

April 23, 2013

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

FROM: Glenn M. Tracy, Director */RA/*
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 OIG recommendations in the June 10, 2011, memorandum to the Executive Director for Operations, transmitting the Office of the Inspector General's (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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* via email

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 December 20, 2012:

On December 6, 2012, the Office of the Inspector General (OIG) obtained clarification from the agency that NRC anticipates finalizing the rulemaking to revise Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 for full conformity with the Energy Reorganization Act (ERA) of 1974, As Amended, Section 206, Noncompliance, no later than December 2014. This clarification and the proposed corrective actions described in the agency response above meet the intent of the recommendation. Therefore, this recommendation is resolved and will be closed upon completion and OIG review of the 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 pertaining to 10 CFR Part 21. The NRC published Revision 3 of NUREG-1022 in January 2013, and it takes 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 *Energy Reorganization Act (ERA) of 1974, As Amended, Section 206, Noncompliance*. The Office of the General Counsel (OGC) reviewed the CA Note and offered no legal objection.

Target Completion Date: Complete.

- 2) The staff developed a draft regulatory issue summary (RIS) 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 in order 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 *Energy Reorganization Act (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 the regulatory basis.

Target Completion Date: Changed—Finalize regulatory basis in September 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 the regulatory basis is September 2013. The staff will undertake regulatory guidance development in parallel with the development of the proposed rule.

Target Completion Date: Finalize regulatory basis in September 2013.

Point of Contact: Paul Prescott, NRO/DCIP/CQAB
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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 December 20, 2012:

On December 6, 2012, OIG obtained clarification from the agency on the actions planned to issue interim guidance via a public meeting and by publication of a regulatory basis document that specifies the basis for proposed future changes to Part 21 reporting, in accordance with the *Energy Reorganization Act of 1974, As Amended, Section 206, and Noncompliance*. The agency reiterated that a form of interim guidance was earlier promulgated via the 2011 and 2012 NRC Regulatory Information Conferences, and that the slides from those presentations are publically available via the agency Web site and serve as guidance. As part of its ongoing communication efforts to industry, the agency confirmed that NRC staff will communicate the Part 21 regulatory basis to stakeholders during a public meeting on January 24, 2013, and

either schedule more public meetings or finalize and publish the regulatory basis in the FR. OIG noted that publication of a regulatory basis document does not provide guidance but communicates the proposed basis for future rulemaking. The regulatory basis document states that its purpose is to promote early stakeholder feedback and does not state that it provides interim guidance for Part 21.

The agency also provided a copy of the regulatory basis document that will be communicated. OIG verified that it more clearly articulates the staff's position on revising 10 CFR Part 21 to full conformity with ERA Section 206, though it does not in and of itself constitute guidance. The agency stated that it will also provide to OIG for review, the presentation materials to be used to inform stakeholders. OIG recognizes that because rulemaking is not expected to be final until December 2014, agency staff will periodically provide stakeholders with communications throughout the rulemaking process and will issue additional guidance that further specifies requirements for Part 21 reporting in accordance with the *Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance*.

As noted above, while the regulatory basis document does not constitute interim guidance, the proposed corrective action to communicate the staff position on Part 21 reporting requirements is an action that assists in meeting the intent of the recommendation. This recommendation will be closed upon staff completion and OIG review of any additional guidance that specifies Part 21 reporting requirements, until such time that the agency's actions in response to Recommendation 1 are met.

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 will schedule additional meetings for specific areas of the rulemaking. There was a public meeting held on April 10, 2013, for 50.50(e); and a meeting on April 11, 2013, for the fuel cycle facility rulemaking initiatives. 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 the regulatory basis is September 2013. 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 regulatory basis in September 2013.

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

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.

OIG Analysis dated December 20, 2012:

The proposed corrective action meets the intent of the recommendation. This recommendation will be closed upon staff completion and OIG review of the final revised version of NUREG-1022 that includes the corrected sections that are in conflict with the *Energy Reorganization Act of 1974, as Amended, Section 206, Noncompliance*.

Status: Resolved

Update:

The staff revised and issued NUREG-1022, Revision 3, "Event Reporting Guidelines: 10 CFR 50.72 and 50.73," for public comment in a FR notice published October 13, 2011. On February 2, 2012, the staff met with the Nuclear Energy Institute and other stakeholders to discuss the public comments. The discussion pertaining to 10 CFR Part 21 has been removed.

In parallel, and in accordance with Recommendation 2, the staff will coordinate with the rulemaking effort to ensure that clear and proper guidance is communicated and issued to the industry to avoid ambiguity in reporting requirements.

Target Completion Date: NUREG-1022, Revision 3, was published in January 2013, and will take effect July 1, 2013.

Point of Contact: Timothy Kobetz, NRR/DIRS/IRIB
301-415-1932

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 December 20, 2012:

The agency's proposed corrective actions continue 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/CQAB
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.

OIG Analysis dated December 20, 2012:

The agency's proposed action meets the intent of the recommendation. This recommendation will be closed when the agency incorporates requirements to inspect licensee reporting of Part 21 defects into the appropriate inspection procedure.

Status: Resolved

Update:

To address OIG's most recent concern, the staff further enhanced Inspection Procedure (IP) 71152, Section 02.01, to specifically state that the inspector's routine (daily) screening of problem identification and resolution issues include an assessment of whether the licensee should perform an evaluation in accordance with 10 CFR Part 21 of any defects or nonconformances that have been identified. This will ensure that the inspectors are evaluating potential 10 CFR Part 21 issues on a continual basis.

Target Completion Date: Complete. The staff issued a revision to IP 71152 on January 31, 2013.

Point of Contact: Timothy Kobetz, NRR/DIRS/IRIB
301-415-3969

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

- 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)
- 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)
- 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 Reporting Guidelines 10 CFR 50.72 and 50.73," issued for public comment October 13, 2011 (ADAMS Accession No. ML11273A065)
- 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. (ADAMS Accession No. ML062080399)