August 18, 2011

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

FROM: Eric J. Leeds, Director ***/RA/ (Jack A. Grobe for)***
Office of Nuclear Reactor Regulation

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

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

Enclosure:
As stated

CONTACT: Kerby V. Scales, NRR/DE
(301) 415-1369

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**NRC Staff Response to Office of the Inspector General 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*

Agency response dated April 27, 2011:

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

OIG Analysis dated June 10, 2011:

The proposed corrective action contains indirect and ambiguous phrases that do not affirm that the agency will complete actions needed to revise 10 CFR Part 21 for full conformity with the

Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance. Therefore, the agency response did not address the intent of OIG's recommendation.

Specifically, the agency response to Recommendation 1:

- Does not state that the agency agrees that it will revise Part 21. The response states that it agrees that Part 21 and associated staff guidance are open to interpretation. The fact that NRC staff and licensees have varying interpretations of Part 21 reporting requirements is the problem OIG identified in the subject report.

- Does not clearly indicate that the staff will propose clarification so that Part 21 is in full conformity with Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance, with regard to industry's obligation to report to NRC defects in basic components that could cause a substantial safety hazard.

This recommendation will be resolved when the agency states the specific actions it will take and the date that it expects to complete the revision to 10 CFR Part 21 for full conformity with the Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance.

Status: Unresolved

Update:

Actions taken and planned: The staff has reevaluated its initial proposed approach to address this recommendation. The staff agrees that because of the differing interpretations associated with 10 CFR Part 21 (Part 21) and its associated guidance that full conformance with the Energy Reorganization Act of 1974, As Amended, Section 206 could be impacted. As identified in the OIG's report and reiterated in the OIG response to the staff's initial proposed resolution for Recommendation 1, varying interpretations of Part 21 reporting requirements exist. The concern is the use of only the 10 CFR 50.72/50.73 evaluation criteria in lieu of Part 21 evaluation criteria.

The staff proposes to take the following actions to meet the intent of this recommendation:

1) NUREG-1022, "Event Reporting Guidelines: 10 CFR 50.72 and 50.73, Revision 3" is currently being revised and issued for public comment. The discussion pertaining to Part 21 has been removed since this document provides guidance on how to meet 10 CFR 50.72/50.73 and these regulations do not discuss Part 21. Target date for issuing draft NUREG-1022 to the Federal Register Notice for public comment is by December 2011.

   Target Completion Date: Issue revised guidance by December 31, 2012.

2) The staff is preparing a Commissioner Assistants (CA) Note to communicate the staff's position to ensure full conformity with the *Energy Reorganization Act (ERA) of 1974, As Amended, Section 206, Noncompliance*. The CA Note will be reviewed and concurred on by Office of General Counsel (OGC). This existing position does not require a revision to Part 21.

a. The staff's position is:

> If the evaluation of a deviation in basic component under the guidance for §§ 50.72 and 50.73 results in a report, the obligations under Part 21 for evaluation and reporting have been met. In the event that the evaluation of a deviation under the guidance for §§ 50.72 and 50.73 does not result in a report, licensees must ensure that the evaluation also meets Part 21 and its associated guidance to ensure Part 21 reporting requirements are satisfied.

This is consistent with the existing staff position which is identified in NUREG-0302 "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," and Part 21.2 (a) (4) (c) which states in part "…evaluation of potential defects ***and*** (emphasis added) appropriate reporting of defects under §§ 50.72, 50.73, or 73.71 of this chapter, satisfies each person's evaluation, notification and reporting obligation…" The staff believes that this position fully meets the original intent of Part 21, ensures conformity with Section 206 of the ERA of 1974 and obviates the necessity of Part 21 rulemaking.

Target Completion Date: Commissioner Assistants note by October 28, 2011.

3) Following issuance of the CA Note and consistent with Recommendation 2, the staff will expedite development and issuance of interim guidance communicating this staff position (see Recommendation 2 for additional information).

   Target Completion Date: Unchanged – Issue interim guidance by March 31, 2012

4) Consistent with Recommendation 4, the staff will revise NUREG-0302 to ensure reporting guidance associated with Part 21 is clear (see Recommendation 4 for additional information).

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

5) The staff continues to pursue rulemaking by working with NRO on its Commission Paper on Part 21 rulemaking. The intended rulemaking will clarify the Part 21 language and prevent interpretations that could potentially allow less than full conformity with Section 206 of the ERA.

   Target Completion Date: Unchanged – Issue Commission paper by September 30, 2011.

   Point Of Contact: Martin Murphy, NRR/EQVB
   (301) 415-3969

**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 April 27, 2011:

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

OIG Analysis dated June 10, 2011:

The proposed corrective action meets the intent of the recommendation. In fact, OIG notes that NRC staff has already begun promulgating interim guidance through presentations at industry meetings, such as the March 2011 Regulatory Information Conference. These presentations clarify that defects that cause substantial safety hazards, even if they do not cause reportable events, are nonetheless reportable under Part 21. This recommendation will be closed when OIG receives documentation of interim guidance that specifies requirements for Part 21 reporting in accordance with the *Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance.*

Status: Resolved

Update:

Actions taken and planned: The staff is preparing a Commissioner Assistants (CA) Note to clarify the staff's position to ensure full conformity with the *Energy Reorganization Act of 1974, As Amended, Section 206, Noncompliance*. The CA Note will be reviewed and concurred on by OGC. Following issuance of the CA Note the staff will expedite development and issuance of interim guidance. NRR will coordinate this effort with NRO.

Target Completion Date: Unchanged – Issue interim guidance by March 31, 2012

Point Of Contact: Martin Murphy, NRR/EQVB
(301) 415-3969

**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.

Agency response dated April 27, 2011:

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 ongoing revision which is necessary to address ongoing under-reporting of safety system functional failures.

Target Completion Date: December 31, 2012

OIG Analysis dated June 10, 2011:

The proposed corrective action does not address the intent of OIG's recommendation because the response states that NUREG-1022 will be revised if the staff determines it is necessary to do so. OIG's recommendation was to revise NUREG-1022, not to determine if changes are necessary. Additionally, a single sentence in NUREG-1022 currently enables the underreporting of defective nuclear safety significant components in the industry. The removal or modification of this sentence could be incorporated into the currently ongoing revision process.

This recommendation will be resolved when the agency's response includes clear and timely actions that will 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: Unresolved

Update:

Actions taken or planned: Part 21 reports are not discussed in 10 CFR 50.72 or 50.73 regulations. Therefore, to avoid potential conflicts with any future guidance that the staff issues regarding Part 21 reporting requirements (e.g., potential rulemaking, interim guidance and/or an update to NUREG-0302), the staff has removed section 5.1.8, "10 CFR Part 21 Reports" from the draft NUREG-1022, Rev. 3. Part 21 reporting will not be discussed in the NUREG. NUREG-1022 is currently being revised and should be published in the Federal Register for public comment in the 1st quarter of fiscal year 2012. The staff expects to publish the final NUREG by December 2012 once all of the public comments have been addressed.

Target Completion Date: Unchanged – Issue revised guidance by December 31, 2012.

Point Of Contact: Timothy Kobetz, NRR/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.

Agency response dated April 27, 2010:

The staff accepts the recommendation to issue formal guidance on Part 21. NRR will coordinate with NRO 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.

OIG Analysis dated June 10, 2011:

The proposed corrective action meets the intent of the recommendation. This recommendation will be closed when OIG receives the finalized revision to 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, and determines it continues to provide clear defect reporting guidance.

Status: Resolved

Update:

Actions taken and planned: NRR plans to revise NUREG-0302 to ensure evaluation and reporting guidance associated with Part 21 is clear. NRR will commence a revision to NUREG-0302 to incorporate the interim guidance once issued. A more extensive revision will be addressed once the NRO proposed rulemaking effort is concluded.

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

Point Of Contact: Martin Murphy, NRR/EQVB
(301) 415-3969

**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.
Agency response dated April 27, 2010:

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

OIG Analysis dated June 10, 2011:

The proposed corrective action does not address the intent of OIG's recommendation because the response states that the staff will review and revise to incorporate IP 36100 into the ROP baseline inspection program if the staff determines it is necessary to do so co-incident with the ROP realignment effort. OIG did not recommend that the staff evaluate to determine whether such changes were needed; rather OIG recommended that IP 36100 be incorporated into the ROP baseline inspection program.

This recommendation will be considered resolved when OIG receives an agency response that states that it will definitively 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: Unresolved

Update:

Actions taken or planned: IP 36100 is a programmatic based inspection which does not align well with the performance based approach of the ROP inspection program. Therefore, in lieu of incorporating IP 36100 directly in to the baseline inspection program the elements of the Part 21 and non-conforming part inspection will be incorporated into an existing baseline inspection procedure (e.g., IP 71152, "Problem Identification and Resolution" or another IP). The staff is currently performing its bi-annual ROP realignment review. NRR will work with the regional offices to determine the best IP to implement a periodic review of licensee documents (e.g., condition reports, corrective action reports, etc.) for adherence to the requirements of Part 21. This will be completed by December 2011.

Target Completion Date: Unchanged – Incorporate inspection procedures by December 31, 2011.

Point Of Contact: Timothy Kobetz, NRR/IRIB
(301) 415-3969