

November 21, 2013

MEMORANDUM TO: Stephen D. Dingbaum,
Assistant Inspector General for Audits
Office of the Inspector General

FROM: Glenn M. Tracy, Director */RA/ G. Holahan For*
Office of New Reactors

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

Enclosed please find an updated staff response to each of the five Office of the Inspector General's (OIG) recommendations in the June 10, 2011, memorandum to the Executive Director for Operations, transmitting the OIG Audit Report, "Audit of the Nuclear Regulatory Commission's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance" (OIG-11-A-08).

Enclosure:
NRC Staff Response to OIG Report

CONTACT: Paul F. Prescott, NRO/DCIP
301-415-3026

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NRO-002

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NRC Staff Response to Office of the Inspector General Audit Report
“Audit of NRC’s Implementation of 10 CFR Part 21, Reporting of Defects and
Noncompliance” (OIG-11-A-08)

Recommendation 1:

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

OIG Analysis dated July 23, 2013:

The Office of the Inspector General (OIG) recognizes that the rulemaking effort will more clearly articulate the staff’s position by revising Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 to full conformity with the *Energy Reorganization Act (ERA) of 1974, As Amended, Section 206, Noncompliance*. OIG also recognizes that the next step in the rulemaking effort is to complete the regulatory basis, which will require stakeholder interaction. The proposed corrective actions described in the agency response above meet the intent of the recommendation. This recommendation is therefore resolved and will be closed upon completion and OIG review of the relevant, completed staff actions as listed above.

Status: Resolved.

Update:

- (1) The staff revised and issued for public comment NUREG-1022, Revision 3, “Event Reporting Guidelines: 10 CFR 50.72 and 50.73,” in a *Federal Register* (FR) notice published October 13, 2011. The staff removed the discussion related to 10 CFR Part 21, “Reporting of Defects and Noncompliance.” The U.S. Nuclear Regulatory Commission (NRC) published Revision 3 of NUREG-1022 in January 2013, and it took effect July 1, 2013.

Target Completion Date: Complete.

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 ERA of 1974, as amended, Section 206, Noncompliance.

Target Completion Date: Complete.

- (2) The staff developed a draft regulatory issue summary documenting the staff’s position detailed in the CA note. However, on July 5 and July 12, 2012, the staff held discussions with OIG on the staff’s proposal to shift resources to the ongoing rulemaking effort to meet Recommendation 1. The rulemaking effort will more clearly articulate the staff’s position by revising 10 CFR Part 21 to full conformity with the ERA of 1974, as amended, Section 206, Noncompliance.

Enclosure

As noted below, regarding Recommendation 2, the staff's next major milestone will be to finalize Revision 1 of the draft regulatory basis.

Target Completion Date: Changed—Finalize Revision 1 of the draft regulatory basis in December 2013.

- (3) Consistent with Recommendation 4, the staff will revise NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," to ensure reporting guidance associated with 10 CFR Part 21 is clear (see Recommendation 4 for additional information).

Target Completion Date: Unchanged—Issue guidance by June 26, 2015.

The Office of New Reactors (NRO) continues to work with other offices on 10 CFR Part 21 rulemaking. The rulemaking will clarify the 10 CFR Part 21 language and prevent interpretations that could potentially allow less than full conformity with Section 206 of the ERA. The staff's effort to issue a Commission paper outlining the rulemaking activities has been completed. The staff issued the 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'," on September 29, 2011.

The staff's next major milestone will be to finalize the regulatory basis. The staff expects considerable stakeholder interest and interaction before it can complete this next step in the rulemaking process. The staff's estimate for completing Revision 1 the draft regulatory basis is December 2013. The staff will host public meetings to discuss Revision 1 with stakeholders in early 2014. Based on the outcome of those public meetings, the staff will determine whether the regulatory basis is adequate to begin development of the proposed rule. The staff will undertake regulatory guidance development in parallel with the development of the proposed rule.

Target Completion Date: Changed—Finalize Revision 1 of the draft regulatory basis in December 2013.

Point of Contact: Paul Prescott, NRO/DCIP/QVIB
301-415-3026

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*.

OIG Analysis dated July 23, 2013:

OIG obtained clarification that Draft Regulatory Guide DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance," does not yet exist. This document is a number and title place holder. According to agency staff, the content of the Regulatory Guide DG-1291 will be written after the regulatory basis is complete and will be issued in parallel with the rulemaking.

These actions assist in meeting the intent of the recommendation. This recommendation continues to be resolved and will be closed upon staff completion and OIG review of interim guidance that specifies Part 21 reporting requirements.

Status: Resolved

Update:

The staff's next major milestone will be to finalize the regulatory basis. On January 24, 2012, the staff conducted a public meeting with stakeholders to discuss the Part 21 draft regulatory basis. In addition, the staff held public meetings on April 10, 2013, for 10 CFR 50.55(e); on April 11, 2013, for the fuel cycle facility rulemaking initiatives; and on May 30, 2013, for the evaluating and reporting process, related to reporting of defects and noncompliance. The staff continues to receive considerable stakeholder interest and requests for interaction before the staff completes the next step in the rulemaking process. The staff's estimate for completing Revision 1 the draft regulatory basis is December 2013. The staff will host public meetings to discuss Revision 1 with stakeholders in early 2014. Based on the outcome of those public meetings, the staff will determine if the regulatory basis is adequate to begin development of the proposed rule. The staff anticipates making this decision in March 2014. As part of the rulemaking, the staff coordinated with the Office of Nuclear Regulatory Research to create Draft Regulatory Guide DG-1291, "Evaluating Deviations and Reporting Defects and Noncompliance." The staff will undertake regulatory guidance development in parallel with the development of the proposed rule. This effort will begin following issuance of the regulatory basis.

Target Completion Date: Changed—Finalize Revision 1 of the draft regulatory basis in December 2013.

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Recommendation 3:

Correct the sections of NUREG-1022, *Event Reporting Guidelines 10 CFR 50.72 and 50.73, October 2000*, that are in conflict with the *Energy Reorganization Act of 1974, as Amended, Section 206, Noncompliance* and 10 CFR Part 21.

Status: Closed

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."

OIG Analysis dated July 23, 2013:

The agency's proposed action continues to meet the intent of the recommendation. This recommendation will be closed upon completion and OIG review of the revisions to NUREG-0302.

Status: Resolved

Update:

Staff guidance will be developed to clarify evaluating and reporting concurrent with NRO's rulemaking on 10 CFR Part 21.

Target Completion Date: Unchanged—Issue guidance by June 26, 2015.

Point of Contact: Paul Prescott, NRO/DCIP/QVIB
301-415-3026

Recommendation 5:

Incorporate Inspection Procedure 36100, *Inspection of 10 CFR Parts 21 and 10 CFR 50.55(e) Programs for Reporting Defects and Noncompliance* into the NRC Baseline Inspection Program.

Status: Closed

Correspondence Reference
OIG-11-A-08, "Audit of NRC's Vendor Inspection Program"

NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," dated October 1977 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML062080399).

Office of the Inspector General (OIG) Audit OIG-11-A-08, "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance," dated March 23, 2011 (ADAMS Accession No. ML110820426).

Memorandum from S. Dingbaum to R. W. Borchardt, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated June 10, 2011 (ADAMS Accession No. ML111610150).

Memorandum from E. Leeds to S. Dingbaum, "Status of Recommendations from Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated August 18, 2011 (ADAMS Accession No. ML112150597).

Memorandum from S. Dingbaum to R. W. Borchardt, "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated September 16, 2011 (ADAMS Accession No. ML112590026).

Memorandum from N. Mamish to Commissioner Assistants, "Clarification of Staff Position on Part 21 Reporting Requirements," dated September 19, 2011 (ADAMS Accession No. ML11258A065).

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).

Draft NUREG-1022, Revision 3, "Event Report Guidelines 10 CFR 50.72 and 50.73," issued for public comment October 13, 2011 (ADAMS Accession No. ML11273A065).

Memorandum from G. Tracy to S. Dingbaum, "Status of Recommendations from 'Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08),' " dated November 13, 2012 (ADAMS Accession No. ML12293A210).

Memorandum from S. Dingbaum to R. W. Borchardt "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated December 20, 2012 (ADAMS Accession No. ML13007A030).

Memorandum from E. Leeds to S. Dingbaum, "Status of Recommendation 3 from Audit of 'U.S. NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance' (OIG-11-A-08)," dated December 27, 2012 (ADAMS Accession No. ML12353A311).

Correspondence Reference
OIG-11-A-08, "Audit of NRC's Vendor Inspection Program"

Memorandum from S. Dingbaum to R. W. Borchardt "Status of Recommendations: Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (OIG-11-A-08)," dated July 23, 2013 (ADAMS Accession No. ML13220A024).