



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

**OFFICE OF THE
INSPECTOR GENERAL**

April 24, 2018

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 13, 2018

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 13, 2018. Based on OIG's analysis of this response, recommendations 1, 2, and 4 are closed. Recommendations 3 and 5 were previously closed. All recommendations from this audit are now closed.

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
J. Jolicouer, OEDO
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 13, 2018:

Actions taken and planned:

In April of 2018, the staff issued Regulatory Guide (RG) 1.234, Rev. 0, "Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21." RG 1.234 was previously issued as Draft Guide (DG)-1291 dated July 2017. Regarding 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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Status of Recommendations

Recommendation 1 (con't.):

In June of 2017, the staff issued RG 1.164, Rev. 0, "Dedication of Commercial-Grade Items for use in Nuclear Power Plants." RG 1.164 was previously issued as DG-1292, dated June 2016. Regarding the development of DG-1292, in June 2012, the 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 regulations. EPRI 3002002982 replaces the original commercial-grade dedication (CGD) guidance from 1988 to reflect lessons learned and address challenges that have been identified through expanded use of the original guidance. The staff issued DG-1292, which proposes the endorsement of EPRI 3002002982, for public comment in Volume 81 of the *Federal Register* (FR), page 44,670 (81 FR 44670), on July 8, 2016. The comment period ended on September 6, 2016. As finalized, RG 1.164 approves the use of EPRI 3002002982 with the exceptions or clarifications listed in Section C, "STAFF REGULATORY GUIDANCE," of RG 1.164. EPRI 3002002982 provides guidance and examples on how to use and/or develop a combination of acceptance methods as part of the CGD of items and services for use in nuclear power plants. Section 4.6, "Select Acceptance Methods and Develop and Document Acceptance Criteria," of EPRI 3002002982 provides the guidance to the industry of how to select and utilize one or more of the four dedication acceptance methods when performing CGD.

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Status of Recommendations

Recommendation 1 (con't.):

Furthermore, Section 5, "COMMERCIAL-GRADE DEDICATION PROCESS," of EPRI 3002002982 provides more detailed information for each of the steps involved in the CGD process.

Target Completion Date: The staff issued the final RG 1.234 (previously DG-1291) in April 2018 and RG 1.164 (previously DG-1292) in June 2017.

Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-2
(301) 415-6441

OIG Analysis:

Staff terminated Part 21 rulemaking under Commission direction in April 2016, and OIG subsequently agreed with the staff's proposal to issue alternative guidance in lieu of rulemaking. OIG has reviewed RG 1.234 and RG 1.164, and verified that this guidance meets the original intent of the recommendation. This recommendation is now closed.

Status:

Closed.

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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 April 13, 2018:	<p>Actions taken and planned:</p> <p>As noted in Recommendation 1, in April 2018, staff issued RG 1.234 which provides new guidance for an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This new guide endorses NEI 14-09, Revision 1. The staff issued the final RG 1.164 in June 2017.</p> <p><u>Target Completion Date:</u> The staff issued the final RG 1.234 in April 2018 and RG 1.164 in June 2017.</p> <p>Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-2 (301) 415-6441</p>
OIG Analysis:	OIG has reviewed RG 1.234 and RG 1.164, and verified that this guidance meets the intent of the recommendation regarding Part 21 reporting requirements. This recommendation is now closed.
Status:	Closed.

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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

<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 13, 2018:	<p>Actions taken and planned:</p> <p>As indicated in the staff's updates to Recommendations 1 and 2, in April of 2018, staff issued RG 1.234 which proposed new guidance for providing an acceptable method of evaluating and reporting defects under 10 CFR Part 21. This new guide endorses NEI 14-09, Revision 1.</p> <p><u>Target Completion Date:</u> The staff issued the final RG 1.234 in April 2018.</p> <p>Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB-2 (301) 415-6441</p>
OIG Analysis:	OIG has reviewed RG 1.234, and verified that the guidance meets the intent of this recommendation and appropriately supersedes NUREG-0302. This recommendation is now closed.
Status:	Closed.