



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

**OFFICE OF THE
INSPECTOR GENERAL**

March 30, 2015

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

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

SUBJECT: STATUS OF RECOMMENDATIONS: AUDIT OF NRC'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 14, 2015

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 14, 2015. 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 July 10, 2015.

If you have questions or concerns, please call me at 415-5915, or RK Wild, Team Leader, at 415-5948.

Attachment: As stated

cc:
M. Galloway, OEDO
B. Pham, 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
January 14, 2015:

NRC Staff Update: Actions taken and planned: As previously noted, the U.S. Nuclear Regulatory Commission (NRC) staff revised and issued NUREG-1022, Revision 3, "Event Reporting Guidelines: 10 CFR 50.72 and 50.73," in a *Federal Register* notice published February 11, 2013. The staff removed the discussion related to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance." The NRC published Revision 3 of NUREG-1022 in January 2013, and it took effect July 1, 2013. In addition, the staff issued a Commissioners' Assistants (CA) note, "Clarification of Staff Position on Part 21 Reporting Requirements," dated September 19, 2011. The CA note communicated the staff's position to ensure full conformity with the *Energy Reorganization Act* (ERA).

The staff continues to make progress on its rulemaking efforts to revise 10 CFR Part 21. The rulemaking will clarify the 10 CFR Part 21 requirements and resolve problems with implementing the existing regulatory language. The revisions should prevent interpretations that could potentially allow less than full conformity with Section 206 of the ERA. The staff's progress includes 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

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Status of Recommendations

Recommendation 1 (cont.):

(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 on the evaluation and reporting of defects and noncompliance NEI 14-09, Revision 0, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," in August 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14245A415). NEI 14-09 is currently under staff review. If the staff concludes that NEI 14-09 is an acceptable means of demonstrating compliance with the NRC's regulations, then the document will be found acceptable for use through DG-1291 in parallel with the development of the proposed rule.

Regarding the development of DG-1292, NEI submitted for staff review a draft of the guide, 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). Revision 1 to EPRI NP-5652 and TR-102260 are currently under staff review. 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 in parallel with the development of the proposed rule.

The table below outlines the staff's updated schedule.

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Status of Recommendations

Milestones	Target Date
Conduct Internal Collaboration on Draft Revision 1 of the Regulatory Basis	Ongoing
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	February 2015
Hold Public Meetings to Discuss Draft Revision 1 of the Regulatory Basis	March 2015
Finalize Draft Revision 1 of the Regulatory Basis	June 2015
Issue Proposed Rule with Draft Regulatory Guides	January 2017
Issue Final Rule	February 2019

Target Completion Date:

Issue draft Revision 1 of the Regulatory Basis in February 2015. Issue proposed rule and draft guides, DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items" in January 2017. Issue final rule in February 2019. Point of Contact: Antoinette Sakadales, NRO/DCIP/QVIB 301-415-6441

OIG Analysis:

OIG agrees with the agency's proposed actions based on the expectation that Revision 1 of the draft Regulatory Basis will be finalized in June 2015. OIG notes that staff has provided a revised schedule, and will assess the progress of completing the actions to address this recommendation in revised milestones to OIG in future audit follow-up submissions.

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

Status:

Resolved.

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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
January 14, 2015:

Staff submitted draft Revision 1 of the Regulatory Basis to the Office of the General Counsel (OGC) and received it back with extensive comments. While in the process of addressing the comments, the NRC received a July 8, 2014, letter from NEI (ADAMS Accession No. ML14189A169), outlining a number of outstanding industry concerns. The NEI letter also recommended that the NRC delay the schedule of proposed rulemaking, and postpone publication of the revised draft regulatory basis until all the outstanding industry concerns have been resolved. Furthermore, the NEI letter also noted their belief that rulemaking was not a practical solution to resolve the regulatory issues associated with Part 21 and that those issues can be completely addressed by issuing guidance. In the NRC's October 28, 2014, letter to NEI (Adams Accession No. ML14232A816), staff acknowledged and replied to these concerns and informed NEI that the NRC is committed to maintaining an effective and efficient regulatory process consistent with the Principles of Good Regulation and that the 10 CFR Part 21 rulemaking effort is consistent with the guidelines proposed in SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process."

Also, as noted above, the staff has been working with internal and external stakeholders to develop guidance that can potentially be found acceptable through regulatory guides. Accordingly, DG-1291 may find acceptable NEI 14-09, which would provide more comprehensive guidance than previously available. The staff's next major milestone will be to finalize draft Revision 1 of the Regulatory Basis. The staff will undertake regulatory guidance development in parallel

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Status of Recommendations

Recommendation 2 (cont.):

with the development of the proposed rule. This effort will begin following issuance of final version of Revision 1 of the regulatory basis.

Target Completion Date: Finalize Revision 1 of the regulatory basis in June 2015.

OIG Analysis:

OIG notes the continued development of the draft Regulatory Basis and associated delays related to OGC and NEI review. OIG concurs with agency actions based on the agency's response of January 14, 2015, and discussion with agency staff. This recommendation will be closed upon staff completion and OIG review of interim guidance that specifies Part 21 reporting requirements.

Status:

Resolved.

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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 14, 2015:

As indicated in the staff's updates to Recommendations 1 and 2, DG-1291 is currently in draft, and NEI 14-09 is currently under staff review. 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.

Target Completion Date:

Issue draft Revision 1 of the Regulatory Basis February 2015. Issue proposed rule and draft guides, DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," and DG-1292, "Dedication of Commercial Grade Items" in January 2017. Issue final rule in February 2019.

OIG Analysis:

The agency's proposed action continues to meet the intent of the recommendation. As with recommendations 1 and 2, and given the extended targeted dates for completion of the Part 21 rulemaking, OIG encourages staff to expedite review of NEI 14-09 so as to provide updated guidance in the place of NUREG-0302. This recommendation will be closed upon completion and OIG review and approval of the updated guidance in the form of NEI 14-09.

Status:

Resolved.