



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

**OFFICE OF THE
INSPECTOR GENERAL**

March 7, 2016

MEMORANDUM TO: Victor M. McCree
Executive Director for Operations

FROM: Stephen D. Dingbaum */RA/*
Assistant Inspector General for Audits

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

REFERENCE: DIRECTOR, OFFICE OF NEW REACTORS,
MEMORANDUM DATED JANUARY 7, 2016

Attached is the Office of the Inspector General's analysis and status of recommendations 1, 2, and 4, as discussed in the agency's response dated January 7, 2016. Based on OIG's analysis of this response, recommendations 1, 2, and 4 remain in resolved status. Recommendations 3 and 5 were previously closed. Please provide an update on the status of the resolved recommendations by August 19, 2016.

If you have questions or concerns, please call me at 415-5915, or Paul Rades, Team Leader, at 415-6228.

Attachment: As stated

cc: J. Uhle, NRO
B. Pham, OEDO
J. Jolicoeur, OEDO
EDO_ACS Distribution Resource

Audit Report

AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF DEFECTS AND NONCOMPLIANCE

OIG-11-A-08

Status of Recommendations

Recommendation 1: Revise 10 CFR Part 21 for full conformity with the *Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance.*

Agency Response Dated January 7, 2016: 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

Audit Report

AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF DEFECTS AND NONCOMPLIANCE

OIG-11-A-08

Status of Recommendations

Recommendation 1 (cont.):

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.

Audit Report

AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF DEFECTS AND NONCOMPLIANCE

OIG-11-A-08

Status of Recommendations

Recommendation 1 (cont.):

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.

OIG Analysis: 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.

Audit Report

AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF DEFECTS AND NONCOMPLIANCE

OIG-11-A-08

Status of Recommendations

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.*

Agency Response Dated
January 7, 2016:

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

Audit Report

AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF DEFECTS AND NONCOMPLIANCE

OIG-11-A-08

Status of Recommendations

Recommendation 2 (cont.):

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.

OIG Analysis: 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.

Audit Report

AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF DEFECTS AND NONCOMPLIANCE

OIG-11-A-08

Status of Recommendations

- 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.*
- Agency Response Dated January 7, 2016: 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.
- OIG Analysis: 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.