

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 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 August 13, 2015:

OIG agrees with the agency's proposed actions based on the issued final Regulatory Basis. OIG notes that staff has revised the milestones after addressing specific points raised in industry's latest round of comments. OIG will continue to assess the progress of completing the actions to address this recommendation in future audit follow-up submissions.

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

Status: Resolved

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

NRC Staff Update:

Actions taken and planned:

The staff continues to make progress on its efforts to revise 10 CFR Part 21, resolve problems with implementing the existing regulatory language. 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 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 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 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 the 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 related 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 the Office of 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.

Regarding the Part 21 proposed rule, the Part 21 rulemaking has been prioritized as a low priority as part of the Project AIM 2020 rebaselining 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.

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

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 31, 2015
Hold Public Meetings to Discuss Draft Revision 1 of the Regulatory Basis (COMPLETE)	April 28, 2015
Issue Final Regulatory Basis (COMPLETE)	August 31, 2015
Issue DG-1292	Summer 2016
Issue Proposed Rule with DG-1291	TBD
Issue Final Rule	TBD

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 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 August 13, 2015:

With issuance of the final regulatory basis, OIG concurs with proposed agency actions to undertake regulatory guidance development in parallel with the development of the proposed rule. 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. 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). 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 the 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 Part 21 proposed rule, the Part 21 rulemaking has been prioritized as a low priority as part of the Project AIM 2020 rebaselining effort. As such, the staff will focus its efforts on the development and endorsement of the guidance DG-1291 until final direction on the staff's Part 21 rulemaking efforts is provided by the Commission.

Target Completion Date: Issue 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 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 August 13, 2015:

The agency's proposed action continues to meet the intent of the recommendation. Despite rulemaking delays, OIG notes ongoing 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, DG-1291 is currently in draft, and NEI 14-09 is being revised by NEI, and is anticipated to be submitted in January 2016. 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.

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

Target Completion Date: Issue 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 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"

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 being revised by NEI, and is anticipated to be submitted in January 2016. 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.

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

Target Completion Date: Issue 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 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
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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.: ML15323A233

*via e-mail

NRO-002

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DATE	12/10/2015	12/23/2015	01/07/2016	

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Memorandum to Stephen D. Dingbaum from Jennifer Uhle dated January 07, 2016

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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).

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).

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).