



Fuel Handling Equipment & Crane Manufacturing
Westinghouse Electric Company
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To: U.S. Nuclear Regulatory Commission
ATTENTION: Document Control Desk
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From: Matthew M. Rohr
Phone: 651-415-4363
Date: January 16, 2015

Our Reference: FHE&CM-QAL-15-002
Your Reference: 99901452/2014-201

Subject: Reply to Notice of Violation and Notice of Nonconformance cited in NRC Inspection Report No: 99901452/2014-201 dated December 4, 2014

Westinghouse acknowledges receipt of NRC Inspection Report Number 99901452/2014-201, Notice of Violation 99901452-2014-201-01 and Notice of Nonconformance Items 99901452/2014-201-02 and 99901452/2014-201-03 dated December 4, 2014. Westinghouse takes any notice of violation or nonconformance received from the NRC seriously and is taking appropriate actions to completely resolve these issues in a timely manner, and is committed to be in compliance with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocess Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Westinghouse also values the results from this thorough review of our Fuel Handling Equipment and Crane Manufacturing activities. In consideration of NRC comments made both during the inspection and in the exit meeting, Westinghouse immediately initiated many corrective actions to resolve the specific items identified in the Notice of Violation and Notice of Non-Conformances.

As requested, details of actions associated with each issue are described below.

Summary of Issues Identified and Actions Taken During the Inspection

Violation 99901452-2014-201-01

Title 10 of the Code of Federal Regulations (10 CFR) Part 21.21, "Notification of failure to comply or existence of a defect and its evaluation," Section (a)(1) requires "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviation and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of

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discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.”

Section 21.21(a)(2) requires “Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days of discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in Section 21.21(d)(5). This interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

Contrary to the above, as of October 24, 2014, FHE&CM failed to evaluate a deviation potentially associated with a substantial safety hazard in accordance with 10 CFR 21.21(a)(1) or provide an interim report in accordance with 10 CFR 21.21(a)(2). Specifically, FHE&CM did not conduct an evaluation or provide notification of a commercial-grade dedication (CGD) deviation potentially associated with a substantial safety hazard identified in Corrective Action, Prevention, and Learning System (CAPAL) Issue ID 100000536, dated July 12, 2013, which was related to a cask crane trolley upgrade that was shipped to V.C. Summer Unit 1 in February 2013.

This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement policy).

Response:

The actions for this Violation are tracked under Westinghouse CAPAL 100059406.

(1) The reason for the noncompliance:

Westinghouse accepts the Notice of Violation and offers the following discussion regarding the circumstances which resulted in the Violation:

As part of the evaluation to determine cause, an Apparent Cause Analysis (ACA) was performed. This investigation identified two underlying areas of apparent cause.

- FHE&CM Issue Review Committee (IRC) members lacked the knowledge in July 2013 to determine the correct answer to the safety assessment question in the Corrective Action program. During IRC review it is critical that the proper safety assessment be performed. The time metrics established for notification per WEC 21.0, *Identification and Reporting of Conditions Adverse to Safety*, begin once the issue is identified. This will only begin if properly indicated in the CAPAL issue after assignment by the IRC. In this case, if the IRC did not recognize the impact of the issue that was identified, then the issue would not have been coded as a Condition Adverse to Nuclear Safety. As a result, no evaluation

took place. One contributing factor was the limited representation of Quality Assurance at the IRC during this timeframe. During July 2013, a transition was in place for FHE&CM Quality leadership. The Quality Manager abruptly resigned from Westinghouse during that month after returning to work from a lengthy absence. The interim replacement was not named until late in the month. Consequently, the Quality representation at the IRC consisted of only the Issue Screener.

- WEC 18.1, *Internal Audits*, does not provide guidance to the audit team to evaluate findings as potential conditions adverse to nuclear safety. The internal audit procedure relies solely on the IRC to make this determination. There was a missed opportunity during the internal audit WEC-13-40 to identify this issue as a potential Condition Adverse to Nuclear Safety. Given the involvement of Westinghouse subject matter experts during the internal audit, it would have been beneficial for findings to be considered as potential Conditions Adverse to Nuclear Safety similar to how they are handled in the IRC. This would also help prevent 10 CFR Part 21 notification calendar erosion from the moment of discovery to the time the issue is entered by the Audit Team Lead.

(2) Corrective steps that have been taken and the results achieved:

- V.C. Summer Unit 1 customer was notified in writing by FHE&CM of the potential 10 CFR Part 21 condition. The customer was notified that the condition was under evaluation by Westinghouse. Engineering justification for the acceptance of the components in question was completed on November 15th, 2014. A summary letter including this justification was provided to the V.C. Summer Unit 1 permitting the continued use of the components without restriction.
- The 10 CFR Part 21 investigation was completed in accordance with WEC 21.0 by Westinghouse Regulatory Compliance. The investigation was completed on December 2nd, 2014 including an extent of condition for previous shipments, including spare parts. The conclusion of the investigation is the condition was found not to be reportable under 10 CFR Part 21.
- Training was conducted by the Westinghouse Regulatory Compliance Manager for all FHE&CM employees on the requirements of 10 CFR Part 21 reporting and WEC 21.0. This training was conducted on August 19th, 2014.
- Training was conducted by the Westinghouse Regulatory Compliance Manager for the full FHE&CM management staff (IRC members) on the requirements of 10 CFR Part 21 reporting and WEC 21.0. This training was specifically targeted towards IRC members with an emphasis on the process by which an issue gets flagged for 10 CFR Part 21 evaluation and the vital role the IRC contributes to this process. This training was conducted on August 19th, 2014.
- A training course was provided by the J-E-T-S Quality Consulting group on July 2nd and July 3rd, 2014, for all FHE&CM Quality Engineers and Mechanical/Electrical Engineers involved with the development of Commercial Grade Dedication (CGD) procedures. This course provided the knowledge and skills needed to understand, interpret, and comply

- with the requirements of 10 CFR Part 21. This included exercises to help interpret and apply these requirements in realistic situations as well as industry lessons learned.
- A review of CAPAL issues was conducted by the Westinghouse Global Corrective Action Manager. As part of this review, a specific emphasis was placed on unassigned (by IRC) issues that were marked for potential conditions adverse to nuclear safety by the issue submitter. This review identified one issue (100036553) that was unassigned after 43 days from CAPAL entry. Upon identification of this issue, it was assigned by the respective IRC and the issue was evaluated for Part 21 consideration. This evaluation has been completed and it has been determined that this issue does not meet the criteria for a condition adverse to nuclear safety. This issue was identified as part of the Apparent Cause Analysis as similar to the 100000536 issue in that there was a delay in identifying the need for Part 21 evaluation. A CAPAL issue has been entered to address the delay in assignment of the 100036553 issue.
 - A CAPAL issue was entered to improve WEC 18.1, Internal Audits. The specific improvement targeted in this issue will be for an additional step to evaluate internal audit findings as potential conditions adverse to nuclear safety. This will add an additional layer of defense in identifying potential conditions that require evaluation for 10 CFR Part 21 applicability.

The training identified above was performed prior to the violation being identified by the NRC vendor inspection team. The internal training was requested by FHE&CM management to reinforce 10 CFR Part 21 awareness and requirements. The external training was requested by Westinghouse executive Quality management in an effort to re-baseline organizational understanding of the requirements. Since the timeframe that these trainings were completed, FHE&CM has shown a significant increase in the number of issues that have been identified for 10 CFR Part 21 evaluation. Starting in September 2014, thirteen CAPAL issues that have been identified by the IRC as requiring 10 CFR Part 21 evaluations. This increase in evaluations reflects an improved understanding of the fundamental requirements and a heightened awareness of the issues that potentially warrant an evaluation.

(3) Corrective actions that will be taken:

- An extent of condition will be conducted on all FHE&CM CAPAL issues identified as Conditions Adverse to Quality (CAQ) over the past 3 years. These CAQ's will be reviewed to determine if the nuclear safety assessment has been identified correctly.
- A training refresher led by the FHE&CM Quality Manager for all IRC members on the following topics: Conditions Adverse to Nuclear Safety assessments, WEC 21.0, Significant Conditions Adverse to Quality (SCAQ) criteria, and WEC 16.11 (*Issue Review Committee*).
- A lessons learned communication shall be developed and distributed to all Westinghouse qualified audit team leaders. This communication will discuss the lessons learned from the Notice of Violation identified at FHE&CM.

(4) Date When Full Compliance will be Achieved:

Full compliance will be achieved utilizing the actions and commitments outlined above by April 17th, 2015.

Nonconformance 99901452/2014-201-02

A. Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."

Section 5.5.1 of the Westinghouse Electric Company (WEC) Quality Management System (QMS), Revision 7, states, in part, that "Conditions adverse to the quality of items and services are identified, documented, analyzed, and corrected in accordance with established procedures." Section 5.5.3 of the WEC QMS, Revision 7, states, in part, that, "Quality data is analyzed for trends in items, services, processes, and systems that may require action to eliminate causes of potential conditions adverse to quality."

Section 7.6.1 of WEC 16.2, "Westinghouse Corrective Action Program," Revision 7.0, states, in part, that "The following timeliness expectations apply to all Level 1 Significance Issues, as well as to all SCARs [Supplier Corrective Action Requests], Trends and Level 2, Level 3, and Level 4 Significance Issues that are defined in the corrective action program database as CAQs [Conditions Adverse to Quality], customer identified, or Quality or EHS [Environment, Health, and Safety] Controlled... Level 1 – Issue closure due date – 365 days from Issue origination; Level 2 – Issue closure due date – 180 days from Issue origination; Level 3 – Issue closure due date – 180 days from Issue origination; and Level 4 – Issue closure due date – 120 days from Issue origination."

Section 7.11.1 of WEC 16.2, Revision 7.0, states, "Issues documented in the corrective action database shall be analyzed at least quarterly to identify potential adverse trends and cross-cutting deficiencies that require corrective action."

Contrary to the above, WFHE&CM failed to establish measures to assure that conditions adverse to quality were promptly identified and corrected, and for significant conditions adverse to quality, corrective actions were taken to preclude repetition. Specific examples include:

- 1) As of October 22, 2014, 177 of the 386 issues in the Corrective Action, Prevention, and Learning System (CAPAL) database for WFHE&CM were past their due dates. The NRC inspection team found no objective evidence of due date extension approvals for these CAPALs, as required by WEC 16.2. Examples include:
 - a. CAPAL Issue ID 100000228 – a Level 1 CAPAL that was 362 days past due
 - b. CAPAL Issue ID 100000508 – a Level 2 CAPAL that was 305 days past due
 - c. CAPAL Issue ID 100010212 – a Level 4 CAPAL (with a potential Condition Adverse to Nuclear Safety) that was 53 days past due
- 2) Beginning with the first quarter of Fiscal Year 2014, WFHE&CM failed to analyze the corrective action database on at least a quarterly basis to identify potential adverse trends and cross-cutting deficiencies that require corrective action as required by Section 5.5.1 of the WEC QMS and Section 7.11.1 of WEC 16.2.
- 3) WFHE&CM failed to ensure that conditions adverse to quality related to commercial grade dedication were adequately corrected. CAPAL Issue ID 100000536, “Method 2 and Method 3 Dedication Noncompliances,” was opened on July 12, 2013, with some corrective actions signed off as completed. However, as of October 24, 2014, those corrective actions were found to be inadequate because commercial grade surveys of the suppliers and evaluations of dedicated items were not being performed.

Response:

The actions for this Nonconformance are tracked under Westinghouse CAPAL 100066598.

(1) The reason for the noncompliance:

As part of the evaluation to determine cause, an Apparent Cause Analysis (ACA) was performed. This investigation identified 3 underlying areas of apparent cause.

- Inconsistent oversight and emphasis of the CAPAL program. This area was identified by exploring why CAPALs were past due, why the CAPAL program was not being analyzed, and why issues with conditions adverse to quality had not been adequately corrected in a timely manner. The investigation found that competing priorities and lack of tracking/trending tools were not identified and corrected since oversight and emphasis of the CAPAL program was inadequate.
- Procedural weakness of changing Issue Owners of CAPALs. This area was identified by exploring why CAPALs were past due. The investigation found that many CAPAL issues had changed issue owners for several reasons and that a thorough turnover of the issues had not taken place. This left a gap for the new issue owner to attempt to figure out the status and direction of the issue.
- Inadequate validation of effectiveness of Issue Owner and Issue Screener training. This area was identified by exploring why CAPALs were past due and why the CAPAL program was not being analyzed. The investigation found that issue owners and issue

screeners had been trained in accordance with procedures, however some issue owners and issue screener were unclear of their roles and responsibilities and did not fully understand how to navigate the CAPAL database. These conditions led to ineffective management of the issues and extended time commitments for on the job training and inadequate CAPAL program analysis.

(2) Corrective Action steps that have been taken and the results achieved:

- Westinghouse has taken action to reinforce the priority of maintaining our CAPAL program by bringing high visibility to the past due CAPALs. This is evidenced in the following:
 - Executive review dashboards that are published for Westinghouse senior executives. This provides managers real-time data regarding CAPAL performance by their respective organizations. This includes high level trend data for customer/regulatory identified issues, 10 CFR Part 21 issues, delivered deficiencies, etc.
 - Rollout of new enterprise reporting systems to provide all employees and managers with improved access of CAPAL performance and tracking.
 - Implementation of an escalation process for IRC unassigned issues to provide improved oversight and limit the time delay in assigning issues
- Westinghouse FHE&CM personnel have brought closure to a significant number of the past due issues, and are trending in a positive direction. In the last four months of 2014, FHE&CM made the following performance metric improvements:
 - Increase in issue closure timeliness of 22%
 - Reduction in total open issues of 12%
 - Reduction in total late issues of 27%
- Tracking/trending capabilities within the CAPAL database have been implemented.
- A self-assessment was performed in November 2014 by Westinghouse FHE&CM on the closure quality of CAPAL issues. The deficiencies noted in this self-assessment were documented in CAPAL and a stand down training with all Issue Owners was held to provide the lessons learned from this assessment.

(3) Corrective steps that will be taken to avoid further violations:

- A continued focus on the health of the CAPAL program will be monitored by consistent tracking/trending reporting to the top levels of management within Westinghouse.
- Procedural guidelines will be developed to assure adequate and consistent turnover of information in cases where issue owners are changed.
- Identify and implement a robust system of validating issue owner and issue screener effectiveness of training.

(4) Date When Full Compliance will be Achieved:

Full compliance will be achieved utilizing the actions and commitments outlined above by June 26th, 2015.

Nonconformance 99901452/2014-201-03

Criterion XII of Appendix B to 10 CFR Part 50 states, "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits." WEC QMS commits to Regulatory Guide 1.28 which endorses American Society of Mechanical Engineers (ASME) NQA-1-2008 with 2009 Addenda. NQA-1 section 303.2, states, in part, that "When measuring and test equipment is lost, damaged, or found to be out-of calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested shall be evaluated." WEC 12.1, "Control of Inspection, Measuring & Test Equipment," Revision 4, states in part, that "IM&TE found to be out of tolerance shall be reported and dispositioned in the organization's specified reporting system (CAPAL) and/or WEC 16.2, "Westinghouse Corrective Actions Process." The Inspection, Measuring and Test Equipment (IM&TE) shall be evaluated within 30 days to determine the impact on the validity of previous uses, and the results of the evaluation shall be documented." Contrary to these requirements, as of October 24, 2014, WFHE&CM did not ensure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality were properly calibrated. Specifically, contrary to WEC 16.2, Revision 7.0, WFHE&CM failed to take corrective actions for 9 devices identified as out of calibration or broken during the last 2 years. These devices included a magnetic particle testing (MT) yoke, a thermometer, a surface probe, a gauss meter, inside diameter (ID) micrometers, a dynamometer, a torque tester and a crimper. Further, contrary to WEC QMS, Revision 7.0, WFHE&CM did not perform evaluations for the acceptability of previous measurement, inspection or test results.

Response:

The actions for this Nonconformance are tracked under Westinghouse CAPAL 100054629.

(1) The reason for the noncompliance:

As part of the evaluation to determine cause, an Apparent Cause Analysis (ACA) was performed. It was identified that the two following areas of weakness existed.

- There was a lack of knowledge and insufficient training of IM&TE controls as required by WEC 12.1 Rev 4.0, including the impact of out of tolerance IM&TE on past product.
- WEC 12.1 Rev 4.0 clearly states that a CAPAL is required for out of tolerance conditions; however it does not provide guidance on who is responsible for this action. A potential contributing cause is the absence of a site specific procedure or guideline.

(2) Corrective Action steps that have been taken and results of investigation:

CAPAL 100054629 identified the nine pieces of Measuring and Test Equipment (IM&TE) that were found during the inspection to have been out of tolerance at some point during manufacturing while being stored and used at the NuCrane Manufacturing facility. The IM&TE identified in the CAPAL were all either adjusted to bring them into calibration or taken out of service at the time the out of tolerance condition was identified, but there was no reporting of this condition per our procedure, WEC 12.1 Rev 4.0, "Control of Inspection, Measuring and Test Equipment". Since the out of tolerance conditions were not reported immediately, an extent of condition to determine if the quality of any components accepted by the IM&TE were affected was not initiated.

An extent of condition has been performed on each of the identified pieces of IM&TE that were found out of calibration to determine if these pieces were used to accept any components that are now invalid or indeterminate. Based on FHE&CM's 10 CFR Part 21 extent of condition evaluation, it has been concluded there was no deviation in a delivered basic component. The full extent of condition determined that the out of tolerance condition identified in the nine pieces of M&TE did not affect the quality of any components or assemblies.

Since October 27th, 2014 four go-no-go thread gauges and one Dillon load cell were discovered out of calibration and needed replacement or repair. This was identified as part of FHE&CM's routine quality practices and not as a result of the extent of condition investigation. These pieces of IM&TE are listed below along with the associated CAPAL numbers that were entered. The extent of condition is currently underway for these items.

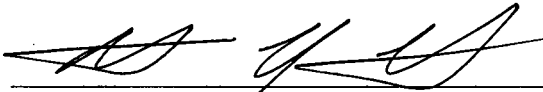
1. Dillion Load Cell, ID# 30006941 CAPAL# 100055686
2. Thread plug gauge, ID# 30002229 CAPAL# 100060784
3. Thread plug gauge, ID# 30002214 CAPAL# 100060786
4. Thread plug gauge, ID# 30002212 CAPAL# 100060806
5. Thread plug gauge, ID# 30002216 CAPAL# 100060808

(3) Corrective steps that will be taken to avoid further violations:

A new site specific Level 3 procedure is currently being generated to provide additional guidance of how FHE&CM will meet WEC 12.1 requirements. This procedure will provide additional clarity of who is responsible for submitting the CAPALs for any pieces of IM&TE found out of tolerance and the timeline to perform the extent of condition. Once this procedure is released the entire team at NuCrane will be re-trained on this procedure as well as WEC 12.1 including a review of action steps required to properly sign in and sign out IM&TE equipment as well as what to do when items are found to be beyond calibration date or in the case of the torque tester, when disagreement exists between tester and torque wrench being tested prior to and after use.

(4) Date when the corrective action will be completed.

Full compliance will be achieved utilizing the actions and commitments outlined above by March 27th, 2015.



22 JAN 2015

Date

Matthew M. Rohr,
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