October 29, 2009

Jeffrey A. Graves, President
C&D Technologies, Inc.
1400 Union Meeting Road
Blue Bell, PA 19422

SUBJECT: NRC INSPECTION REPORT NO. 99901385/2009-201, NOTICE OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Graves:

From September 15 to September 18, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the C&D Technologies, Inc (C&D) facility in Blue Bell, Pennsylvania. The enclosed report presents the results of this inspection.

This was a limited scope inspection, which focused on assessing your compliance with the provisions of Part 21 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 21) "Reporting of Defects and Noncompliance," and selected portions of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because NRC inspectors identified that C&D failed to meet the requirements set forth in 10 CFR Part 21 for: 1) inadequate procedure to evaluate deviations and failures to comply and, 2) failure to perform 10 CFR Part 21 evaluations within 60 days of discovery of a deviation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

During this inspection, NRC inspectors also found that implementation of your QA program failed to meet certain NRC requirements contractually imposed on you by your customers. The NRC inspectors noted four deficiencies for: 1) failure to identify root causes for QA problems to prevent recurrence; 2) lack of documentation and technical justification for a design engineering change; 3) failure to follow a dedication procedure and an inadequate procedure for the Customer Complaint process; and 4) failure to adequately categorize audit observations and failure to perform a survey instead of an audit. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,

Patrick Hiland, Director ***/RA/***
Division of Engineering
Office of Nuclear Reactor Regulation

Docket No.: 99901385

Enclosures:
1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901385/2009-201
4. Attachment

Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

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Sincerely,

Patrick Hiland, Director ***/RA/***
Division of Engineering
Office of Nuclear Reactor Regulation

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NOTICE OF VIOLATION

C&D Technologies, Inc.
1400 Union Meeting Road
Blue Bell, PA 19422

Docket Number 99901385
Inspection Report No. 99901385/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted September 15 to September 18, of activities performed at C&D Technologies, Inc. (C&D), two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR Part 21, Section 21.21(a)(1), "Notification of failure to comply or existence of a defect and its evaluation," states in part that, "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations 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 discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected."

   Contrary to the above, as of September 18, 2009:

   C&D 10 CFR Part 21 implementing procedure, A-14-8, "Evaluation, Notification & Responsibility in Accordance with USNRC 10CFR 21 Regulations," Revision 8, dated October 21, 2008, was not an appropriate procedure to ensure effective identification and timely evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, C&D procedure A-14-8:

   1. Did not contain guidance on how to evaluate deviations in accordance with Part 21 requirements.

   2. Did not establish an adequate process in that it allowed C&D an extra period of time to perform a Part 21 evaluation.

   This issue has been identified as Violation 99901385/2009-201-01.

This is a Severity Level IV violation (Supplement VII).

B. 10 CFR Part 21, Section 21.21(a)(1), "Notification of failure to comply or existence of a defect and its evaluation," states in part that, "each individual, corporation, partnership, or other entity subject to 10 CFR Part 21 shall adopt appropriate procedures to evaluate deviations 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 discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected."

   C&D Standard Policy and Procedure A-14-8, "Evaluation, Notification & Responsibility in Accordance with USNRC 10CFR 21 Regulations," Revision 8, dated October 21, 2008,

states in part that, “All C&D management personnel and C&D representative/agent shall advise the C&D Product Safety Committee of any deviation or failure to comply with the requirements of C&D products supplied as Class 1E reported to them or of their knowledge.”

Contrary to the above, as of September 18, 2009:

1. C&D management and personnel failed to perform a Part 21 evaluation within 60 days of discovery of a deviation.

2. The Nuclear Product Manager did not inform the Product Safety Committee of a deviation that was identified by him. As a result no Part 21 evaluation had been performed.

This issue has been identified as Violation 99901385/2009-201-02.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," you are required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, with a copy to the Director, Division of Engineering, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency-wide Documents Access and Management System (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection, described in 10 CFR 73.21.

Dated this 29th day of October 2009

NOTICE OF NONCONFORMANCE

C&D Technologies, Inc.
1400 Union Meeting Road
Blue Bell, PA 19422

Docket Number 99901385
Inspection Report No. 99901385/2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted September 15 to September 18, of activities performed at C&D Technologies, Inc (C&D), certain activities were not conducted in accordance with NRC requirements, which were contractually imposed upon C&D by NRC licensees.

A. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50, 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."

C&D's Quality Manual, Issue V, dated September 2007, Paragraph 8.5.2(a), states in part that, "Corrective action is directed at revising the facility quality management system, policies, procedures, and work instruction in order to identify and eliminate the root cause(s) of quality problems and non-conformities and prevent their recurrence."

C&D Quality Operating Procedure BB-QOP 8.5.2, Revision 2, dated June 4, 2009, "Corrective Action," Paragraph 3, "Responsibility," states in part that, "The Quality Assurance department is responsible to ensure that the corrective action requirements of… 10CFR50 Appendix B requirements and 10CFR21 are established and followed as stated in subsequent Quality Operating Procedures."

Contrary to the above, as of September 18, 2009:

C&D failed to identify the root causes for quality problems and prevent their recurrence. Specifically:

1. The corrective action for Form RS-1037, "Corrective/Preventive Action," #07-027, documented a NUPIC finding for failure to audit several vendors. Two vendors were subsequently audited as a result to this finding. However, they were not placed on C&D's "Critical Nuclear Commercial Grade Suppliers [Approved Suppliers List] ASL."

2. The corrective action for Form-1037, #06-060, documented an audit finding by Stone & Webster with Attica's completed commercial-grade dedication packages to be sent to Blue Bell for proper storage. However, the procedure implementing this policy had not yet been applied.

This issue has been identified as Nonconformance 99901380/2009-201-03.

B. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, states in part that, "Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related

functions of the structures, systems and components. ”C&D’s Quality Manual, Issue V, dated September 1, 2008, Section QM 7.3, paragraph 7.3.7.C-1, “Change Management Process,” states in part that, “C&D Technologies, Inc. may have to make design changes to new or existing products as part of continual improvement. Design changes, which may be required during the product life cycle, are documented and managed to ensure that they do not adversely affect the quality, reliability or design intent of the product. The procedures related to design changes are maintained.”

C&D’s Engineering Change Control Procedure No. BB-WOP 7.3.7a, Revision NEW, dated October 21, 2005, states in part that, “Engineers shall evaluate the requested changes for their impact on constituent parts and products already produced. The pending changes shall be reviewed, verified/validated via testing or analysis documented and approved prior to full implementation. Design review, as necessary, shall be documented and maintained with documented records.”

Contrary to the above, as of September 18, 2009:

Quality Operation Procedure No. BB-WI-7.4.3-1, “Nuclear Dedication Requirements,” dated September 3, 2009, and it predecessor IP 396.5, “Nuclear Dedication Requirements,” dated January 1998, both contained Table 1 that defined the critical characteristics and dedication requirements for battery components. The battery cell cover’s safety function, defined in Procedure No. BB-WI-7.4.3-1, was down-graded from the requirements defined in IP 396.5. C&D failed to document justification for the engineering change of down-grading the battery cover’s safety-related function.

This issue has been identified as Nonconformance 99901385/2009-201-04.

C. Criterion V, “Instructions, Procedures, and Drawings” of Appendix B to 10 CFR Part 50, states, “Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. The instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.”

C&D Quality Manual, Issue V, dated September 1, 2008, Section 5.0 titled, “Instructions, Procedures and Drawings,” paragraph 5.4.2, “Quality Management System Planning,” states in part that, “quality system planning is executed to meet the requirements of 10 CFR 50 Appendix B.”

C&D Quality Procedure No. IP 396.5, “Nuclear Dedication Requirements”, dated January 1998, states in part that, “safety-related battery cells shall be manufactured in accordance with generic quality plan traveler QP-XXX.0 (RS1034). Sample plans for individual components shall be per relevant receiving inspection procedure. The safety-related components shall be inspected for critical characteristics as identified in Table 1.” Table 1 identified the container jar critical characteristics as material and part number. The dedication requirements in Table 1 required certification (certificate of conformance), mold quality, dimensions, and material test.

C&D Quality Work Instruction No. BB-WI-8.2.1-2, "Customer Complaints", dated August 12, 2009, states in part that, "The following issues have been identified as REQUIRED to generate a customer complaint and correct action. Customer Service will continue their established process to resolve the customer issues, but it is now a requirement that we identify the issues and request corrective action. The following issues require a customer complaint log: Non-communication of items back-ordered; Shipping/delivery issues (shipped to wrong location & freight damages); Missing parts/hardware; RMA's for wrong product shipped; Ship dates missed by plant; Orders not re-scheduled that missed original ship date, therefore customers not notified of reschedule dates; Pricing errors/invoice errors; Customer drawing request not received when expected; and Part numbers in COM that prevent order (too long to generate LPFA's)."

Contrary to the above, as of September 18, 2009:

1. C&D failed to follow the dedication procedure for the container jar. Specifically, Entergy Dedication Package P.O. No. 10070193, dated November 24, 2004 contained the generic quality plan traveler QP-033.0, but lacked a certificate of conformance for the container jar.

2. C&D failed to establish an adequate procedure for all issues related to nuclear related products. Specifically, Work Instruction No. BB-WI-8.2.1-2 did not address operating experience problems that could affect the quality or performance of the nuclear related products.

This issue has been identified as Nonconformance 99901385/2009-201-05.

D. Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, states in part that "a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check list by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, shall be taken where indicated."

C&D's Quality Manual, Issue V dated September 2007, paragraph 8.4c), states in part that, "Data is collected and analyzed to provide information related to: Supplier performance, including capability, on-time delivery, conformance to specified requirements."

C&D's Quality Operating Procedure (QOP) BB-QOP-7.4.3b, Supplier Audits/Commercial Grade Surveys," Paragraph 2.0, "Scope," states in part that, "For Nuclear 1E applications *audits* are performed on 1E suppliers with 10CFR50 Appendix B programs; while *commercial grade surveys* are performed on commercial grade suppliers whose parts or services C&D must dedicate for class 1E applications."

Paragraph 5.4, "Audit Results," states in part that, "Audit findings shall be classified in three levels, with Level 1 being the most critical:

Level 1: Nonconformances shall be a violation of a requirement (regulatory and/or C&D) of the QMS and shall be documented with a corrective action request per BB-QOP 8.5.2.

Level 2: Product-Related Observations are suggestion for areas of improvement that affect the form, fit or function of product. These observation will be documented within the audit report and require 60-day response from the auditee.

Level 3: Programmatic/Administrative-Related Observations are suggestions for areas of improvement that do not affect the form, fit or function of product. These observations will be documented within the audit report, but don not require a corrective action or a response form the auditee. Follow-up of level 3 observances are performed at the next audit."

Contrary to the above, as of September 18, 2008:

1. C&D failed to perform a survey instead of an audit for Daramic, a commercial-grade supplier.

2. C&D failed to issue a nonconformance to Daramic for failure to properly implement the regulatory requirement of segregating nonconforming material. C&D documented the issue as an observation that did not require a response from the vendor.

This issue has been identified as Nonconformance 99901385/2009-201-06.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Director, Division of Engineering, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid non-compliances; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or Safeguards Information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial

information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated this 29th day of October 2009

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF ENGINEERING
VENDOR INSPECTION REPORT

Docket No.:	99901385
Report No.:	99901385/2009-201
Vendor:	C&D Technologies, Inc. 1400 Union Meeting Road Blue Bell, PA 19422
Vendor Contact:	Stan Flores Quality Assurance Manager Phone: (215) 285-2136 Sflores@cdtechno.com
Nuclear Industry:	C&D Technologies, Inc. produces and markets systems for the power conversion and storage of electrical power including industrial batteries and electronics.
Inspection Dates:	September 15 - September 18, 2009
Inspection Team Leader:	Carla Roquecruz, DE/NRR
Inspectors:	Aaron Armstrong, DE/NRR Jonathan Ortega-Luciano, DCIP/NRO Matthew McConnell, DE/NRR Paul Prescott, DE/NRR
Approved by:	Dale Thatcher, Chief ***/RA/*** Quality & Vendor Branch Division of Engineering Office of Nuclear Reactor Regulation

ENCLOSURE 3

EXECUTIVE SUMMARY

C&D Technologies, Inc.
99901385/2009-201

The purpose of this inspection was to review selected portions C&D Technologies, Inc. (C&D's) quality assurance (QA) and 10 CFR Part 21 (Part 21) programs. The inspectors focused on C&D's products and services supplied as basic components to NRC-licensed facilities. The inspection was conducted at C&D's facility in Blue Bell, Pennsylvania.

The NRC inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations;* and
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

There were no NRC inspections of C&D's facility in Blue Bell, Pennsylvania in the previous five years. The results of this inspection are summarized below.

10 CFR Part 21 Program

The inspectors identified two violations of Part 21. Violation 99901385/2009-201-01 was cited for an inadequate procedure due to the failure to adequately prescribe the process to perform an evaluation and meet timeliness requirements as specified in Part 21. The first example of Violation 99901385/2009-201-02 was cited due to the failure to perform an evaluation within the time requirements specified in Part 21. The second example of Violation 99901385/2009-201-02 was cited due to failure to perform an evaluation. With the exception of the violations noted above, the inspectors concluded that C&D's Part 21 program was consistent with regulatory requirements.

Corrective Action

The inspectors identified two Nonconformances of Appendix B to10 CFR Part 50. Nonconformance 99901385/2009-201-03 was cited for failure to identify the root causes for quality problems and prevent their recurrence. The first example of Nonconformance 99901385/209-201-05 was cited for an inadequate procedure for the corrective action process of Customer Complaints. With the exception of the above nonconformances, the inspectors determined that C&D's corrective action program and implementation met the requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

Commercial-Grade Dedication

The inspectors identified two Nonconformances of Appendix B to 10 CFR Part 50. Nonconformance 99901385/209-201-04 was cited for failure to justify an engineering change in a dedication package when a component's safety-related function was down-graded. The second example of Nonconformance 99901385/209-201-05 was cited for failure to follow the procedure during the dedication of a container jar. With the exception of the above mentioned

nonconformances, the inspectors determined that C&D's commercial-grade dedication process and implementation was in compliance with regulatory requirements and industry guidance.

Audits

The inspectors identified one Nonconformance of Appendix B to 10 CFR Part 50. Nonconformance 99901385/2009-201-06 was cited for failure to adequately categorize audit observations as findings, which resulted in C&D taking no action to properly document and disposition the items, and failure to perform a survey instead of an audit. With the exception of the Nonconformance noted above, the inspectors concluded that C&D's audit program requirements and implementation were consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The inspectors reviewed C&D Technologies', Inc. (C&D's) Power Solutions Quality Manual, Issue V, dated September 1, 2007, and procedures that govern the 10 CFR Part 21 (Part 21) program to determine compliance with the regulation. Specifically, the inspectors focused on Standard Policy and Procedure A-14-8, "Evaluation, Notification & Responsibility in Accordance with USNRC 10CFR 21 Regulations," Revision 8, dated October 21, 2008, Quality Operating Procedure BB-QOP 8.5-2, "Corrective Action," Revision 2, dated June 4, 2009, Quality Work Instruction BB-WI-8.2.1-2, "Customer Complaints," Revision 4, dated October 12, 2008, and Quality Work Instruction, "Nonconformance of Tested Material," Revision 0, dated September 11, 2009.

The inspectors discussed the Part 21 process with members of C&D's management to evaluate the vendor's Part 21 program and reviewed a sample of completed Part 21 evaluations.

b. Observations and Findings

The inspectors verified that C&D's procedure A-14-8 met the requirements of Part 21. The inspectors noted that procedure A-14-8 outlined the process used by C&D for the reporting of defects and noncompliance, as well as the responsibilities of employees, managers, and the Quality Assurance (QA) Manager with respect to Part 21. The inspectors noted that the section entitled, "Definitions," specifically section 2.6 of procedure A-14-8, stated that: "Time Line - For the purpose of this procedure and timing of reports to the Officers of the Company, Directors, Licensee, and NRC, all timing shall start from the time the deviation or failure to comply is reported to the Product Safety Committee for evaluation. The Chairman of the Product Safety Committee, or designee, shall log the time and date of the report on the RS-776 report form." The "Time-Line" term, as defined in procedure A-14-8, permitted an extra period of time to identify a deviation that exceeds the time frame allowed by Part 21 to then perform an evaluation. In discussions with the Director of Quality and the QA Manager it was noted that the vendor incorrectly defined "discovery" as the completion of the RS-776 report by the Product Safety Committee and not when the issue was first documented identifying the existence of a deviation or failure to comply. This issue was identified as one example of Violation 99901385/2009-201-01.

The inspectors also identified that procedure A-14-8 does not prescribe the process to perform an evaluation of a deviation or failure to comply to identify if the deviation or failure to comply is associated with a substantial safety hazard as required by Part 21. Procedure A-14-8 defines the responsibilities of the Product Safety Committee and the timeliness requirements from Part 21, but does not prescribe how to perform a Part 21 evaluation. Procedure A-14-8, Section 3: "Responsibility," describes the functions of Product Safety Committee and its members. The Product Safety Committee is

composed of the Vice President of Engineering (Chairman), Vice President of Operations, Director of Quality, and the Director of Product Development.

Section 4.2 of A-14-8 states in part that: "The Product Safety Committee will ensure that the deviations and failure to comply associated with substantial safety hazards are evaluated as soon as practical…" The Part 21 evaluations performed by the Product Safety Committee are documented in "10CFR21 Nonconformance Report," (RS-776). The inspectors reviewed this form and noted that there was no guidance to perform the Part 21 evaluation. The inspectors later confirmed, in a discussion with the Director of Quality, that the process utilized by the Product Safety Committee to perform Part 21 evaluations is not defined nor documented in C&D's current procedures. This was another example of Violation 99901385/2009-201-01.

During a review of a sample of Part 21 evaluations performed by the Product Safety Committee, the inspectors noted that C&D failed to perform a Part 21 evaluation for an incident that involved three Class 1E batteries. C&D sent a letter to Waterford 3 dated June 29, 2009. The letter contained an Inspection Report (C&D Reference Number: 09-78820) where C&D provided inspection findings and comments on three batteries that Waterford 3 sent to C&D due to low voltage. The battery inspection report explained in detail what was found during the teardown of the three cells. In the summary section of this report, the inspectors noted that one of the comments/observations listed by the vendor was that one of the cells had failed due to a manufacturing defect.

This letter from the vendor to the licensee constituted the completed documentation first identifying a deviation. Section 3.1 of A-14-8 states in part that: "All C&D management and personnel and C&D representatives/agents shall advise the C&D Product Safety Committee of any deviation or failure to comply with requirements in C&D products supplied as Class 1E reported to them or of their knowledge." During a discussion with the Director of Quality, the inspectors found that management, including some of the members of the Product Safety Committee, were aware of the deviation, but were waiting on the conclusion of laboratory tests in order to have more details to then initiate the evaluation. As of September 18, 2009, the Product Safety Committee had not generated an RS-776 to initiate a Part 21 evaluation. C&D failed to evaluate this deviation to identify if there is a defect that could be associated with a substantial safety hazard as soon as practicable and within the 60 days from the discovery date, that in this case, was June 29, 2009. This issue was identified as one example of Violation 99901385/2009-201-02.

During the review of the implementation of C&D's Part 21 program, the inspectors found a letter from the vendor that was sent to Waterford 3 on March 31, 2009. The letter was generated in response to a document from Waterford 3 questioning if C&D would perform a Part 21 evaluation based on the results of a May 2008, Battery B performance test. The letter from C&D explained that they had reviewed the results of the performance test and provided recommendations that would improve the capacity and performance of the battery. This issue associated with the performance of Waterford's B Battery was handled by C&D's Nuclear Product Manager. The Nuclear Product Manager concluded that this particular issue with the Waterford Class 1E battery is typically limited in scope and impacted just the cells made in that one manufacturing lot

(usually one battery string). He also concluded that this type of issue need not be evaluated under the C&D Part 21 program since the problem would not impact batteries made for other nuclear plants.

The inspectors noted that the Nuclear Product Manager did not have a clear understanding of the requirements in Part 21 and C&D's Part 21 program. Additionally, the Nuclear Product Manager assumed the role of the Product Safety Committee by making the determination that this issue involving the performance of a Class 1E battery was not reportable under Part 21. The Nuclear Product Manager failed to generate a RS-776 form to request the Product Safety Committee to perform a Part 21 evaluation for this issue with the Waterford 3 Class 1E battery and as a result no evaluation was performed. This issue was identified as another example of violation 99901385/2009-201-02.

c. Conclusions

The inspectors identified two violations of Part 21. Violation 99901385/2009-201-01 was cited for one example of an inadequate procedure due to the failure to prescribe the process to perform an evaluation as specified in Part 21 and a second example of providing additional time to perform an evaluation by incorrectly defining the point of discovery for a deviation. One example of Violation 99901385/2009-201-02 was cited due to the failure to perform an evaluation within the time requirements specified in Part 21. The second example of Violation 99901385/2009-201-02 was cited for the failure to perform a Part 21 evalution. With the exception of the violations noted above, the inspectors concluded that C&D Part 21 program was consistent with regulatory requirements.

2. Corrective Action

a. Inspection Scope

The inspectors reviewed the QA procedures that govern the implementation of C&D's corrective action program to ensure the procedures provided adequate guidance consistent with the requirements of Appendix B to 10 CFR Part 50 and Part 21. The inspectors also reviewed a sample of Corrective/Preventive Action Reports (CARs) to assess C&D's implementation of its corrective action program. Additionally, the inspectors reviewed C&D's customer complaint process and implementing procedures. The inspectors evaluated the effectiveness of the vendor's corrective action program, including nonconformances, deficiencies, process control anomalies reporting, tracking, and resolution. The inspectors also evaluated the vendor's engineering support for products supplied to nuclear power plant licensees. Additionally, the inspectors reviewed documentation related to the vendor's actions associated with Waterford 3 Nuclear Power Plant's (Waterford 3) recent battery failure.

The inspectors reviewed C&D's Quality Manual, Issue V, dated September 1, 2007, Corrective Action Quality Operating Procedure BB-QOP-8.5.2, Revision 2, dated June 4, 2009 and Customer Complaint Quality Work Instruction BB-WI-8.2.1-2 to determine the effectiveness of the vendor's corrective action program.

b. Observations and Findings

The inspectors noted that the vendor's Corrective Action and Customer Complaint processes are maintained as two separate corrective action activities. The inspectors noted that the Customer Complaint process was to be implemented for complaints and issues associated with the vendor's nuclear grade (i.e., Class 1E) products. Upon reviewing the vendor's Customer Complaint Work Instruction, the inspectors identified that the work instruction had a limited specific list of issues that were required to be reported as items that need corrective action.

The inspectors had reviewed a sample of known operating experience issues associated with C&D's nuclear grade products to assess the vendor's engineering support for these products. The inspectors requested the customer complaints associated with these operating experience issues, but the vendor was not able to produce any Customer Complaint Reports related to the requested sample. The Customer Complaint Work Instruction was an inadequate procedure in that it did not address reporting of all potential problems that could affect the quality or performance of the vendor's nuclear grade products. This issue was identified as an example of nonconformance 99901385/2009-201-05.

The inspectors reviewed documentation related to C&D's actions associated with a recent battery failure at Waterford 3. In May 2008, Waterford 3 performed a performance discharge test on the 125-volt direct current Battery 3B-S in accordance with its Technical Specification Surveillance Requirement 4.8.2.1.e. The results of this test showed that the capacity of Battery 3B-S decreased from 100.83% (from the previous performance test in November 2003) to approximately 86%. Based on a drop of more than 10% in capacity from its average on previous performance tests and that the capacity dropped to below 90% of the manufacturer's rating, Waterford 3 initiated discussions with the vendor to troubleshoot the unexpected drop in capacity. In discussions with the vendor, the inspectors noted that Waterford 3 performed an additional battery performance discharge test to validate the previous test. The results of this test showed a battery capacity of approximately 72%. Based on this result, Waterford 3 decided to replace and dispose of the failed battery and concluded that the battery failed based on a manufacturing defect (impurities added to battery during manufacturing process).

The inspectors noted that the vendor disagreed with Waterford 3's assessment that the battery failed due to a manufacturing defect. C&D was not able to perform a failure modes and effects analysis to identify the root cause of the failure, since the battery was disposed of by Waterford 3. Based on the existing information and interviews with C&D's employees, the inspectors concluded that the vendor adequately managed this issue.

The inspectors reviewed a sample of Forms RS-1037, "Corrective/Preventive Action." Form RS-1037, #07-027, documented a Nuclear Procurement Issues Committee finding for failure to audit several vendors. The inspectors identified that two of the vendors, Iron Mountain and Koenig had been audited as part of the corrective actions for this finding. However, the vendors were not placed on C&D's "Critical Nuclear Commercial

Grade Suppliers [Approved Suppliers List] ASL." Iron Mountain is a vendor that stores and maintains records. Koenig provides testing and calibration services. This issue was identified as one example of Nonconformance 99901385/2009-03.

The inspectors reviewed Form RS-1037, #06-060, which documented a problem identified during an audit by Stone & Webster with C&D's record storage practices. In order to meet NQA-1 requirements for record storage, the records may either be stored in rated fireproof cabinets or stored in multiple locations. Per AQOP-7.4.1, "Safety Related Manufacture, Procurement and Dedication," Revision C, all dedication records for safety-related orders are to be maintained in accordance with AQOP-4.2.3, "Control of Documents." In addition, these records will be maintained in boxes designated "nuclear" and stored on shelves labeled "nuclear." A copy of all said records will also be sent to corporate headquarters in Blue Bell. However, the inspectors identified that dedication records were not being forwarded to Blue Bell. This problem was identified in December 2006 and the procedure still had not been implemented. This issue was identified as another example of Nonconformance 99901385/2009-03.

d. Conclusion

The inspectors identified two Nonconformances of Appendix B to10 CFR Part 50. Nonconformance, 99901385/2009-201-03, had two examples of inadequate and untimely corrective actions. One example of Nonconformance, 99901385/2009-201-05, was cited for C&D's inadequate procedure to address customer complaints as part of their corrective action activities. With the exception of the above nonconformances, the inspectors determined that C&D's corrective action program was consistent with regulatory requirements.

3. Commercial-Grade Dedication Process

a. Inspection Scope

The Inspectors reviewed C&D Quality Manual, Issue V, dated September 1, 2008, and the implementation process for commercial-grade dedication activities. Specifically, the inspectors reviewed C&D Quality Operation Procedure (QOP) BB-QOP 7.3.7a, "Engineering Change Control," Revision NEW, dated October 21, 2005, and QOP No. BB-WI-7.4.3-1, "Nuclear Dedication Requirements", dated September 3, 2009, Revision 2, and it predecessor, Inspection Procedure (IP) 396.5, "Nuclear Dedication Requirements," dated January 1995. The inspectors also reviewed the Attica QOP No. (AQOP) 7.4.1, "Safety Related Procurement and Dedication," dated June 19, 2009, from C&D's Attica facility.

The inspectors reviewed the quality and work procedures governing the implementation of commercial-grade dedication activities, and a sample of completed dedication packages.

b. Observations and Findings

QOP BB-QOP 7.3.7a, outlined the management system for directing, controlling, documenting the activities, and approvals needed for engineering change control of products. This procedure applied to all battery related products. The Engineering Change Request (ECR) form provides the means to evaluate equipment, specification, product, and drawing changes. C&D's Engineers evaluate these requested changes for their impact on battery parts and products. The pending changes are reviewed, verified, and validated via test or analysis. The changes are documented and approved before full implementation.

QOP No. BB-WI-7.4.3-1 provided guidance in handling dedication requirements for parts and components of battery assemblies as safety-related equipment and complied with industry guidance for performing commercial-grade dedication. Procedure BB-WI-7.4.3-1 contained Table 1, which identified the critical characteristics and acceptance requirements for battery racks and battery cell components. Table 1 identified the battery cell cover's safety function as "no direct SR [safety-related] function," and had no requirements listed for critical characteristics or dedication requirements.

The inspectors reviewed IP 396.5, the predecessor to corporate procedure BB-WI-7.4.3-1. IP 396.5 contained the same Table 1 as procedure BB-WI-7.4.3-1. The table identified the battery cell cover's safety function as "acid containment" and the critical characteristics were "material and seal integrity." IP 396.5 further identified the dedication requirements of the battery cell cover as "certification (certification of conformance), mold quality, dimensions, and material test."

The inspectors requested the ECR that evaluated the re-classification of the safety function for the battery cell cover in support of the change in procedure BB-WI-7.4.3-1 from IP 396.5. C&D was unable to provide an ECR for the down-grade in the battery cell cover's safety-related classification. This issue was identified as Nonconformance 99901385/2009-201-04.

C&D's dedication activities are performed at their Attica facility. C&D Attica follows the higher-level corporate procedure BB-WI-7.4.3-1 for dedication, but also has supplemental procedures and processes for activities at their facility. The inspectors contacted the Attica facility, and interviewed the Attica quality department. The inspectors received Attica's supplemental procedure No. AQOP 7.4.1. The procedure defined the process for the purchase and dedication of materials used within C&D's Attica facility to ensure that purchased and manufactured products conform to the specified purchase requirements for safety-related items. Procedure AQOP 7.4.1 also contained Table 1 that was identical to IP 396.5.

The Inspectors reviewed Entergy Dedication Package P.O. No. 10070193, dated November 24, 2004. The Inspectors noted that the dedication package contained the generic quality plan traveler QP-033.0. The dedication package lacked a certificate of conformance for the container jar as required by the procedure; however, the Attica facility subsequently produced the certificate of conformance. This issue was identified as another example of Nonconformance 99901385/2009-201-05.

c. Conclusion

The inspectors identified two nonconformances to 10 CFR Part 50, Appendix B. Nonconformance, 99901385/2009-201-04, was cited for C&D failing to document justification for engineering changes in accordance with Procedure BB-QOP 7.3.7a. The second example of Nonconformance, 99901385/2009-201-05, was cited for the dedication package lacking a certificate of conformance for the container jar as required by the dedication procedure. With the exception of the above nonconformances, the inspectors determined that C&D's commercial grade dedication program was consistent with regulatory requirements.

4. Audits

a. Inspection Scope

The inspectors reviewed Section QM 7.4, "Purchasing," of C&D's Quality Manual, Issue V and implementing procedures that govern the process for internal and external audits. The inspectors evaluated a sample of internal and external audit reports and corrective actions implemented by C&D for findings identified during audits.

b. Observations and Findings

1. External Audits

The inspectors noted that Section QM 7.4, "Purchasing," of C&D's Quality Manual (QM) provided a general description of the process and requirements for performing external audits. C&D Quality Operating Procedure (QOP) BB-QOP 7.4 .3b, Revision 4, "Supplier Audits/Commercial Grade Surveys," described the process for conducting periodic audits/commercial-grade surveys of suppliers to evaluate the effectiveness of their quality program and of their ability to supply materials in accordance with specified requirements. Procedure BB-QOP 7.4.1b, "Supplier Evaluation," defined the process for supplier qualification and on-going evaluation of supplier performance.

The inspectors evaluated a sample of external audit/survey and supplier evaluation reports. The following external audit/survey reports were reviewed:

IMR Test Labs of Lansing, NY: Testing/calibration laboratory supplier audit performed July 28, 2009;

Ashtabula Rubber Company of Ashtabula, OH: External supplier audit performed December 4, 2008. The vendor provides custom molded hard and soft rubber mechanical goods;

Daramic LLC. of Piney Flats, TN: External supplier audit performed November 18, 2008. The vendor supplies battery plate separator material;

Laboratory Testing Inc. of Hatfield, PA: Testing/calibration laboratory supplier audit performed July 22, 2009;

Mack Molding Co. of Arlington, VA: Commercial-grade survey performed September 1, 2009, and an external audit September 1, 2009. The vendor provides the battery jars;

Nuclear Logistics Inc. of Fort Worth, TX: Testing/calibration laboratory supplier external audit performed July 29, 2009;

PM Fasteners Inc. of Harleysville, PA: Commercial-grade survey performed August 31, 2009. The vendor supplies hardware for the battery trays and;

Storm Copper Components Co. of Decatur, TN: Commercial-grade survey performed September 3, 2009, and an external audit performed November 19, 2008. The vendor supplies battery posts and cables.

The inspectors noted that in BB-QOP 7.4.3b, it describes that audit findings shall be classified in three levels. Level 1 are nonconformances that are a violation of a requirement (regulatory and/or C&D) of the quality management systems and shall be documented with a corrective action requirement. Level 2 are product related observations and are suggestions for areas of improvement that affect the form, fit or function of product. These observations are to be documented within the audit report and require a 60-day response from the auditee. Level 3 are programmatic/administrative-related observations and are suggestions for areas of improvement that do not affect the form, fit or function of the product. These observations are to be documented within the audit report, but do not require a corrective action or a response form the auditee. Follow-up of Level 3 observations are performed at the next audit. The inspectors noted in the Daramic audit that one observation was that nonconformance material was always tagged and was placed together with "good" material. C&D did not require a response from the vendor. The inspectors determined this to be a failure to properly implement a quality requirement to ensure nonconforming material could be not used in a quality application. This issue was identified as one example of Nonconformance 99901385/2009-201-06.

The inspectors also noted that the Daramic audit was a limited scope audit of a vendor with an ISO 9000 QA program. Daramic manufactures battery separators and membranes. The vendor does not maintain a quality program that meets Appendix B to 10 CFR Part 50. The inspectors determined that a commercial-grade survey of the vendor should have been performed instead of an audit. The inspectors noted that C&D did correct this oversight for the original audits that were performed for Mack Molding and Storm Copper Components. This issue was identified as another example of Nonconformance 99901385/2009-201-06.

The inspectors reviewed two supplier evaluation reports. The evaluation reports were of Richardson Molding Inc. and Daramic LLC. The inspectors did not identify any findings of significance.

2. Internal Audit

The inspectors reviewed Section QM 8.2.2, "Internal Audit," of C&D's Quality Manual and procedure BB-QOP-8.2.2, revision 3. QM 8.2.2 described the purposes for performing internal audits, responsibilities, training requirements for auditors and frequency of audits. BB-QOP-8.2.2 established the process by which a system of planned audits will be carried out by C&D to verify compliance of the Quality Management System and effectiveness of the program.

Additionally, the inspectors reviewed a sample of C&D's latest internal audit reports. The audit reports included the date of the previous and current audit, lead and associate auditors, applicable procedures and the number of any CARs (Form RS-1037) initiated as a result of audit findings. An Audit Finding Report form (RS-1014) which included: audited quality element, participants, program requirements, findings and recommended corrective actions was also attached to each audit report. The table where the results of the audit were documented also identified which criteria of Appendix B were applicable. No findings of significance were noted related to internal audits.

The inspectors evaluated a sample of internal audits reports. The following internal audit reports were reviewed:

Design & Development – Leola Internal Audit performed May 19, 2009;

Contract Review/Order Entry Internal Audit performed June 2, 2009; and Materials Lab & Nuclear Dedication – Leola Internal Audit performed May 19, 2009.

No findings of significance were noted related to internal audits.

c. Conclusion

The inspectors identified one nonconformance to 10 CFR Part 50, Appendix B. The first example of Nonconformance 99901385/2009-201-06 involved failure to adequately categorize audit observations as findings which resulted in C&D taking no action to properly document and disposition the items. Additionally, the inspectors identified a second example of a failure to perform a survey instead of an audit. With the exception of the nonconformance noted above, the inspectors concluded that C&D is implementing an internal and external audit process in compliance with regulatory requirements and industry guidance.

5. Exit Meeting

On September 18, 2009, the inspectors presented the inspection scope and findings during an exit meeting with C&D's Senior Vice President and CFO, Ian J. Harvie, and other C&D personnel.

ATTACHMENT

1. PERSONS CONTACTED

I. Harvie, Senior Vice President, C&D Technologies Inc.
M. Frick, Senior Quality Systems Manager, C&D Technologies Inc.
S. Flores, Director of Quality, C&D Technologies, Inc.
L. Carson, Nuclear Product Manager, C&D Technologies Inc.
J. Jergl, VP Engineering and Product Development, C&D Technologies Inc.

2. INSPECTION PROCEDURES USED

IP 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance"
IP 43001, "Reactive Inspection of Nuclear Vendors"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no NRC inspections of C&D's facility in Blue Bell, Pennsylvania in the previous five years.

Item Number	Status	Type	Description
99901385/2009-201-01	Opened	NOV	Part 21
99901385/2009-201-02	Opened	NOV	Part 21
99901385/2009-201-03	Opened	NON	Criterion XVI
99901385/2009-201-04	Opened	NON	Criterion III
99901385/2009-201-05	Opened	NON	Criterion V
99901385/2009-201-06	Opened	NON	Criterion XVIII

4. LIST OF ACRONYMS USED

AQOP	Attica Quality Operating Procedure
ASL	Approved Suppliers List
CAR	Corrective/Preventive Action Report
C&D	C&D Technologies, Inc.
DC	Direct Current
ECR	Engineering Change Request
IP	Inspection Procedure
NON	Notice of Nonconformance
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
Part 21	10 CFR Part 21
QA	Quality Assurance
QM	Quality Manual
QOP	Quality Operating Procedure