



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

**OFFICE OF THE  
INSPECTOR GENERAL**

September 7, 2016

**MEMORANDUM TO:**

Victor M. McCree  
Executive Director for Operations

**FROM:**

*Steven E. Zane*  
Steven E. Zane  
Acting 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 AUGUST 19, 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 August 19, 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 April 14, 2017.

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

Attachment: As stated

cc: R. Lewis, OEDO  
H. Rasouli, OEDO  
J. Jolicouer, OEDO  
J. Bowen, OEDO  
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## 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 August 19, 2016: Actions taken and planned: As part of the project AIM re-baselining effort, the NRC staff recommended termination of the 10 CFR Part 21 rulemaking effort. The staff described the Project AIM re-baselining effort in SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities," January 31, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16028A189). Specifically, Enclosure 1 (line item 2) to SECY-16-0009 shows 10 CFR Part 21 rulemaking on the shed list (ADAMS Accession No. ML16028A212). The Commission accepted the staff's recommendation in a memo to the Executive Director for Operations dated April 13, 2016 (ADAMS Accession No. ML16104A158). Therefore, the staff has ceased efforts to revise 10 CFR Part 21. However, the staff continues working with stakeholders in a public process to support the development of industry guidance documents that can potentially be found acceptable by the NRC. The NRC's acceptability for use would be accomplished through two draft regulatory guides (DGs): DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants." Regarding the development of DG-1291, in February 2016, the Nuclear Energy Institute (NEI) submitted for NRC staff review and approval NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," Revision 1, (ADAMS Accession No. ML16054A825). The staff has completed its review 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, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," dated March 2, 2011

## 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 (con't.):

(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). DG-1291 is currently under review by staff in the Office of Nuclear Regulatory Research. Regarding the development of DG-1292, NEI submitted Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" ADAMS Accession No. ML12213A608) for NRC 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* (FR DOC #2016-16422) on July 8, 2016. The comment period ends on September 6, 2016. The staff plans to address public comments and issue the final Regulatory Guide by the spring of 2017.

Target Completion Date: Issue DG-1291, "Guidelines for implementation of 10 CFR Part 21, 'Reporting of Defects and Noncompliance,'" by March, 2017.

OIG Analysis:

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.

## Audit Report

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

OIG-11-A-08

#### Status of Recommendations

<u>Recommendation 2:</u>	Expedite publication of interim guidance that specifies requirements for Part 21 reporting in accordance with the <i>Energy Reorganization Act of 1974, as amended, Section 206, Noncompliance.</i>
Agency Response Dated August 19, 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, NEI submitted for NRC staff review and approval the guidance document NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," (ADAMS Accession No. ML16054A825). 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. Regarding the development of DG-1292, NEI submitted Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" ADAMS Accession No. ML12213A608) for NRC 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 <i>Federal Register</i> (FR DOC #2016-16422) on July 8, 2016. The comment period ends on September 6, 2016. The staff plans to address public comments and issue the final Regulatory Guide by 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 re-baselining effort. As such, the staff will focus its efforts on the development and endorsement of the guidance in DG-1291.

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OIG-11-A-08

#### Status of Recommendations

Recommendation 2 (con't.):

Target Completion Date: Issue DG-1291, "Guidelines for Implementation of 10 CFR Part 21, 'Reporting of Defects and Noncompliance,'" by March 2017.

OIG Analysis:

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.

## 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  
August 19, 2016:

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, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," (ADAMS Accession No. ML16054A825) 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. 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 re-baselining effort.

Target Completion Date: Issue DG-1291, "Guidelines for Implementation of 10 CFR Part 21, 'Reporting of Defects and Noncompliance,'" by March 2017.

OIG Analysis:

The agency's proposed action continues to meet the intent of the recommendation. OIG continues to follow agency progress on DG-1292, DG-1291, 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.