C&D TECHNOLOGIES, INC.
Power Solutions

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February 19, 2016

Nuclear Regulatory Commission
Reply to a Notice of Non-Conformance

Attn: Michael Cheok
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Dear Mr. Cheok:

C&D is responding to the Notice of Non-conformance 99901385/2015-201-01 and 99901385/2015-201-02. These issues have been entered into our Condition Reporting system as CR-16-22 and CR 16-21. I have attached the details of these corrective actions in the accompanying documents, which include the contributing causes, containment actions taken, and corrective actions that have been or will be taken, along with anticipated completion dates.

A copy of this correspondence has been sent by overnight mail to the NRC Document Control Desk. Please contact me with any questions or comments.

Best Regards,

Robert Malley
VP Quality and Process Engineering
C&D Technologies, Inc.

cc: A. Lauzon – CEO
D. Anderson – VP General Counsel
S. DiMauro – Quality Systems Manager

IE09
NRD

C&D TECHNOLOGIES, INC.
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Nonconformance 99901385/2015-201-01
Corrective Action Response

C&D Reference CR-16-22

Third Party Description

USNRC Reference NON 99901385/2015-201-01

Summary Description

C&D failed to take measures to assure the prompt identification and correction of conditions adverse to quality and to take measures to preclude repetition of significant conditions adverse to quality.

Condition Description

A. Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance 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 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. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

   C&D procedure BB-QOP 8.5.2, "Corrective Action Request (CAR)," Revisions 4 thru 6, dated February 26, 2014 to December 17, 2014:

   - Step 6.1.3 states, "If the issue is significant (Level A), determination actions required to address the root causes of the condition and actions to prevent recurrence."
   - Step 8.3 states that the corrective action will be closed after verification shows the actions are effective.
   - Step 8.4 states a responsible individual will verify that all actions have been completed, implemented, and are effective in elimination the recurrence of this condition.

Contrary to the above, C&D failed to take measures to assure the prompt identification and correction of conditions adverse to quality and to take measures to preclude repetition of significant conditions adverse to quality as demonstrated through the following three examples.

1) In corrective action report (CAR) 14-55, dated April 23, 2014, C&D identified a significant condition adverse to quality, but failed to take corrective action to preclude repetition. Specifically, C&D closed CAR 14-55 without correcting the failure to initiate their Part 21 procedure to evaluate deviations and without addressing the root cause to preclude repetition. As a result, C&D repeated the same failure to initiate their Part 21 process to evaluate the deviations identified in the CAR 14-55.

2) In CAR 15-37, dated April 23, 2014, C&D documented multiple examples identified in the 2014 NRC inspection where they failed to enter issues into their nonconformance process. C&D performed an extent of condition and identified additional improperly documented nonconformances; however, failed to correct the condition adverse to quality and enter any of the identified issues into their nonconformance process.

3) In CAR 14-16, dated April 23, 2014, C&D stated that "A procedure will be developed to ensure that as applicable IEEE standards are revised, the qualification is reviewed and the cross-reference document updated to reflect that review" to address an issue identified during the 2014 NRC inspection. However, C&D failed to correct the condition adverse to quality and did not develop a procedure to update and maintain the cross-reference document as stated in the CAR.

These issues are identified as Nonconformance 99901385/2015-201-01.

Significance Level: A

Containment Actions Taken:

1) An improved method to ensure the timely evaluation of Part 21 issues is being used and no repeat issues have been identified to date.
2) CR 15-63 was initiated and several actions put in place to ensure the comprehensive approval and control of the NCR process. These actions include the institution of a Material Review Board to regularly review NCRs and ensure acceptable closure.

Determination of Cause:

1) It was assumed that the 'Determination of Cause' for CR 14-55 was sufficient to address issues and formal root cause analysis was not utilized. The issues cited in 14-55 are handled through a separate corrective action system associated with customer complaints (iSight) that has an equivalent corrective action process of containment, root cause analysis and corrective action. All customer related (including nuclear customer related) non-conformances and corrective actions are handled on this system. An extent of condition for all flooded battery complaints (non-conformances) since 2009 and classification as to whether a significant condition adverse to quality with regard to 1E products had been performed. This was not made clear during the re-inspection process.

2) The review of previous nonconformance focused on assurance that none posed a significant safety hazard. CR 14-37 imposed this review but did not require re-entry of these dispositioned items into the Attica NCM logs. The action of reviewing the non-conformances for significant conditions adverse to quality had been performed as per the CR, however, the additional action of entry into the logs was not performed as no further actions could have been taken after the dispositioning of the material.
3) As described in the NRC Report, CR 14-16 states that "A procedure will be developed to ensure that as the applicable IEEE standards are revised, the qualification is reviewed and the cross-reference document updated to reflect that review." In fact a cross-reference document was created but never formalized to ensure revision control and appropriate review/approval going forward. C&D thought that the creation of this document was sufficient to address the NRC's concerns.

Actions

1) The process of entering information from customers using flooded batteries (including nuclear product) has been redesigned to assure prompt entry into the iSight CAR system and classification into deviations and potential defects (SCAQ). The initial classification is now performed by Quality Assurance, with further routing of the iSight case as appropriate. The processes surrounding the execution of the A-14 (defect analysis) process have also been redesigned, with bi-weekly meetings that include executive management, logs of actions and schedules for reporting issues to the NRC or customers as appropriate. Actions completed December 2015, objective evidence of execution available on request.

2) CR 15-63 was entered to redesign the non-conforming materials system in the Attica facility. Actions are completed and are in the process of being evaluated. Actions include:
    a. Redesign of NCM logs into electronic databases.
    b. Formal MRB review of all non-conformances with link into A-14 process
    c. Layered audit of NCM conditions and log entries.

    Further evaluation and integration of the NCM system into daily management via SEQDEC™ boards is in process, and may be the subject of a future improvement action. Records of current activities are as available on request.

3) New qualification reports are being documented to reconstitute the design basis of the battery systems by linking specification requirements to specific test results required by IEEE specifications. These reports show compliance to each IEEE requirement via test results and engineering analysis as permitted by the specifications. On completion of the qualification reports a procedure will be documented and approved to have the reports updated as necessary with new issues of IEEE documents. Completion of all qualification reports expected by June 1, 2016, examples are available on request.

C&D TECHNOLOGIES, INC.
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Nonconformance 99901385/2015-201-02
Corrective Action Response

C&D Reference CR-16-21

Third Party Description

USNRC Reference NON 99901385/2015-201-02

Summary Description

C&D failed to take measures to assure the prompt identification and correction of conditions adverse to quality and to take measures to preclude repetition of significant conditions adverse to quality.

Condition Description

Criterion I, "Organization," of Appendix B to 10 CFR Part 50 states, in part, that, the quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed; and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. These persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

Contrary to the above, from September 15, 2009, to September 25, 2015, C&D failed to ensure that portions of the QA program were effectively executed, and verify that activities affecting safety-related functions have been correctly performed. Specifically, C&D failed to take timely and effective corrective actions to address a significant condition adverse to quality. This included appropriately evaluating deviations in order to identify if reportable defects exists. Additionally, C&D failed to verify that conditions adverse to quality identified during the 2009 and 2014 NRC inspections were being identified and corrected in accordance with C&D procedural requirements and NRC regulatory requirements. In addition, C&D failed to ensure persons performing quality assurance functions have sufficient authority and organizational freedom. Specifically, C&D's quality staff reports to operations, which does not provide sufficient authority and organizational freedom to identify quality problems. These examples occurred between September 2009 and September 2015, which indicates C&D did not effectively implement portions of their QA program during this time period.

These issues are identified as Nonconformance 99901385/2015-201-02.

Significance Level: A

Containment Actions Taken:

1) The management of C&D has been restructured and a new reporting relationship for the VP, Quality and Process Engineering to the CEO has been established.
2) Monthly corrective action meetings are being conducted with Plant Managers and the executive team to ensure timely correction of identified issues.
3) More robust Safety Committee meetings are being conducted with particular attention paid to due dates. In addition, the process for initial reporting of customer identified issues has been established so that the Quality Systems manager conducts the first review of the issue as soon as correspondence begins with a nuclear customer. The issue is evaluated for applicability early on in the process and forwarded for Safety Committee review in a timely manner.

Determination of Cause:

1) The A-14 process called for safety committee meetings on an ad-hoc basis dependent on input from the customer complaint, NCR and other sources of information. Delays in organizing and executing meetings resulted in delays in dispositioning cases.

2) Previous management structure did not facilitate visibility on A-14 safety reviews to the entire executive management team except where Part 21 reports were issued.

3) The A-14 and CAR processes were not effectively audited to detect problems with timeliness of responses.

Actions

1) Re-design and re-organize the safety committee process. Institute bi-weekly meetings with standardized formats and timetables for reaching conclusions on outstanding issues. Report results to executive management, including due dates for filing reports with the NRC. Include results in regular management review sessions, and internal/external audits. This has been completed.
2) Restructure the management team to include direct reporting of the quality function to the CEO. This has been completed.
3) Institute a third party A-14 and Appendix B audit program, using experienced and qualified personnel reporting directly to the CEO and General Counsel. Execute audits semi-annually. Inputs to the audits will include all customer communications, customer complaint information, A-14 and safety committee records. First audit is expected to occur by the end of March 2016.