

April 27, 2011

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

FROM: Martin J. Virgilio */RA/*
Deputy Executive Director for Reactor
and Preparedness Programs
Office of the Executive Director for Operations

SUBJECT: AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21,
REPORTING OF DEFECTS AND NONCOMPLIANCE
(OIG-11-A-08)

This is in response to your March 23, 2011, memorandum to the Executive Director for Operations, transmitting Office of the Inspector General (OIG) Audit Report OIG-11-A-08, "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance." I have enclosed the staff's responses to each of the five OIG recommendations.

Enclosure:
As stated

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
SECY

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**NRC STAFF RESPONSE TO OFFICE OF INSPECTOR GENERAL AUDIT REPORT,
OIG-11-A-08, "AUDIT OF NRC'S IMPLEMENTATION OF 10 CFR PART 21, REPORTING OF
DEFECTS AND NONCOMPLIANCE"**

Recommendation 1:

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

Response:

The U.S. Nuclear Regulatory Commission (NRC) staff agrees that Part 21 and associated staff guidance can be open to interpretation regarding a licensee's evaluation and subsequent reporting obligations.

The Office of New Reactors (NRO) is currently developing a Commission paper that will recommend that the staff undertake rulemaking for 10 CFR Part 21 to address items associated with Office of the Inspector General (OIG) Audit Report OIG-10-A-20, "Audit of NRC's Vendor Inspection Program," dated September 28, 2010. NRO identified this action in its response to Recommendation 5 of OIG-10-A-20 dated October 30, 2010 (Agencywide Documents Access and Management System Accession No. ML102950598). The Office of Nuclear Reactor Regulation (NRR) is actively working with NRO and the Office of Nuclear Material Safety and Safeguards (NMSS) on this activity and will seek input from other program offices as needed throughout the Commission paper development and potential rulemaking process.

Development of the Commission paper will include Recommendation 1, in Audit Report OIG-11-A-08, "Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance," dated March 23, 2011, as an additional item for discussion. This Commission paper will address the need and priority for rulemaking, guidance (i.e., regulatory guide), and outreach efforts. The paper will also outline options that the staff recommends for clarifying the requirements of 10 CFR Part 21. Concurrently addressing this item and existing similar NRO OIG audit recommendations will enhance the staff's effectiveness and coordination.

To address Recommendation 1 in the Commission paper, the staff plans to propose clarification of the wording in 10 CFR Part 21 associated with duplicate reporting, specifically, 10 CFR Part 21.2(c). The NRC will subsequently 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," Revision 1, dated July 12-26, 1977, or will develop other guidance to reflect the clarification.

Target Completion Date for Commission Paper: September 30, 2011

ENCLOSURE

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*.

Response:

The staff accepts the recommendation and plans to promote timely development and issuance of interim guidance identifying its position on 10 CFR Part 21 evaluation and reporting.

NRR will coordinate with NRO, NMSS, and other offices as necessary to ensure applicability of the interim guidance for all affected offices. The staff will coordinate this effort with the Office of the General Counsel to ensure that the appropriate regulatory tool is used for issuing guidance and that consideration of a singular staff position is conveyed in this guidance

Target Completion Date and Publication of Guidance: March 31, 2012. Note that the response from the Commission on the need for 10 CFR Part 21 rulemaking may impact the issuance of the guidance.

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.

Response:

The staff accepts the recommendation to correct sections of NUREG-1022.

The NRC will revise NUREG-1022, as necessary, following resolution of the first two Recommendations above. This revision will follow, and will not be tied to the currently on-going revision which is necessary to address ongoing under-reporting of safety system functional failures.

Target Completion Date: December 31, 2012

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*.

Response:

The staff accepts the recommendation to issue formal guidance on Part 21.

NRO will coordinate with NRR and other offices as necessary to develop updated guidance on 10 CFR Part 21. Potential rulemaking will impact the specific guidance that would be issued and the associated document format(s) that may be used has not yet been determined. NRR intends to issue draft guidance concurrent with the issuance of a draft 10 CFR Part 21 rule. Issuance of the final guidance should be concurrent with the final rule.

Target Completion Date: June 26, 2015. The scope and target date for development and issuance of the guidance are pending Commission direction on 10 CFR Part 21 rulemaking.

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.

Response:

The staff accepts the recommendation to incorporate Inspection Procedure 36100 into the NRC Baseline Inspection Program.

The NRR staff will review the baseline inspection program and make changes, as necessary, to verify licensee reporting of defects and noncompliance. The review and procedural changes (if necessary) will coincide with the Reactor Oversight Process realignment effort.

Target completion Date: December 31, 2011

Attachments:

1. Response to OIG Report OIG-11-A-08
(10 CFR Part 21 Implementation)
2. Continued Non-Concurrence for
Response to OIG Email dtd 04/20/11