

30 November 2009

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, DC 20555-0001

Subject: Reply to Notices of Violation (2) and Nonconformance (4)

Director,

This letter and its attachments are C&D Technologies Response to the NRC Inspection at C&D's Blue Bell, Pennsylvania location from 15-18 September 2009, and the resultant NRC report of the Inspection, dated 29 October 2009 and received by C&D on 2 November 2009. C&D does not contest the Inspection findings. C&D's root cause determinations and corrective actions both completed and planned – with dates are in the attached C&D RS-1037 corrective action forms. Each of the violation or nonconformance findings has a unique corrective action tracking RS-1037. Part A (Deficiency/Nonconformity) on the form states the NRC's findings verbatim. C&D's Part B (Extent of Nonconformance) and Part C (Root Cause) detail the reasons for the noncompliance. Part D (Corrective action) details the corrective steps that will be taken or have been taken to avoid future non-compliances. For those corrective actions that have been completed, selected verification documentation is also attached.

The table below cross-references the attachments to the NRC violation/nonconformance numbers.

NRC Violation/ Nonconformance ID	C&D RS-1037 Corrective Action ID	Additional Documentation Attached
Violation A	09-49	V10 draft C&D Procedure A-14
Violation B	09-50	Two RS-776 procedure A-14 evaluation summary documents
Nonconformance A	09-54	none
Nonconformance B	09-51	none
Nonconformance C	09-55	none
Nonconformance D	09-53	none

C&D is committed to full compliance in meeting both the letter and the spirit of all contractual and statutory requirements. We believe the corrective actions attached will prevent recurrence of the issues identified by the NRC.

IE09  
NRK

Please call or write if you have any questions or would like additional information. I look forward to your feedback.

Sincerely,



**Matthew K. Frick**  
Senior Quality Systems Manager  
**C&D Technologies, Inc**  
1400 Union Meeting Road  
Blue Bell, PA 19422-0858  
[mfrick@cdtechno.com](mailto:mfrick@cdtechno.com)  
215-619-7849 (w)  
215-285-2136 (c)

Cc: Patrick Hiland (NRC)  
Director, Division of Engineering (NRC)  
Carla Roquecruz (NRC)  
Paul Prescott (NRC)

Files: see table above

Ref: NRC docket # 99901385

## Corrective / Preventive Action

<b>Type of Action:</b>	<b>Source of Action:</b> 15-18 September NRC Inspection at Blue Bell	
Corrective Action	<b>Type of Request:</b> September 2009 NRC Inspection	
Corrective Action # 09- 49	Date Issued: 7 October 2009	Date parts B-D Due: 18 November 2009 (rev.)
	Updated from NRC formal report: 11/4/09	
To: Matt Frick, Stan Flores	From: Matt Frick	
(filename = RS-1037 09-49 NRC VA.doc)		

A) **Deficiency/Non Conformity:** Describe in detail the nature of the problem, list the facts, and indicate any applicable documents.  
Note: include checksheet question #s - for standard references refer to the internal audit checksheet.

NOTICE OF VIOLATION A – from NRC Inspection report:  
 "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) **Investigation of the Extent:** Evaluate the extent/Impact of the problem – completed by C&D.

Nonconformity 1) was restricted to a procedural documentation issue.

Nonconformity 2) did not impact on the ability of C&D to meet the timeliness requirements of past 10 CFR Part 21 reporting requirements.

C) **Determination of Root Cause:** Before resolution, root cause needs to be identified – completed by C&D.

Nonconformity 1) & 2):

C&D sought to strengthen existing processes and procedures and sent four associates to GQA 10 CFR Part 50 Ap.B and commercial grade dedication training in April 2009. C&D also retained a GQA consultant to review and make recommendations for improvement to our nuclear Quality program including the commercial grade dedication system. Upgrades were made as the result of these activities. NUPIC identified additional opportunities for improvement in August. A comprehensive redraft of C&D procedure A-14, incorporating

## Corrective / Preventive Action

upgrades for implementing 10 CFR Part 21 requirements, was made as the result of the NUPIC identified deficiencies. Nonetheless, with respect to 10 CFR Part 21 timeline requirements, the procedure did appear to be technically correct, but was being interpreted in a manner inconsistent with the statute.

**D) Corrective Action:** Indicate the resolution plan and controls to prevent recurrence with responsibilities and target dates assigned – completed by C&D.

Nonconformity 1) & 2):

A) Undertake a comprehensive reassessment of C&D's current v9 of Procedure A-14 governing our 10 CFR Part 21 evaluation and reporting process, in light of the regulations, published information about the regulations, and NRC feedback. – Completed.

B) Revise the procedure to include the method and protocol by which the C&D Safety Committee performs 10 CFR 21 evaluations. Also, revise the procedure so that the timelines and timeliness requirements in the procedure are an exact match to the regulations time requirements. – Assigned for completion by 30 November 2009

C1) Conduct training for the Safety Committee on the updated A-14 procedure. Conduct training for the Nuclear Product Manager on 10 CFR Part 21 and the upgraded A-14 procedure. – assigned for completion by 31 December 2009.

C2) Enlist the Nuclear Product Manager, and other key individuals to be identified for professional, accredited 10 CFR Part 21 Commercial Grade Survey training as C&D's 2<sup>nd</sup> wave for such training. – Assigned for completion by 28 February 2010.

C3) Until training described in (C1) above is completed, the Senior Manager - Quality Systems shall review with the nuclear product manager each nuclear complaint for applicability of initiating procedure A-14 for nuclear complaints via weekly and ad hoc meetings. If for any reason during this period, the Sr. QS manager is not available for such a review, the Nuclear product manager shall submit the incident to the Safety Committee procedure A-14 evaluation. – Assigned for completion by 31 March 2010.

Updated by M.K. Frick on 19 November 2009

Date Corrective Action Assigned: 28 October 2009

Signature of Manager: *Matthew K. Frick*

**E) Verification:** Verification statement of the corrective action implementation

Actual Completion Date:

Verified by:

**F) Disposition:** Open

Closed by:

Date:

Follow-up Date:

N

Indicate if review for 10 CFR Part 21 applicability is required (ref: C&D Standard Policy & Procedure A-14): **Y** or **N**

**STANDARD POLICY AND PROCEDURE**

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 1 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/M. Frick	<b>REV. DATE:</b> 11/30/09

**1.0 PURPOSE & SCOPE**

- 1.1 This procedure applies to Basic Components supplied or to be supplied by C&D Technologies, Incorporated to Nuclear Regulatory Commission (NRC) licensed facilities in compliance with Part 21 of Title 10, Chapter 1 of the Code of Federal Regulations (10 CFR Part 21) and with Section 206 of the Energy Reorganization Act of 1974. It is applicable to all C&D locations that design, manufacture and test basic components or their subassemblies, the corporate units at Blue Bell and Leola, PA. and the manufacturing site at Attica, IN.
- 1.2 This procedure defines the process of identification, Evaluation and Notification of conditions and circumstances that could result in a Substantial Safety Hazard caused by any of the following:
- Defects
  - Deviations
  - Test or inspection acceptance criteria not met
  - Fraudulent or suspected fraudulent conditions or items
  - Failures to comply
  - Conditions adverse to quality
  - Suspected deviations

**2.0 DEFINITIONS**

2.1 *Basic component:*

(1) When applied to nuclear power plants licensed under 10 CFR part 50, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition;  
or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a) (1), § 50.67(b) (2), or § 100.11 10 CFR Part 21 as applicable.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 2 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

(2) Basic components are items designed and manufactured under a quality assurance program complying with Appendix B to 10 CFR 50 or commercial grade items which have successfully completed the dedication process.

(3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of 10 CFR Part 21, whether these services are performed by the component supplier or others.

### 2.2 *Commercial Grade Item:*

When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

### 2.3 *Commission:*

The Nuclear Regulatory Commission or its duly authorized representatives:

### 2.4 *Constructing or Construction:*

The analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in 10 CFR Part 21 and consulting services related to the facility or activity that are safety related.

### 2.5 *Critical Characteristics:*

When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 3 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

### 2.6 *Dedicating Entity:*

When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating

entity, pursuant to § 21.21(c) of 10 CFR Part 21, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

### 2.7 *Dedication:*

When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

### 2.8 *Defect:*

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in 10 CFR Part 21 if, on the basis of an evaluation, the deviation could create a substantial safety hazard;

(2) The installation, use, or operation of a basic component containing a defect as defined in 10 CFR Part 21;

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 of 10CFR, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 4 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 of 10 CFR; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

### 2.9 *Deviation:*

A departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

### 2.10 *Director:*

An individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, director means the individual.

### 2.11 *Discovery:*

The completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21. (a) of 10 CFR Part 21.

### 2.12 *Evaluation:*

The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

### 2.13 *Failure to Comply:*

Any failure to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the NRC relating to substantial safety hazards.

### 2.14 *Notification:*

The communication via telephone to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 5 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

### 2.15 *Operating or Operation:*

The operation of a facility or the conduct of a licensed activity which is subject to the regulations in 10 CFR Part 21 and consulting services related to operations that are safety related.

### 2.16 *Procurement Document:*

A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

### 2.17 *Responsible Officer:*

The president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

### 2.18 *Substantial Safety Hazard:*

A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of 10 CFR Part 21.

### 2.19 *Supplying or Supplies:*

Contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in 10 CFR Part 21.

## 3.0 Responsibility

- 3.1. Any C&D Technologies employee who identifies a potential Deviation, condition or circumstance noted in paragraph 1.2 above, in a component or a product that has been or could be supplied to a nuclear facility shall immediately notify a supervisor, manager or Responsible Officer of C&D Technologies, Inc.
- 3.2. The President or, in his absence, another Corporate officer is responsible for notifying the NRC of all Defects and Failures to Comply.
- 3.3. If an individual believes that the officers of C&D Technologies have failed to report to the NRC any potential conditions or circumstances as noted in paragraph 1.2 above, he is encouraged to report such potential conditions or circumstances

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 6 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

directly to the NRC. As authorized by law, the identity of anyone so reporting will be withheld from disclosure.

- 3.4. All C&D management personnel and C&D representatives/agents 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. Trained and qualified members of the management team, limited to the Sr. Manager Quality, are authorized to pre-screen identified defects and deviations to include only those related to basic components.

- 3.4.1. The Product Safety Committee is composed of:

Vice President of Engineering - Chairman  
Vice President of Operations  
Director of Quality  
Director of Product Development

## 4.0 PROCEDURE

### 4.1 Discovery and Evaluation

- 4.1.1 Discoveries will be initiated as a result of communications from end users, dedicating entities, commercial grade parts suppliers or internal notification or corrective actions. Discoveries are to be submitted to the Safety Committee.
- 4.1.2 Once the Discovery has been identified to the Safety Committee; the Director of Quality shall (within five days of discovery) in conjunction with the Director of Product Development assess if the defect requires engineering evaluation and if this evaluation can be completed within 60 days.
- 4.1.3 For the cases that do not require technical evaluation, the Director of Quality shall prepare form RS-776 and submit recommendations to the Safety Committee for review and approval.
- 4.1.4 For cases requiring technical evaluation, the Director of Product Development will be responsible of coordinating and supplying to the Director of Quality the Engineering supporting analysis and associated documentation of the defect evaluation. The Director of Quality will then prepare and submit form RS-776 to the Safety Committee for review and approval.
- 4.1.5 In the event that the required technical evaluation cannot be completed within the sixty (60) days of discovery, the Director of Quality will be responsible for coordinating all

Uncontrolled if printed.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				POLICY NUMBER A-14, Rev. 10 draft
				PAGE 7 OF 11
Approved: VP Eng. J. Jergl	Approved: VP Operations R. Sell	Approved: Dir. Eng. R. Malley	Originator: Dir. QA S. Flores/ M. Frick	REV. DATE: 11/30/09

efforts such that notifications to NRC Operations Center, NRC Document Control and end users are completed within the required time frame as specified in section 4.2 below.

- 4.1.6 Notification means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk of an identified failure to comply or existence of a defect, as the result of Product Safety Committee's evaluation.

#### 4.2 Evaluation Notifications

- 4.2.1 The Product Safety Committee will ensure that deviations and failures to comply associated with substantial safety hazards are evaluated as soon as practicable, and except as provided in paragraph 4.3 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.

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 from 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 10 CFR 21. The exception is for cases where evaluation requires that the batteries involved be inspected, broken down and analyzed, but they have not been returned by the purchaser or licensee in time; See section 4.2.3 below for such cases. The 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 the same 60 day period from discovery of the deviation or failure to comply, as required in section 4.3.

- 4.2.2 The Product Safety Committee will ensure that a responsible C&D officer subject to the regulations of this part is informed as soon as practicable, and, in all cases within the five (5) working days after completion of the evaluation described in paragraph 4.1 and its sub-paragraphs. If the construction or operation of a facility or activity, or a basic component supplied for such facility or activity ...

- 4.2.2.1 ...fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

- 4.2.2.2 ...contains a defect.

- 4.2.3 If the deviation or failure to comply is discovered by C&D or a sub-tier supplier of basic components or services associated with basic components, and C&D determines that it does not have the capability to perform the evaluation to determine if a defect exists – including

Uncontrolled if printed.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 8 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

cases where evaluation requires that the batteries involved be inspected, broken down and analyzed, but they have not been returned by the purchaser or licensee in time - then C&D must inform the purchasers or affected licensees within five (5) days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to Section 21.21(a) of 10CFR Part 21. C&D shall also notify the purchaser or licensee in writing that should the batteries not be returned, if necessary, in time for us to meet the timeliness requirements required in section 4.2.1, C&D will not be required to make report to the NRC pursuant to section 4.2.1 in accordance with 10 CFR Part 21 section 21.21(a); however, the purchaser or licensee's obligations with respect to Section 21.21 (a) of 10CFR21 remain unchanged.

4.2.4 A dedicating entity is responsible for:

4.2.4.1 Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items, and maintaining auditable records for the dedication process.

4.2.5 The notification of the NRC of a failure to comply or of a defect under paragraph 4.2.1 of this section is not required if the Director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

4.2.6 The Director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that this shall not relieve the Director or responsible officer of his or her responsibility under this paragraph.

4.2.7 Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

4.3 Notification required by paragraph 4.2.1 of this section must be made as follows:

4.3.1 Initial notification by facsimile, which is the preferred method of notification, shall be made to the NRC Operations Center at 301-816-5151 or by telephone at 301-816-5100 within two days following receipt of information by the Director or responsible corporate officer under paragraph 3.2 of this procedure, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in 4.2.1 of this section.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				POLICY NUMBER A-14, Rev. 10 draft
				PAGE 9 OF 11
Approved: VP Eng. J. Jergl	Approved: VP Operations R. Sell	Approved: Dir. Eng. R. Malley	Originator: Dir. QA S. Flores/ M. Frick	REV. DATE: 11/30/09

4.3.2 Written notification to the NRC at the address specified in the 10CFR21 paragraph 21.5 within 30 days following the receipt of information by the Director or responsible corporate officer under paragraph 3.2 of this procedure, on the identification of a defect or a failure to comply. The written report shall include, but need not be limited to, the following:

- Name and address of the individual or individuals informing the NRC,
- Identification of the Basic Component supplied for such facility or such activity within the United States which Fails To Comply or contains a Defect,
- Identification of the firm supplying the Basic Component which Fails To Comply or contains a Defect,
- The nature of the Defect or Failure To Comply and the safety related hazard which is created or could be created by such Defect or Failure To Comply,
- The date on which information of such Defect or Failure To Comply was obtained,
- The number and location of all such Basic Components in use at, supplied for, or being supplied for, or may be supplied for, manufactured for or being manufactured for one or more facilities or activities subject to the regulations in 10 CFR Part 21,
- The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action,
- Any advice related to the Defect or Failure to comply about the Basic Component that has been, is being or will be given to purchasers or licensees.

4.4 The Safety committee shall be responsible for arranging, through the Vice President Sales, a report to any licensed nuclear facilities that are or may be affected by the reporting of any Defect or Failure to comply with the NRC.

4.5 The Product Safety Committee shall review the supporting data, actions, notifications, and close-out. The completed 10CFR21 Nonconformance Report (RS-776) and all related data and documents including those below shall be archived within one year of the close-out date and maintained in the Product Safety Committee files.

4.5.1 Records of Evaluations of conditions or circumstances noted in paragraph 1.2 above shall be prepared and maintained for a period of not less than five (5) years from the date of the evaluation.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				<b>POLICY NUMBER</b> A-14, Rev. 10 draft
				<b>PAGE 10 OF 11</b>
<b>Approved: VP Eng.</b> J. Jergl	<b>Approved: VP Operations</b> R. Sell	<b>Approved: Dir. Eng.</b> R. Malley	<b>Originator: Dir. QA</b> S. Flores/ M. Frick	<b>REV. DATE:</b> 11/30/09

- 4.5.2 Records of notifications sent to purchasers and affected licensees shall be prepared and retained for a period of not less than five (5) years from the date of Notification.
- 4.5.3 Records of the purchasers of Basic Components shall be prepared and retained for a period of not less than ten (10) years after delivery of the Basic Component or service associated with the Basic component or service associated with the basic component.
- 4.5.4 Records shall be stored in a manner that safeguards the record from damage and deterioration. Records shall be identifiable and retrievable.

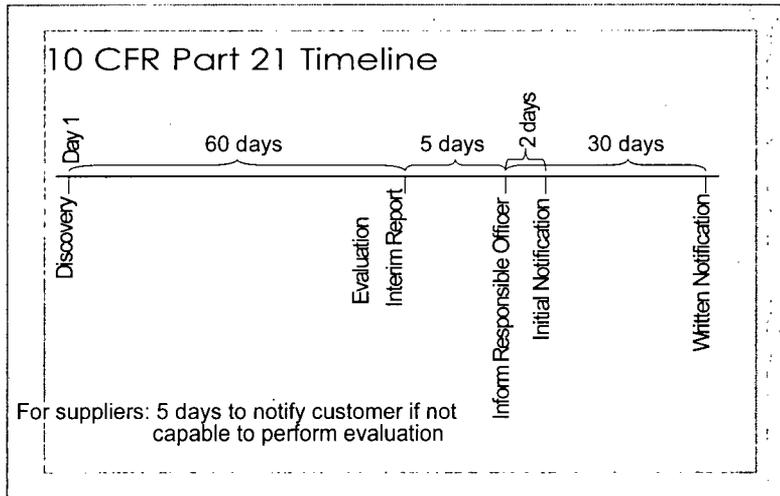
### 5.0 POSTING AND TRAINING

- 5.1 A controlled copy of this procedure shall be available in the corporate intranet site (Sharepoint) under Global Quality. A copy of Section 206 of the Energy Reorganization Act of 1974 shall be posted on appropriate facility bulletin boards together with 10 CFR Part 21 where activities subject to 10 CFR Part 21 are being conducted. Posting of the required documents shall be the responsibility of the Quality Assurance Manager.
- 5.2 All employees impacting quality shall receive training in the requirements of this procedure and general responsibilities for compliance with 10 CFR Part 21. Training shall be documented in individual employee training records.

## STANDARD POLICY AND PROCEDURE

<b>SUBJECT: Evaluation, Notification &amp; Reporting Responsibilities In Accordance With USNRC 10CFR21 Regulations</b>				POLICY NUMBER A-14, Rev. 10 draft
				PAGE 11 OF 11
Approved: VP Eng. J. Jergl	Approved: VP Operations R. Sell	Approved: Dir. Eng. R. Malley	Originator: Dir. QA S. Flores/ M. Frick	REV. DATE: 11/30/09

### 6.0 REFERENCE TIMELINE DIAGRAM



\* courtesy of AEP - Cook plant

#### Document Change Summary

Revision Date	Rev.	Section	Description
10/21/08	8	All Page 5	Updated titles/names. Added Document Change Summary.
9/11/09	9	All	Major rewrite for fill compliance as per feedback from the August 2009 NUPIC audit.
11/30/09	10	3.4 4.1 4.2-4.3 6.0	Authorization for specified members of management to conduct pre-evaluation screening Added Discovery and Evaluation Process Description  Added direction for how to proceed in cases where evaluation requires that batteries be returned in time for inspection. Clarified timeline. Added new Timeline Guide

## Corrective / Preventive Action

<b>Type of Action:</b>	<b>Source of Action:</b> 15-18 September NRC Inspection at Blue Bell	
Corrective Action	<b>Type of Request:</b> September 2009 NRC Inspection	
Corrective Action # 09- 50	Date Issued: 7 October 2009	Date parts B-D Due:
	Updated from NRC formal report: 11/5/09	19 November 2009 (rev.)
To: Matt Frick with Larry Carson & The Safety Com. From: Matt Frick		
(filename = RS-1037 09-50 NRC VB.doc)		

A) **Deficiency/Non Conformity:** Describe in detail the nature of the problem, list the facts, and indicate any applicable documents.  
 Note: include checksheet question #s - for standard references refer to the internal audit checksheet.

NOTICE OF VIOLATION B – from NRC Inspection report:  
 "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 1 E 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)."

B) **Investigation of the Extent:** Evaluate the extent/impact of the problem – completed by C&D.

Nonconformity 1) In those cases where significant time passed between customer notification of an issue and product return for analysis, C&D may have missed the deadline for reporting an inability to make an evaluation of 10 CFR Part 21 applicability. Nonetheless, all such evaluations were completed where required when the batteries were returned, and in no case was a notification to the NRC under 10 CFR Part 21 required.

## Corrective / Preventive Action

Nonconformity 2) A review of records for the past year resulted in no other findings in which the nuclear product manager responded to a request for 10 CFR Part 21 evaluation without involving the safety committee, or members thereof.

**C) Determination of Root Cause:** Before resolution, root cause needs to be identified– completed by C&D.

Nonconformity 1) The incident in question was not recognized as a situation in which it might not be possible to make an evaluation as to 10CFR Part 21 applicability before the statutes time allotments expired, because there was never any uncertainty that with the analysis of the returned batteries completed, C&D would be able to make such an evaluation. C&D did not consider that the time elapsed between communication of the issue and return of the battery might prevent a timely evaluation.

Nonconformity 2) The nuclear product manager, though an expert on our batteries and their applications in the nuclear industry, was not adequately trained in 10 CFR Part 21, and did not understand that his pre-evaluation was de facto a 10 CFR Part 21 evaluation.

**D) Corrective Action:** Indicate the resolution plan and controls to prevent recurrence with responsibilities and target dates assigned – completed by C&D.

Nonconformity 1) & 2):

A) The C&D Safety Committee shall complete evaluations as to 10 CFR Part 21 applicability regarding the batteries in both incidents according to procedure A-14. – Assigned for completion by 30 November 2009.

B) In conjunction with modification of procedure A-14 to satisfy corrective action RS-1037 09-49, also modify the procedure to delineate protocol for instances in which time elapsed between issue reporting and C&D returned battery analysis exceeds the time allotments of 10 CFR Part 21. Also modify procedure A-14 to enable competent trained individuals to conduct pre-evaluation screening before submittal to the corporate Safety Committee for full evaluation (Ex: to screen out incidents that are not 1E applications). – Assigned for completion by 30 November 2009.

C1)\* Conduct training for the Safety Committee on the updated A-14 procedure. Conduct training for the Nuclear Product Manager on 10 CFR-Part 21 and the upgraded A-14 procedure. – assigned for completion by 31 December 2009.

C2)\* Sign up the Nuclear Product Manager, and other key individuals to be identified, for professional, accredited 10 CFR Part 21 Commercial Grade Survey training as C&D's 2<sup>nd</sup> wave for such training. – Assigned for completion by 28 February 2010.

C3)\* Until training described in (C1) above is completed, the Senior Manager - Quality Systems shall review with the nuclear product manager each nuclear complaint for applicability of initiating procedure A-14 for nuclear complaints via weekly and ad hoc meetings. If for any reason during this period, the Sr. QS manager is not available for such a review, the Nuclear product manager shall submit the incident to the Safety Committee procedure A-14 evaluation. – Assigned for completion by 31 March 2010.

\* same as for RS-1037 09-49 corrective action for Violation "A".

Date Corrective Action Assigned: 17 November 2009

Signature of Manager: Matthew K. Frick

**E) Verification:** Verification statement of the corrective action implementation

Actual Completion Date:

Verified by:

**F) Disposition:** Open

Closed by:

Date:

Follow-up Date:

Y

Indicate if review for 10 CFR Part 21 applicability is required (ref: C&D Standard Policy & Procedure A-14): **Y** or **N**

Advise of Non-conformance	Customer/Facility Location: Entergy-Waterford III Leola/Attica Product: LCR-33-NUC Date Shipped: 4/92 & 4/08 C&D Invoice: 500887 Cust PO: <b>10171387</b> Notified By: Larry Carson Notification Time: Date: 3/09 Non-conformance Reported as: Low Voltage
Evaluation	Evaluation of Non-Conformance by (Report Reference): <input type="checkbox"/> Marketing _____ <input type="checkbox"/> Applications Engineering _____ <input checked="" type="checkbox"/> Engineering _____ <input checked="" type="checkbox"/> Quality Assurance _____ <input type="checkbox"/> Field Operations _____ Remarks
Determination	Determination: <input type="checkbox"/> Non-conformance is a defect per 10CFR21 <input checked="" type="checkbox"/> Non-conformance is not a defect per 10CFR21 Signed: <u>Stanley G. Flores</u> Date: <u>11/22/09</u> Approved: <u>Stanley G. Flores</u> Date: <u>11/30/09</u>
Actions	Actions: <input checked="" type="checkbox"/> Identification and Location of similar product <input type="checkbox"/> Product Replaced: N/A <input type="checkbox"/> Notified: NO <input type="checkbox"/> Redesign: N/A
Notification	Notification <input type="checkbox"/> USNRC NO Company Officers/Directors <input type="checkbox"/> President: <input checked="" type="checkbox"/> VP Technology: Yes <input type="checkbox"/> VP Marketing Yes <input checked="" type="checkbox"/> VP Operations Yes <input checked="" type="checkbox"/> Product Safety Committee: Yes <input type="checkbox"/> Location/Users of similar product N/A
Close-Out	Remarks: Inspection Reports Indicate that the failure was caused by a damaged separator (4/08 cell) and sedimentation on the older cells (4/92). These failures are NOT systemic and standard battery maintenance procedures would identify possibly defective cells before system capability is compromised. During transportation the shorts were cleared and the batteries were able to attain capacity requirements. Per Engineering review these are not considered safety related defects. 10CFR21 Nonconformance Report Completed Signed: Stanley G. Flores Title: <u>Dir. Quality</u> Date: <u>11/21/09</u>

Advise of Non-conformance	Customer/Facility Entergy-Waterford III Location: Blue Bell – Nuclear Prod. Mgr.  Notified By: Matt Frick Notification Time: _____ Date: 9/09 Non-conformance Reported as: Failure to Request 10CFR Part 21 Review	Product: LCR-33-NUC Date Shipped: 4/92 & 4/08 C&D Invoice: 500887 Cust PO: <b>10171387</b>
Evaluation	Evaluation of Non-Conformance by (Report Reference): <input type="checkbox"/> Marketing _____ <input checked="" type="checkbox"/> Applications Engineering _____ <input checked="" type="checkbox"/> Engineering _____	
Determination	Determination: <input type="checkbox"/> Non-conformance is a defect per 10CFR21 <input checked="" type="checkbox"/> Non-conformance is not a defect per 10CFR21  Signed: <u>Stanley G. Flores</u> Date: <u>11/22/09</u>  Approved: <u>Stanley G. Flores</u> Date: <u>11/22/09</u>	
Actions	Actions: <input type="checkbox"/> Identification and Location of similar product <input type="checkbox"/> Product Replaced: N/A <input type="checkbox"/> Notified: NO <input type="checkbox"/> Redesign: N/A	
Notification	Notification <input type="checkbox"/> USNRC NO  Company Officers/Directors <input type="checkbox"/> President: <input checked="" type="checkbox"/> VP Technology: Yes <input type="checkbox"/> VP Marketing Yes <input checked="" type="checkbox"/> VP Operations Yes <input checked="" type="checkbox"/> Product Safety Committee: Yes <input type="checkbox"/> Location/Users of similar product N/A	
Close-Out	Remarks: During the handling of complaint #117, Safety Committee was not notified and consequently no Safety Evaluation was performed the Customer was notified that no further action would be required by C&D. Subsequent review by Engineering and Safety Committee indicates that indeed this defect was NOT a safety related issue. Corrective actions to prevent this occurrence have been implemented. These CA address the process by which ALL NUCLEAR related complaints are handled and reviewed, specifically the required safety reviewed by qualified personnel and timeliness of review. This non conformance report is issued to update the Safety Committee of the actions taken and to close out finding #2 in the above mentioned NRC violation and CA-009-50	10CFR21 Nonconformance Report Completed  Signed: Stanley G. Flores  Title: <u>Dir. Quality</u> Date: <u>11/21/09</u>

## Corrective / Preventive Action

<b>Type of Action:</b>	<b>Source of Action:</b> 15-18 September NRC Inspection at Blue Bell	
Corrective Action	<b>Type of Request:</b> September 2009 NRC Inspection	
Corrective Action # 09- 54	Date Issued: 8 October 2009	Date parts B-D Due:
	Updated from NRC formal report: 11/10/09	24 November 2009 (rev.)
To: Carl Lynn	From: Matt Frick	
(filename = RS-1037 09-54 NRC NC5a)		

A) **Deficiency/Non Conformity:** Describe in detail the nature of the problem, list the facts, and indicate any applicable documents.  
Note: include checklist question #s - for standard references refer to the internal audit checklist.

NOTICE OF NONCONFORMANCE A – from NRC Inspection report:  
 "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-1 037, "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-1 037, #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) **Investigation of the Extent:** Evaluate the extent/Impact of the problem – completed by C&D.  
 Nonconformity 1) Table 1 dedication activities were reviewed, specifically with regard to identifying equipment and calibration facilities. No other vendors who should be on the list, but are not, have been identified.  
 Nonconformity 2) All 1E Records

## Corrective / Preventive Action

C) **Determination of Root Cause:** Before resolution, root cause needs to be identified – completed by C&D.

Nonconformity 1) Originally Koenig was not identified as critical particular to 1E due to them being used for all commercial manufacturing testing of product. Upon second pass evaluation after audit, it was recognized they are also used to validate 1E product under our App. B program. Iron Mountain was missed since the service they provide – secure offsite records storage – was not directly related to the product – an oversight.

Nonconformity 2) The action to send copies of required records to Blue Bell was added to procedure once requirement identified, but before the means to implement the solution logistically were identified and set.

D) **Corrective Action:** Indicate the resolution plan and controls to prevent recurrence with responsibilities and target dates assigned– completed by C&D.

Nonconformity 1):

1a) Both suppliers were added to the controlled critical ASL list before the Inspection was completed. – *Completed.*

b) Conduct training with Engineering and Senior Quality personnel on ASL and new critical ASL supplier requirements. Target date 10/15/09. – *Completed.*

Nonconformity 2):

2a) Going forward, procedures will only be activated when the work change has been implemented.

b) An alternate means to securely maintain records for retention has been selected:

- o All new 1E records will be scanned for retention on a secure drive, effective 1December 2009. – Assigned for completion b1 1December 2009.
- o All pre-existing records will be catalogued, with regular scanning for retention on a secure drive, to commence on 4 January 2010, and continue at a rate sufficient to have all pre-existing records stored electronically on the secure drive. – Assigned for completion by 31 August 2010.

Updated by M. Frick 13 November 2009.

Date Corrective Action Assigned: 10/8/09

Signature of Manager: Carl Lynn

E) **Verification:** Verification statement of the corrective action implementation

Actual Completion Date:

Verified by:

F) **Disposition:** Open

Closed by:

Date:

Follow-up Date:

N

Indicate if review for 10 CFR Part 21 applicability is required (ref: C&D Standard Policy & Procedure A-14): **Y** or **N**

## Corrective / Preventive Action

**Type of Action:**

Corrective Action

**Source of Action:** 15-18 September NRC Inspection at Blue Bell

**Type of Request:** September 2009 NRC Inspection

Corrective Action # 09- 51

Date Issued: 8 October 2009

Date parts B-D Due:

Updated from NRC formal report: 11/5/09

19 November 2009 (rev.)

To: Matt Frick, Bob Malley

From: Matt Frick

(filename = RS-1037 09-51 NRC NCB.doc)

A) **Deficiency/Non Conformity:** Describe in detail the nature of the problem, list the facts, and indicate any applicable documents.  
Note: include checksheet question #s - for standard references refer to the internal audit checksheet.

NOTICE OF NONCONFORMANCE B – from NRC Inspection report:

"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."

B) **Investigation of the Extent:** Evaluate the extent/Impact of the problem – completed by C&D.

Justification documentation in the cited case required supplementation.

## Corrective / Preventive Action

C) **Determination of Root Cause:** Before resolution, root cause needs to be identified – completed by C&D.

The ECR/ECN processes require substantial justification and documentation, and additional approvals. Though the table I matrix in the BB-WI-7.4.3-1 is a key engineering document as well as a key quality system document, it's change control did not require the more rigorous controls of the Engineering Change Request (ECR), and Engineering Change Notice (ECN) processes.

D) **Corrective Action:** Indicate the resolution plan and controls to prevent recurrence with responsibilities and target dates assigned – completed by C&D.

Modify BB-WI-7.4.3-1, *Nuclear Dedication Requirements*, to require that changes to the Table 1 Basic Component/Safety Function/Critical Characteristic/Dedication Requirement matrix within that work instruction are rigorously justified and fully documented. These changes shall henceforth be required to be executed via the Engineering Change Request (ECR), and Engineering Change Notice (ECN) processes, in addition to the Quality System document change approval process - *Completed*. Assigned for completion by 20 November 2009.

Date Corrective Action Assigned: 13 November 2009

Signature of Manager: *Matthew K. Frick*

E) **Verification:** Verification statement of the corrective action implementation

Actual Completion Date:

Verified by:

F) **Disposition:** Open

Closed by:

Date:

Follow-up Date:

N

Indicate if review for 10 CFR Part 21 applicability is required (ref: C&D Standard Policy & Procedure A-14): **Y** or **N**

# Corrective / Preventive Action

<b>Type of Action:</b>	<b>Source of Action:</b> 15-18 September NRC Inspection at Blue Bell	
Corrective Action	<b>Type of Request:</b> September 2009 NRC Inspection	
Corrective Action # 09- 55	Date Issued: 8 October 2009	Date parts B-D Due:
	Updated from NRC formal report: 11/10/09	17 November 2009 (rev2)
To: Brian Rooney (re-reassigned 11/10), Matt Frick, Carl Lynn		From: Matt Frick
(filename = RS-1037 09-55 NRC NCC)		

A) **Deficiency/Non Conformity:** Describe in detail the nature of the problem, list the facts, and indicate any applicable documents.  
 Note: include checksheet question #s - for standard references refer to the internal audit checksheet.

NOTICE OF NONCONFORMANCE C – from NRC Inspection report:  
 "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.O (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.1 0070193, 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.

## Corrective / Preventive Action

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

**B) Investigation of the Extent:** Evaluate the extent/Impact of the problem – completed by C&D.

Nonconformity 1) Random audit of additional packages identified no other discrepancies.

Nonconformity 2) Problems with C&D batteries were captured and handled through the warranty claims process and not the customer complaint process.

**C) Determination of Root Cause:** Before resolution, root cause needs to be identified – completed by C&D.

Nonconformity 1) Existing practice did not ensure that all records are maintained together and not filed separately. Specific work instructions did not specify that the documents be maintained together in a single designated location.

Nonconformity 2) Historically, warranty claims and complaints were considered two different streams of customer feedback and were handled independently through two different systems. In the summer of 2009, warranty claims were integrated into the Isight complaint process. At the time of the inspection the integration was underway but not fully deployed.

**D) Corrective Action:** Indicate the resolution plan and controls to prevent recurrence with responsibilities and target dates assigned – completed by C&D.

Nonconformity 1) Procedural implementation that requires all records associated with a Nuclear 1E order to travel with the batteries throughout the manufacturing process gathered in one file, accumulating as the product flows from dept. to dept. Batteries are not permitted to leave one department for processing in the next until all paperwork is verified present in the file, filled out correctly by two different people. – Completed.

Nonconformity 2)

2a) All operating issues and warranty claims for the nuclear industry (both 1E and non-1E) are now sent to the nuclear product manager for review and assignment. Nuclear product manager(s) have been trained on the new Isight process and related responsibilities for entering complaints for issues that are first communicated to such manager from C&D nuclear customers, and are entering such complaints. In order to ensure that the nuclear product manager can better execute his/her responsibilities in this role and other responsibilities associated with C&D compliance to 10 CFR Part 50 Appendix B and 10 CFR Part 21, additional human resources will be allocated to assist him/her. – Assigned for completion by 4 January 2010.

2b) BB-WI-8.2.1-2 will be strengthened to explicitly include that all nuclear operating issues – beyond those requiring standard customer maintenance, or resolved through such maintenance – and warranty claims, be entered as complaints for review and assignment by the nuclear product manager – Assigned for completion by 11 December 2009.

2c) Create a work instruction for field service personnel that prescribes field service responsibilities and work flow to capture and enter customer complaints from warranty claims and other sources first communicated to them – Assigned for completion by 11 December 2009.

2d) Include consideration of compliance with the work instruction identified in 2b above, in internal audit procedures and plans. – assigned for completion by 31 January 2010.

Updated 16 November 2009 by M. Frick

## Corrective / Preventive Action

Date Corrective Action Assigned: 10/8/09

Signature of Manager: Carl Lynn

E) **Verification:** Verification statement of the corrective action implementation (Partial verification by C&D below)

- 1) Document Change Order # 776 completed 6/17/09. Three follow up audits of new process were conducted with satisfactory results. Two in late July and one in August. (Note: the corrective action preceded the NRC finding in September 2009, but not the occasion of the nonconformance itself which occurred in November 2004. - Verified

Actual Completion Date:

Verified by:

F) **Disposition:** Open

Closed by:

Date:

Follow-up Date:

N

Indicate if review for 10 CFR Part 21 applicability is required (ref: C&D Standard Policy & Procedure A-14): **Y** or **N**

## Corrective / Preventive Action

<b>Type of Action:</b>	<b>Source of Action:</b> 15-18 September NRC Inspection at Blue Bell	
Corrective Action	<b>Type of Request:</b> September 2009 NRC Inspection	
Corrective Action # 09- 53	Date Issued: 8 October 2009	Date parts B-D Due:
	Updated from NRC formal report: 11/5/09	19 November 2009 (rev.)
To: Matt Frick	From: Matt Frick	
(filename = RS-1037 09-53 NRC NCD.doc)		

A) **Deficiency/Non Conformity:** Describe in detail the nature of the problem, list the facts, and indicate any applicable documents.  
Note: include checksheet question #s - for standard references refer to the internal audit checksheet.

NOTICE OF NONCONFORMANCE D – from NRC Inspection report:

"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 1 E applications *audits* are performed on 1 E suppliers with 1 OCFR50 Appendix B programs; while *commercial grade surveys* are performed on commercial grade suppliers whose parts or services C&D must dedicate for class 1 E 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 do not require a corrective action or a response from 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."

## Corrective / Preventive Action

B) **Investigation of the Extent:** Evaluate the extent/Impact of the problem – completed by C&D.

- a) Standard practice and procedure is for commercial grade surveys to be performed for commercial grade item suppliers; however there were several audits performed in late 2008 that should have been commercial grade surveys.
- b) Isolated incident – reviews of other audits performed do include appropriate assignment of nonconformances.

C) **Determination of Root Cause:** Before resolution, root cause needs to be identified – completed by C&D.

Nonconformity a) Due to personnel changes, certain commercial grade surveys were incorrectly arranged and planned by individuals who were not properly trained for the task.

Nonconformity b) Auditor error.

D) **Corrective Action:** Indicate the resolution plan and controls to prevent recurrence with responsibilities and target dates assigned – completed by C&D.

Nonconformity a):

- a1) Key C&D personnel including the Sr. Quality Systems Manager, completed a week long professional training in 10 CFR Part 21, commercial grade item dedication and 10 CFR part 50 Appendix B in April 2009. The Quality Systems Manager is now responsible for planning all audits and commercial grade surveys for the company. – Completed.
- a2) For two other prior "audited" CGI suppliers C&D has conducted and reported commercial grade surveys as appropriate. Daramic's commercial grade survey is scheduled for 2010 – Assigned for completion by 30 June 2010.

Nonconformity b) Modify BB-QOP-7.4.3b for supplier audits and commercial grade surveys to streamline and simplify the findings option classifications available to lead auditors/surveyors. Distribute training bulletin concurrent with new procedure release to all qualified auditors/surveyors along with this nonconformance finding as a training aid. – Assigned for completion by 31 December 2009.

Date Corrective Action Assigned: 20 November 2009

Signature of Manager: *Matthew K. Frick*

E) **Verification:** Verification statement of the corrective action implementation

Actual Completion Date:

Verified by:

F) **Disposition:** Open

Closed by:

Date:

Follow-up Date:

N

Indicate if review for 10 CFR Part 21 applicability is required (ref: C&D Standard Policy & Procedure A-14): **Y** or **N**