Proposed Rule with DG-1291	January 2017
Issue Final Rule	June 2018

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,” in January 2017. Issue final rule in June 2018.

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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 30, 2015:

OIG notes the continued development of the draft Regulatory Basis and associated delays related to OGC and NEI review. OIG concurs with agency actions based on the agency's response of January 14, 2015, and discussion with agency staff. This recommendation will be closed upon staff completion and OIG review of interim guidance 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. Accordingly, the staff is reviewing NEI 14-09 and plans on meeting with stakeholders in the near future to discuss amending certain language found in this document. Specifically, issues that need to be resolved include the point of discovery as it relates to the identification of deviations and evaluating of defects for operating reactors in LERs. Since the staff believes that Part 21 rule language changes are necessary prior to finding NEI 14-09 as an acceptable means of demonstrating compliance with the NRC's regulations, staff will be working in parallel on the development of DG-1291 and the proposed rule. The staff's next major milestone will be to issue the final regulatory basis. The staff will undertake regulatory guidance development in parallel with the development of the proposed rule. This effort will begin following issuance of the final regulatory basis.

Target Completion Date: Issue final regulatory basis July 2015.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB
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 March 30, 2015:

The agency's proposed action continues to meet the intent of the recommendation. As with recommendations 1 and 2, and given the extended targeted dates for completion of the Part 21 rulemaking, OIG encourages staff to expedite review of NEI 14-09 so as to provide updated guidance in the place of NUREG-0302. This recommendation will be closed upon completion and OIG review and approval of the updated guidance in the form of NEI 14-09.

Status: Resolved

NRC Staff Update:

Actions taken and planned:

As indicated in the staff's updates to Recommendations 1 and 2, DG-1291 is currently in draft, and NEI 14-09 is currently under staff review. If the staff concludes that NEI 14-09 is an acceptable means of demonstrating compliance with the NRC's regulations, this document would provide proper clarification of Part 21 and replace NUREG-0302. Therefore, NUREG-0302 will be superseded or rescinded.

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," in January 2017. Issue final rule in June 2018.

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

Enclosure:

Correspondence History Reference OIG-11-A-08,
"Audit of NRC's Vendor Inspection Program"

OIG Analysis dated March 30, 2015:

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Status: Resolved

NRC Staff Update:

Actions taken and planned:

As indicated in the staff's updates to Recommendations 1 and 2, DG-1291 is currently in draft, and NEI 14-09 is currently under staff review. If the staff concludes that NEI 14-09 is an acceptable means of demonstrating compliance with the NRC's regulations, this document would provide proper clarification of Part 21 and replace NUREG-0302. Therefore, NUREG-0302 will be superseded or rescinded.

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," in January 2017. Issue final rule in June 2018.

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

Enclosure:

Correspondence History Reference OIG-11-A-08,
"Audit of NRC's Vendor Inspection Program"

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See next page

ADAMS ACCESSION NO.: ML15090A597 *via email NRO-002

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DATE	06/11/2015	06/24/2015	07/06/15	

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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).

Memorandum from N. Mamish to Commissioner Assistants, "Clarification of Staff Position on Part 21 Reporting Requirements," dated September 19, 2011 (ADAMS Accession No. ML11258A065).

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).

Enclosure

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).