



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

**OFFICE OF THE
INSPECTOR GENERAL**

May 2, 2017

MEMORANDUM TO: Victor M. McCree
Executive Director for Operations

FROM: Dr. Brett M. Baker */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: ACTING DIRECTOR, OFFICE OF NEW REACTORS,
MEMORANDUM DATED APRIL 7, 2017

Attached is the Office of the Inspector General's (OIG) analysis and status of recommendations 1, 2, and 4, as discussed in the agency's response dated April 7, 2017. 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 30, 2018.

If you have questions or concerns, please call me at (301) 415-5915, or Paul Rades, Team Leader, at (301) 415-6228.

Attachment: As stated

cc: R. Lewis, OEDO
H. Rasouli, OEDO
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J. Bowen, OEDO
EDO_ACS_Distribution

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
April 7, 2017:

Actions taken and planned: The staff continues to work with stakeholders through a public process to support the development of industry guidance documents that the NRC will potentially find acceptable for use in demonstrating compliance with NRC regulations. The NRC's acceptance of the documents for this purpose would be accomplished through draft regulatory guides DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants."

In regard to 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" 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 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.

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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.):

The Office of Nuclear Reactor Regulation (NRR) staff is currently reviewing DG-1291. The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

In regard to the development of DG-1292, in June 2012, 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", 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's regulations. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in Volume 81 of the *Federal Register*, page 44,670 (81 FR 44670), on July 8, 2016. The comment period ended on September 6, 2016. The staff addressed public comments and sent them to the Office of Nuclear Regulatory Research (RES) in December 2016. The staff plans to issue the final regulatory guide (RG 1.164) in the spring of 2017.

Target Completion Date: The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

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

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 resulting from DG-1291.

Status:

Resolved.

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

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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
April 7, 2017:

Actions taken and planned: As noted in the NRC staff's update to Recommendation 1, the staff has been working with internal and external stakeholders to develop guidance that the NRC can potentially find acceptable in associated regulatory guides. In regard to the development of DG-1291, NEI submitted NEI 14-09 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 10 CFR Part 21 and will supersede NUREG-0302. This approach is consistent with SECY-11-0032 and SECY-11-0135.

In regard to the development of DG-1292, NEI submitted EPRI 3002002982 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's regulations. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in the *Federal Register* (81 FR 44670) on July 8, 2016. The comment period ended on September 6, 2016. The staff addressed public comments and sent them to RES in December 2016. The staff plans to issue the final regulatory guide (RG 1.164) in 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 2020 rebaselining effort. For this reason, the staff will focus its efforts on the development and endorsement of the guidance in DG-1291. The NRR staff is currently reviewing DG-1291. The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.

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Status of Recommendations

Recommendation 2 (con't.):

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 the final regulatory guide resulting from DG-1291, and OIG verifies that this guidance 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

<u>Recommendation 4:</u>	Review, revise as applicable, and reissue NUREG-0302, <i>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.</i>
Agency Response Dated April 7, 2017:	<p>Actions taken and planned: 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 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. The NRR staff is currently reviewing DG-1291. The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.</p> <p>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 2020 baselining effort.</p> <p><u>Target Completion Date:</u> The staff plans to issue DG-1291 for public comment in the summer of 2017, and the final regulatory guide in the spring of 2018.</p> <p>Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-3 301-415-6441</p>
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 the final regulatory guide resulting from DG-1291, and OIG verifies that this guidance specifies requirements for Part 21 reporting.
Status:	Resolved.