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

OFFICE OF THE
INSPECTOR GENERAL

June 10, 2011

MEMORANDUM TO: R. William Borchardt
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: DEPUTY EXECUTIVE DIRECTOR FOR REACTOR AND PREPAREDNESS PROGRAMS, OFFICE OF THE EXECUTIVE DIRECTOR FOR OPERATIONS, MEMORANDUM DATED APRIL 27, 2011

Attached is the Office of the Inspector General's analysis and status of recommendations 1, 2, 3, 4, and 5 as discussed in the agency's response dated April 27, 2011. Based on OIG's analysis of this response, recommendations 1, 3, and 5 are unresolved and recommendations 2 and 4 are resolved.

OIG notes that NRC management has accepted, but uses conditional language to articulate, the actions planned. This obfuscates the agency's intentions with regard to the recommendations. It is paramount for OIG to have a clear understanding of the NRC management position with regard to reportability under Part 21. Recent manufacturing defects at two separate nuclear power plants illustrate why this is important.

One nuclear power plant recently received a Red finding under NRC's Reactor Oversight Program because a safety-related coolant injection valve was discovered to have been broken and unable to perform its safety function for an extended period of time. Had this same valve been out of service for less than 7 days, the failure of the valve would not have been reportable under Part 21 according to some interpretations because it would not have met Part 50 event reporting requirements, and the nuclear industry would not have been informed of a manufacturing defect in a safety-related component.

At another nuclear power plant, the licensee discovered that a safety-related part necessary to operate a circuit breaker had a manufacturing defect that would prevent the breaker from performing its safety function. Some of the breakers were installed in the plant and some were on the shelf in the plant's warehouse. Under the interpretation of some in industry and at NRC, the failure of the part installed in the operating nuclear plant would not be reportable under Part 21 because the failure did not meet Part 50 event reporting requirements, but the same defective part, if in the warehouse, would be reportable under Part 21.

Until NRC makes a final determination as to whether Part 21 defect reporting should be required separate from Part 50 event reporting requirements, some licensees and NRC staff will continue to assume that Part 21 evaluation and reporting is not necessary at operating nuclear power plants unless the defect causes an event. Accordingly, please provide the proposed corrective action for the unresolved recommendations and an updated status of the resolved recommendations by August 20, 2011. If you have any questions or concerns, please call me at 415-5915 or R.K. Wild, at 415-5948.

Attachment: As stated

ADAMS Accession Number: ML111610150

cc: M. Muessle, 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.*
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.

Recommendation 1 (cont.):

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: 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.

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Status of Recommendations

Recommendation 1 (cont.):

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.

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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.*
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:	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.

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Status of Recommendations

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 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 on going revision which is necessary to address ongoing under-reporting of safety system functional failures. Target Completion Date: December 31, 2012
OIG Analysis:	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.

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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.
Response Dated April 27, 2011:	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.
OIG Analysis:	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.

Audit Report

Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance

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Status of Recommendations

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 Dated April 27, 2011:	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.
OIG Analysis:	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.