

May 27, 2009

Donald L. Curtin, President
Conval, Inc.
265 Field Road
Somers, Connecticut 06071-1049

SUBJECT: NRC INSPECTION REPORT NO. 99901367/2009-201, NOTICE OF VIOLATION, AND NOTICE OF NONCONFORMANCE

Dear Mr. Curtin:

On April 21-22, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted a follow-up inspection at the Conval facility in Somers, Connecticut. The purpose of the inspection was to review the implementation of corrective action activities described in Conval's December 13, 2007, letter to the NRC, "Replies to Notice of Violation 99901367/2007-201-I; Notice of Nonconformance's 99901367/2007-201-1, 99901367/2007-201-2a, 99901367/2007-201-2b, and 99901367/2007-201-2c."

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. Specifically, Conval's procedures for Commercial Grade Dedication and 10 CFR Part 21 Implementation failed to provide sufficient guidance to ensure that deviations and failures to comply would be evaluated to determine whether they were associated with substantial safety hazards. This violation of 10 CFR Part 21 is cited in the enclosed Notice of Violation (NOV), and the circumstances surrounding it are described in detail in the subject inspection report.

You are required to provide a written explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NOV. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, based on the results of this inspection, the NRC inspectors determined that the implementation of the corrective action activities described in Conval's December 13, 2007, letter to the NRC failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspectors determined that there were inadequacies in Conval's policies, procedures, and implementing actions for: the dedication of commercial grade items; the control of nonconforming material, parts, or components; and corrective actions. These nonconformances to the requirements of Appendix B to Title 10 Part 50, "Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (10 CFR Part 50) are cited in the enclosed Notice of Nonconformance (NON), and the circumstances surrounding them are described in detail in the subject inspection report. Please provide a written explanation or statement within 30 days of this letter in accordance with the instructions specified in the enclosed NON.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and your response available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide

Documents Access and Management System (ADAMS), accessible 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 be 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, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA/

John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No: 999-01367

Enclosures: 1. Notice of Violation
 2. Notice of Nonconformance
 3. Inspection Report No. 99901367/2009-201

Documents Access and Management System (ADAMS), accessible 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 be 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, "Requirements for the Protection of Safeguards Information."

Sincerely,

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John A. Nakoski, Chief
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Docket No: 999-01367

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NAME	WDeschaine (SC for WD)	GNewman	SCleavenger
DATE	5/12/09	5/12/09	5/12/09
OFFICE	NRO/DCIP/CCIB	NRO/DCIP/CQVB: BC	
NAME	RPascarelli	JANakoski	
DATE	5/21/09	5/27/09	

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NOTICE OF VIOLATION

Conval, Inc.
265 Field Road
Somers, Connecticut 06071-1049

Docket No: 999-01367
Inspection Report Number: 2009-201

During a Nuclear Regulatory Commission (NRC) inspection conducted April 21-22, 2009, at Conval Incorporated (Conval), a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below.

Section 21.21, "Notification of Failure to Comply or Existence of a Defect and Its Evaluation," of Part 21 to Title 10 of the *Code of Federal Regulations* (10 CFR 21.21), paragraph 21.21(a), requires, in part, that each individual, corporation, partnership, or other entity subject to 10 CFR Part 21, "Reporting of Defects and Noncompliance," shall adopt appropriate procedures to evaluate deviations and failures to comply associated with substantial safety hazards as soon as practicable.

Contrary to the above, on April 22, 2009, Conval procedures for Commercial Grade Dedication and 10 CFR Part 21 Implementation failed to provide sufficient guidance to ensure that deviations and failures to comply would be evaluated to determine whether they were associated with substantial safety hazards. Specifically:

1. Conval's 10 CFR Part 21 implementing procedure, corporate procedure (CP) 0240, "Implementation of 10 CFR 21," dated April 20, 2009, misuses the terms "defect" and "deviation" throughout the body of the document. CP-0240 also neglects, in multiple paragraphs, to include "failures to comply" in the guidance for implementing 10 CFR Part 21.
2. Conval quality procedure (QP) 0015, "Control of Nonconformances," dated February 8, 2008, requires Conval quality assurance (QA) staff to review nonconformances captured on reject tags (1) for the need to initiate a CAR and (2) for the applicability of 10 CFR Part 21. Conval's reject tag has a signature space labeled "Reviewed for Corrective Action" for the QA manager's signature, but no signature space for 10 CFR Part 21 applicability. While the tag provides verification that the need for corrective action for a nonconforming material, part, or component has been considered, the reject tag fails to provide verifiable evidence that a review for 10 CFR Part 21 applicability has been performed. Consequently, the reject tag does not provide the basis for a decision that an evaluation of the deviation under 10 CFR Part 21 is not necessary.

These issues have been identified as Violation 99901367/2009-201-01.

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

Pursuant to the provisions of 10 CFR 2.201, Conval is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to John A. Nakoski, Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, 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

ENCLOSURE 1

for the violation, or, if contested, the basis for disputing the violation or severity level; (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.

Since your response will be made available electronically for public inspection in the NRC Public Document Room or through the NRC Agencywide Documents Access and Management System (ADAMS), to the extent possible, the response 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, "Requirements for the Protection of Safeguards Information."

Dated at Rockville, Maryland, this 27th day of May 2009.

NOTICE OF NONCONFORMANCE

Conval, Inc.
265 Field Road
Somers, Connecticut 06071-1049

Docket No: 999-01367
Inspection Report Number: 2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted April 21-22, 2009, at Conval Incorporated (Conval), the NRC staff found that certain activities were not conducted in accordance with NRC requirements that were contractually imposed upon Conval by NRC licensees.

1. Criterion III, "Design Control," of Appendix B to Title 10 Part 50, "Domestic Licensing of Production and Utilization Facilities," of the *Code of Federal Regulations* (10 CFR Part 50), states in part, that, "Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions."

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states, in part, that "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."

Contrary to the above, on April 22, 2009, Conval failed to incorporate the appropriate regulatory requirements into its dedication program documents and did not establish an effective, consistent procedure for commercial grade dedication. Specifically, Conval's quality procedure (QP) 0006, "Dedication of Commercial Grade Items for Nuclear Safety Related Applications," dated December 13, 2006, failed to provide the appropriate 10 CFR 21.3 definition for a commercial grade item as it applies to nuclear power plants licensed pursuant to 10 CFR Part 50. The definition included in the QP-0006 was the definition related to commercial grade items as applied to facilities and activities other than nuclear power plants.

This issue has been identified as Nonconformance 99901367/2009-201-01.

2. Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, states, in part, that "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

Contrary to the above, on April 22, 2009, Conval's procedure failed to provide adequate and complete instructions for staff members to identify and document nonconforming processes and activities to prevent further processing, delivery, installation, and use of nonconforming items. Specifically, the corrective action for Nonconformance 99901367/2007-201-2c identified the commitment to revise QP-0015, "Control of Nonconformances," dated September 25, 2003, to address nonconformances in processes and activities. In the April 15, 2009, revision to QP-0015, this statement had only been added to the purpose of the procedure. The body of the procedure was not

revised, and thus failed to provide any implementing guidance for the identification, documentation, evaluation, or disposition of nonconforming processes or activities.

This issue has been identified as Nonconformance 99901367/2009-201-02.

3. 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. The identification of significant conditions adverse to quality, the cause of the conditions, and corrective actions taken shall be documented and reported to the appropriate levels of management."

Contrary to this requirement, on April 22, 2009, Conval failed to effectively implement corrective actions for findings identified in NRC Inspection Report 99901367/2007-201. Specifically:

- a. Conval's December 13, 2007, letter stated that it had corrected the misuse of the terms, "defect," "deviation," and "failure to comply" in its 10 CFR Part 21 procedure, CP-0240, as a corrective action for Violation 99901367/2007-201-1. However, the NRC inspectors found that many instances still remained in which these terms were misused, despite a concise identification of the issues in NRC Inspection Report 99901367/2007-201.
- b. Nonconformance 99901367/2007-201-2a stated that QP-0006, "Dedication of Commercial Grade Items for Nuclear Safety Related Applications," dated December 13, 2006, did not include the appropriate 10 CFR 21.3 definition for a commercial grade item (CGI) as it applies to nuclear power plants licensed pursuant to 10 CFR Part 50. In Conval's letter dated December 13, 2007, Conval committed to revising QP-0006 to reflect that the dedication process is intended for use for nuclear power plants licensed pursuant to 10 CFR Part 50 as a corrective action for Nonconformance 99901367/2007-201-2a. However, Conval corrective action report (CAR) 641 closed out the Nonconformance by saying that a review of the definition for CGI in the current NRC 10 CFR Part 21 revealed that the Conval definition in QP-0006 was the same as the NRC one and required no revision. The action taken by Conval was incorrect and was also inconsistent with the corrective actions provided to the NRC in its letter.
- c. As a corrective action to prevent recurrence of Nonconformance 99901367/2007-201-2a, Conval's letter to the NRC and CAR 633/641 committed to revising procedure CP-0090, "Quality System Management Reviews," dated February 27, 2008, to add an annual review of the latest edition of 10 CFR Part 21 with the quality manual and implementing procedures to ensure that Conval's 10 CFR Part 21 program is in compliance with the most current 10 CFR Part 21 requirements. This annual review was added as part of the 10 CFR 50-Appendix B quality program review, which is required to be completed during the second quarter of each calendar year. Contrary to these requirements, as of April 22, 2009, no review of Conval's quality manual and implementing procedures had been documented, nor had a 10 CFR 50 - Appendix B program review been conducted during this timeframe.
- d. Conval's December 13, 2007, letter to the NRC stated that the "procedure for the control of nonconformances will be revised to include the control of nonconforming

processes that are adverse to quality...to be completed by Dec. 31, 2007.” However, the NRC inspectors found that procedure QP-0015, “Control of Nonconformances,” dated April 15, 2009, did not provide guidance for the identification, documentation, evaluation, or disposition of nonconforming processes or activities.

These issues have been identified as Nonconformance 99901367/2009-201-03.

4. 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.”

Contrary to the above, on April 22, 2009, Conval procedures failed to provide guidance for the organization to identify and document conditions adverse to quality so that they could be corrected. Specifically, Conval procedure QP-0016, “Corrective Action,” dated May 27, 2008, states that the Quality Assurance Manager is responsible for generating all CARs. The procedure provides no other method for other employees to identify, report, or document conditions adverse to quality.

This issue has been identified as Nonconformance 99901367/2009-201-04.

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 Chief, John A. Nakoski, Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, 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 noncompliances; 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), 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 Website 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 at Rockville, Maryland, this 27th day of May 2009.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT

Docket No.: 999-01367

Report No.: 99901367/2009-201

Vendor: Conval, Inc.
265 Field Road.
Somers, CT 06071-1049

Vendor Contacts: Donald L. Curtin
President and General Manager
860-749-0761
dcurtin@conval.com

Mr. Brian S. Nichols
Quality Assurance Manager
860-749-0761
bnichols@conval.com

Nuclear Industry: Conval manufactures a variety of ½ through 4-inch, Y, Angle and
Activity: T Pattern Globe Stop and Stop-Check Valves, and T Pattern
Bellow Seal Globe Valves at this facility.

Inspection Dates: April 21-22, 2009

Inspectors: Sabrina D. Cleavenger Team Leader, NRO/DCIP/CQVB
Garrett Newman NRO/DCIP/CQVB
Wesley Deschaine NRO/DCIP/CQVB (training)

Approved by: /RA/ 5/27/2009
John A. Nakoski, Chief Date
Quality and Vendor Branch 2
Division of Construction Inspection
& Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Conval Incorporated
99901367/2009-201

The purpose of the inspection was to review the Conval Incorporated (Conval) corrective action activities described in the Conval letter dated December 13, 2007, "Replies to Notice of Violation 99901367/2007-201-I; Notice of Nonconformance's 99901367/2007-201-1, 99901367/2007-201-2a, 99901367/2007-201-2b, and 99901367/2007-201-2c," that responded to the NRC Inspection Report 99901367/2007-201, Notice of Violation and Notice of Nonconformance dated October 16, 2007. The inspection was conducted at Conval's facility in Somers, Connecticut.

The NRC inspection bases were the following:

- 10 CFR Part 21
- Appendix B to 10 CFR Part 50

The NRC staff implemented Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors" and Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance," during the conduct of this inspection.

During the NRC inspection at Conval, daily meetings were conducted between the NRC inspectors and Conval staff to discuss ongoing inspection activities and observations and/or potential findings.

The last NRC inspection conducted at Conval's facility in Somers, Connecticut, occurred in August 2007. During that inspection, the NRC inspectors identified one violation and four nonconformances; a summary of each is included below:

- Violation 99901367/2007-201-1 was issued because Conval failed to adopt an appropriate procedure for the identification, evaluation, and reporting of defects and failures to comply under 10 CFR Part 21.
- Nonconformance 99901367/2007-201-1 was issued because Conval failed to adequately implement documented procedures affecting quality.
- Nonconformance 99901367/2007-201-2a was issued because Conval's procedures governing commercial-grade dedication, an activity affecting quality, did not include the appropriate 10 CFR 21.3 definition for a commercial grade item as it applies to nuclear power plants licensed pursuant to 10 CFR Part 50.
- Nonconformance 99901367/2007-201-2b was issued because of Conval's failure to independently verify and validate the valve flow coefficient values (Cv) for safety-related valve calculations for use in safety-related applications.
- Nonconformance 99901367/2007-201-2c was issued as a result of the failure of Conval procedure QP-0015, "Nonconforming Material Control," dated September 25, 2003, to address "Parts and Components;" require documentation of conditions adverse to quality; solicit corrective actions to correct the conditions adverse to

quality, and require verification that the recommended corrective action was satisfactory and complete.

During its April 2009, inspection, the NRC inspectors concluded that the corrective actions taken by Conval in response to the findings contained in NRC Inspection Report 99901367/2007-201, Notice of Violation, and Notice of Nonconformance were effectively implemented and were in compliance with the applicable requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50, with the exception of the areas described below:

Violation 99901367/2009-201-01

The NRC inspectors identified Violation 99901367/2009-201-01 based on inadequate procedural guidance to implement the requirements of 10 CFR Part 21. Specifically, Conval's 10 CFR Part 21 implementing procedure misused the terms "defect" and "deviation" throughout the body of the document, and neglected to include "failures to comply" in the guidance for implementing 10 CFR Part 21. Additionally, Conval's procedure for the control of nonconformances required Conval quality assurance (QA) staff to review nonconformances captured on reject tags for the applicability of 10 CFR Part 21; however, there was no documented evidence that such reviews had been completed. These issues are further discussed in Sections 1 and 5 of this report.

Nonconformance 99901367/2009-201-01

The NRC inspectors identified Nonconformance 99901367/2009-201-01 as a result of Conval's failure to incorporate the appropriate regulatory requirements into its dedication program documents and to establish an effective, consistent program for commercial grade dedication. This issue is further discussed in Section 3 of this report.

Nonconformance 99901367/2009-201-02

The NRC inspectors identified Nonconformance 99901367/2009-201-02 because Conval's nonconformance procedure, QP-0015, "Control of Nonconformances," dated April 15, 2009, failed to provide adequate and complete instructions for staff members to identify and document nonconforming processes and activities to prevent further processing, delivery, installation, and use of nonconforming items. This issue is further discussed in Section 5 of this report.

Nonconformance 99901367/2009-201-03

The NRC inspectors identified Nonconformance 99901367/2009-201-03 in response to Conval's failure to effectively implement corrective actions for findings identified in NRC Inspection Report 99901367/2007-201. This issue is further discussed in Sections 1, 3, and 5 of this report.

Nonconformance 99901367/2009-201-04

The NRC inspectors identified Nonconformance 99901367/2009-201-04 because Conval's corrective action procedure, QP-0016, "Corrective Action," dated May 27, 2008, failed to provide adequate guidance for staff level personnel to identify and document conditions adverse to quality so that they could be corrected. This issue is further discussed in Section 5 of this report.

REPORT DETAILS

1. REVIEW OF CORRECTIVE ACTIONS - VIOLATION 99901367/2007-201-1

a. Inspection Scope

The NRC inspectors reviewed Conval corrective action records, quality assurance program implementing procedures, training records, and additional documents, as applicable, associated with the corrective actions Conval has implemented in response to Violation 99901367/2007-201-1 to verify compliance with the requirements of 10 CFR Part 21. Specifically, the NRC inspectors reviewed the following documents:

- Conval Corrective Action Report (CAR) 631, dated December 7, 2007
- Conval Corporate Procedure (CP) 0240, "Implementation of 10CFR21," revisions dated November 6, 2003, and April 20, 2009

b. Observations and Findings

Violation 99901367/2007-201-1 was issued because Conval's 10 CFR Part 21 implementing procedure, QCP-0240, "Implementation of 10 CFR 21," dated November 6, 2003, failed to provide sufficient guidance to ensure that deviations and failures to comply would be evaluated to determine whether they were associated with substantial safety hazards.

In Conval's response letter to the NRC, dated December 13, 2007, Conval stated that it had performed the following corrective actions:

- Revised the definitions contained in CP-0240 to be consistent with those contained in 10 CFR Part 21;
- Added language in CP-0240 to distinguish Commercial Quality Components - a Conval definition of non-nuclear related parts, from Commercial Grade Items - a 10 CFR Part 21 definition, clarified that Commercial Grade Items designated for dedication are subject to the requirements of 10 CFR Part 21, and eliminated former confusing language in that regard;
- Corrected the misuse of the terms "defect," "deviation," and "failure to comply" in CP-0240;
- Added the requirement to CP-0240 to perform an evaluation relative to product operability, functionality and potential safety related hazards of any situation, condition or circumstance contrary to quality, as defined in 10 CFR Part 21;
- Restated records retention practices in CP-0240, Section 7, "Records" to conform with 21.51(a) and 21.51(b) of 10 CFR Part 21; and
- Added a requirement to CP-0240 to require that conditions or circumstances adverse to quality that relate to a basic component as reported on corrective action reports undergo a screening to determine 10 CFR Part 21 applicability.

The NRC inspectors verified that Conval had appropriately revised the definitions for the terms basic component, dedication, and defect to be consistent with the current regulations;

however, the inspectors did note that Conval included the entire definitions for these terms (portions applicable to nuclear power plants *and* facilities other than nuclear power plants) from the regulations, even though only the former portion of the definitions applies to Conval's scope of supply. Upon discussion of Conval's use of the incorrect definition for commercial grade item (CGI) in its dedication procedure (as initially identified in Nonconformance 99901367/2007-201-2a), Conval was able to understand the proper application of these definitions. Upon opening CAR 764 for a revision to CP-0240, Conval included actions to revise the definitions to be consistent with Conval's scope of supply.

The NRC inspectors verified that Conval had added language to distinguish Commercial Quality Components from Commercial Grade Items in CP-0240. In an effort to clarify the requirements of 10 CFR Part 21 for dedicated CGIs, Conval added the following statement to CP-0240: "Commercial quality components whether purchased or manufactured by Conval for non-nuclear industry use, are not subject to the regulations of 10 CFR Part 21 until and unless they have been designated to undergo commercial grade dedication for use as a basic component." Although commercial grade items are not subject to the requirements of 10 CFR Part 21 until after they have completed the dedication process and are basic components, Conval has elected to exercise the requirements of 10 CFR Part 21 on CGIs during the dedication process. Although this intent is expressed in the Purpose statement of CP-0240, the body of the procedure does not provide instructions to Conval staff to exercise the 10 CFR Part 21 identification, evaluation, and notification processes for CGIs as it does for basic components. Because the application of 10 CFR Part 21 to CGIs during dedication is not a regulatory requirement, this issue was identified to Conval's QA manager for disposition.

Conval's December 13, 2007, letter stated that it had corrected the misuse of the terms, "defect", "deviation," and "failure to comply" in CP-0240. However, the NRC inspectors found that many instances still remained in which these terms were misused, despite a concise identification of the issues in NRC Inspection Report 99901367/2007-201. Conval's failure to effectively implement its corrective action program to resolve this previously identified violation of NRC requirements has been included as an example of Nonconformance 99901367/2009-201-03.

Paragraph 3.2 of CP-0240 states that "The president, or in his absence, another Corporate officer is responsible for notifying the NRC of all suspected defects and deviations." Vendors are required to notify the NRC of failures to comply with NRC regulations (as discussed later in this section) and defects in basic components that could cause a substantial safety hazard if left uncorrected. The use of the phrase "suspected defects and deviations" is unclear because there is no reporting requirement for suspected defects and deviations. 10 CFR Part 21 requires reporting of defects and failures to comply; it should also be noted that vendors are not required to notify the NRC of deviations, unless the vendor is unable to perform an evaluation of the deviation within 60 days of discovery, at which time the vendor must submit an interim report to the NRC.

Similarly, paragraph 6.0, "Notification," of CP-0240 requires Conval's President to notify the NRC by phone or facsimile within 2 days and in writing within 30 days of receiving information on a "reportable defect or deviation." The 2 day initial notification and 30 day written notification apply only to defects and failures to comply. The only notification applicable to a deviation would occur when the vendor is unable to complete its evaluation of a deviation within 60 days of discovery, as stated above.

CP-0240 neglects, in multiple paragraphs, to include “failures to comply” in the guidance for implementing 10 CFR Part 21. For example:

- Paragraph 3.2 states that “The President or, in his absence, another Corporate officer is responsible for notifying the NRC of all suspected defects and deviations.”
- Paragraph 5.2 states that the engineering manager is responsible for evaluating the “reported condition, potential defect, or deviation” to determine if a reportable condition exists.
- Paragraph 6 requires Conval’s president to notify the NRC of any “reportable defect or deviation.”

In addition to evaluating deviations to determine if they could be associated with substantial safety hazards, Conval is responsible for evaluating 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 to determine if the failure to comply is reportable under 10 CFR Part 21.

The failure of Conval to translate the requirements of 10 CFR Part 21 into CP-0240 has been identified as Violation 99901367/2009-201-01. Conval opened CAR 764, dated April 22, 2009, to address the issues identified in this violation.

NRC Inspection Report 99901367/2007-201 identified that the retention times required for Part 21 documents, although not required to be part of the procedure, were not consistent with the requirements of the current regulation. The NRC inspection team verified that these retention times in QCP-0240, dated April 20, 2009, had been corrected to be consistent with the regulations.

c. Conclusions

Except for the examples identified in Violation 99901367/2009-201-01 and Nonconformance 99901367/2009-201-03, the NRC inspectors concluded that the corrective actions Conval implemented in response to Violation 99901367/2007-201-1 were consistent with the regulatory requirements of 10 CFR Part 21 and were effectively implemented.

2. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99901367/2007-201-1

a. Inspection Scope

The inspectors reviewed Conval’s corrective and preventive actions associated with Nonconformance 99901367/2007-201-1, which was identified during the August 2007, NRC inspection.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- QP-003, “Sampling Inspection,” revisions dated March 14, 2005, April 9, 2009, and April 18, 2008
- Indoctrination & Training Record, Subject: Sample Inspection per QP-003, dated November 29, 2007
- Training Session Report, Subject: Revised Quality Procedures, dated April 20, 2009

b. Observations and Findings

During the August 2007, inspection, the inspectors identified Nonconformance 99901367/2007-201-1 with NRC requirements for Conval's failure to adequately implement documented procedures affecting quality. Specifically, Conval did not perform sampling as prescribed in its established sampling procedure QP-003, dated March 14, 2005.

Conval initiated CAR 640 to address Nonconformance 99901367/2007-201-1 and identify actions taken to prevent recurrence. CAR 640 stated that the root cause of this nonconformance was that the Conval inspector failed to follow the sampling procedure, QP-003, while performing a sample inspection. In the evaluation section of CAR 640, Conval stated that a final inspection of completed items' critical dimensions would be done as the parts were produced. CAR 640 stated that the corrective action to address the nonconformance and to preclude recurrence was to train all Conval inspectors in the use of the sampling plan procedure.

The NRC inspectors reviewed the training record dated November 29, 2007, for the training given on procedure QP-003, dated March 14, 2005 (the revision that was identified in the CAR 640). Since the August 2007, NRC inspection, Conval has updated QP-003. The most current revision is dated April 18, 2008. The inspectors also reviewed the training record for the training given on this revision. The training was conducted on April 20, 2009. All of the appropriate personal for Conval completed each training session. Initial training to satisfy CAR 640 was completed by the due date of December 15, 2007. The inspectors observed a sample receipt inspection to verify that the training was effective. The sample was taken from 276 size 3 glands, part number 1130, material code D01-BJF. According to Conval's sample procedure, 14 pieces were to be randomly selected, and characteristics identified on the part's drawing were to be measured. The inspectors verified that these characteristics had been verified on the requisite number of parts and that Conval's procedure for sampling was adequately implemented.

c. Conclusions

The inspectors reviewed the corrective actions associated with Nonconformance 99901367/2007-201-1, as described in Conval CAR 640. The inspectors concluded that the corrective actions were completed as stated in the CAR and were effective in preventing recurrence of the condition. As such, Nonconformance 99901367/2007-201-1 is closed.

3. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99901367/2007-201-2a

a. Inspection Scope

The NRC inspectors reviewed Conval corrective action records, quality assurance program implementing procedures, training records, and additional documents, as applicable, associated with the corrective actions Conval has implemented in response to Nonconformance 99901367/2007-201-2a to verify compliance with the requirements of 10 CFR Part 21. Specifically, the NRC inspectors reviewed the following documents:

- Conval CAR 633/641, dated December 7, 2007
- Conval Quality Procedure (QP) 0006, "Dedication of Commercial Grade Items for Nuclear Safety Related Applications," revisions dated December 13, 2006, and May 28, 2008

- Conval CP-0090, "Quality System Management Reviews," revisions dated May 17, 2006, and February 27, 2008

b. Observations and Findings

Nonconformance 99901367/2007-201-2a identified that Conval's procedure for commercial grade dedication, QP-0006, dated December 13, 2006, did not contain the appropriate definition for commercial grade item. The procedure included the definition for commercial grade items as applied to facilities and activities *other than* nuclear power plants, which is inappropriate since the procedure applies to dedication of CGIs for nuclear power plants.

Conval initiated CAR 633 (changed to CAR 641 as a result of a database change), dated December 7, 2007, in response to the nonconformance. The CAR initiated a review of QP-0006 to verify that the procedure is complete and current with the latest NRC requirements and was closed on April 17, 2009, with the following remarks: "Verified QP-0006, 5-28-08 definition of Commercial Grade Item is the same as that contained in 10CFR21 on nrc.gov dated 2/27/09. CP-0090, 2-27-08 par 3.4 includes a review of current 10CFR21 to the QA manual and implementing procedures. Reviewed QA training record for QP-[0]006."

The NRC inspectors reviewed the definition of CGI contained in the latest revision of QP-0006 (dated May 28, 2008) and found that it had not been revised. The definition still contained the definition for CGIs as applied to facilities and activities *other than* nuclear power plants. As identified in 10 CFR 21.3, "Definitions," there are two definitions for CGIs: definition (1) applies to nuclear power plants licensed pursuant to 10 CFR Parts 30, 40, 50, and 60 whereas definition (2) applies to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72. Conval's failure to incorporate the appropriate definition of CGI in its dedication procedure for safety-related nuclear work (QP-0006) has been identified as Nonconformance 99901367/2009-201-01. Conval initiated CAR 765, dated April 22, 2009, to revise the definition to be consistent with Conval's scope of supply.

In Conval's letter dated December 13, 2007, Conval identified the following corrective action measures to address Nonconformance 99901367/2007-2a: "Procedure QP-0006 will be revised to reflect that the dedication process is intended for use for nuclear power plants licensed pursuant to 10 CFR Part 50." However, Conval CAR 641 closed out the Nonconformance by saying that a review of the definition for CGI in the current 10 Part 21 revealed that the Conval definition in QP-0006 was the same as the NRC definition and required no revision. The action taken by Conval was inconsistent with the corrective actions provided to the NRC. Conval's failure to effectively implement its corrective action program to resolve this previously identified nonconformance with NRC requirements has been included as an example of Nonconformance 99901367/2009-201-03.

The NRC inspectors discussed the finding with Conval staff and found that Conval had evaluated the definitions but had not understood which to use because Conval itself is not an NRC licensed facility. The NRC inspectors explained that because Conval dedicates safety-related components for use in nuclear power plants, it is subject to definition (1) of commercial grade item and needs to incorporate that definition into QP-0006 and related dedication documents.

As a corrective action to prevent recurrence of Nonconformance 99901367/2007-201-2a, Conval's letter to the NRC and CAR 633/641 committed to revising procedure CP-0090, "Quality System Management Reviews," dated February 27, 2008, to add an annual review

of the latest edition of 10 CFR Part 21 with the quality manual and implementing procedures to ensure that Conval's 10 CFR Part 21 program is in compliance with the most current 10 CFR Part 21 requirements. This annual review was added as part of the 10 CFR 50 - Appendix B quality program review, which is required to be completed during the second quarter of each calendar year. Contrary to these requirements, as of April 22, 2009, no review of Conval's quality manual and implementing procedures had been documented, nor had a 10 CFR 50 - Appendix B program review been conducted during this timeframe. Conval staff supplied the NRC with a draft copy of the 2008 Quality System Review (which combined the ISO, Appendix B, and ASME program reviews). This draft report, however, did not include any statements asserting that program documents had been reviewed for compliance with the latest NRC requirements, as committed to in the CAR and CP-0090.

Conval's failure (1) to implement an annual review of Conval QA Manual and Implementing Procedures with the latest revision of 10 CFR Part 21, as committed to in CP-0090, CAR 633/641, and Conval's December 2007, letter to the NRC and (2) to perform the annual 10 CFR 50 - Appendix B quality program review, as required by CP-0090 has been identified as an example of Nonconformance 99901367/2009-201-03.

c. Conclusions

The NRC inspectors concluded that the corrective actions Conval implemented in response to Nonconformance 99901367/2007-201-2a were inadequate and inconsistent with the regulatory requirements of Appendix B to 10 CFR 50 and 10 CFR Part 21. Nonconformance 99901367/2007-201-2a has been reissued as Nonconformance 99901367/2009-201-01. Additionally, Conval's failure to implement its corrective action program effectively to achieve an acceptable resolution of the nonconformance through (1) a revision to QP-0006 and (2) the implementation of an annual review of Conval policies and procedures for consistency with the latest NRC regulatory requirements has been identified as an example of Nonconformance 99901367/2009-201-03.

4. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99901367/2007-201-2b

a. Inspection Scope

The inspectors reviewed Conval's corrective and preventive actions associated with Nonconformance 99901367/2007-201-2b, which was identified during the August 2007 NRC inspection, as documented in Conval's letter to the NRC, dated December 13, 2007, and CAR 642. The inspectors reviewed the original and revised procedures for engineering analysis verification and validation. The inspectors also reviewed a sample of software validation records for later versions of the Blue Ridge Numerics Computational Fluid Dynamics software using the revised procedure. The documents reviewed include:

- Engineering Procedure (EP)-0012, "Analysis Verification and Validation," dated July 3, 2003
- Special Engineering Instruction (SEI)-123-1, "CF Design 5.0 Validation," dated November 10, 2006
- SEI-123-3, "CF Design 8.0 Validation," dated November 10, 2006
- EP-0012, "Analysis Verification and Validation," dated October 25, 2007
- Training Record for "Verification and Validation of Engineering Analyses," dated December 21, 2007
- EP-0012, "Analysis Verification and Validation," dated April 17, 2009

- Training Record for “Analysis Verification and Software Validation,” Dated April 17, 2009
- FE025, “Engineering Analysis Verification and Validation,” for “Validation of CF Design Version 10.0-20080919 Using Yarmouth Test Report 20760,” dated October 21, 2008

b. Observations and Findings

Nonconformance 99901367/2007-201-2b identified that Conval failed to independently verify and validate the valve flow coefficient values (Cv) computed using Blue Ridge Numerics Computational Fluid Dynamics software for valves provided for use in safety-related applications. Rather, Conval compared Cv values with those established by a competitor without ascertaining the quality of the calculation.

Conval initiated CAR 642, dated December 7, 2007 (number and date may differ due to database change), to document Nonconformance 99901367/2007-201-2b for evaluation and corrective action. The CAR identified the following corrective actions: the revision of EP-0012 to specify the correct verification and validation requirements, the creation of a new form and log for flow analyses, and the training of all engineers on the procedure revision.

In Conval’s response letter to the NRC, dated December 13, 2007, Conval stated that it had revised EP-0012 to clearly define 10CFR50, Appendix B requirements. Specifically, Conval described its revised process to require the following steps:

- each analysis performed for a nuclear component or product is logged for traceability,
- the analysis is independently verified,
- the analysis is validated by another person, and
- these verification and validation activities are logged.

The NRC inspectors reviewed the revised EP-0012 and verified that Conval included these steps adequately. The inspectors also reviewed training records that demonstrated that engineers who had previously used the old procedure were trained on the revised procedure. Additionally, the inspectors verified that a recent software validation had been conducted in accordance with the new procedure and that the valve flow coefficient value was independently verified. For the sampled validation, Conval compared Cv values generated by the Computational Fluid Dynamics Design program to values obtained through testing of its valves at the Yarmouth Research and Testing facility. This verification was documented using the newly created separate form for flow analyses, FE025, “Engineering Analysis Verification and Validation.”

c. Conclusions

No findings of significance were identified. The NRC inspectors found that Conval adequately implemented the corrective actions specified in their letter to the NRC dated December 13, 2007, and CAR 642. Nonconformance 99901367/2007-201-2b is closed.

5. REVIEW OF CORRECTIVE ACTIONS - NONCONFORMANCE 99901367/2007-201-2c

a. Inspection Scope

The inspectors reviewed Conval's corrective and preventive actions associated with Nonconformance 99901367/2007-201-2c, which was identified during the August 2007, NRC inspection.

Within the scope of this area of the inspection, the NRC inspectors reviewed the following procedures, records, and other documents:

- QP-0015, "Control of Nonconformances," revisions dated September 25, 2003, February 8, 2008, and April 15, 2009
- Training Session Report, Subject: Revised Quality Procedures, dated April 20, 2009
- Quality Assurance Program Manual (QAM), Rev. 1, Section 16.0, "Corrective and Preventative Action," dated May 5, 1995
- Rejection Tag Number 23023, dated November 13, 2008
- Rejection Tag Number 22268, dated August 20, 2008
- QP-0016, "Corrective Action," revisions dated February 6, 2007 and May 27, 2008

b. Observations and Findings

During the August 2007, inspection, the NRC inspectors identified Nonconformance 99901367/2007-201-2c as a result of the failure of Conval procedure QP-0015, dated September 25, 2003, to require documentation of conditions adverse to quality, solicit corrective actions to correct the conditions adverse to quality, and require verification that the recommended corrective actions were satisfactory and complete. The procedure also failed to address "Parts and Components," as required by Appendix B to 10 CFR Part 50.

Conval initiated CAR 635 to address the nonconformance and to identify corrective actions to preclude recurrence. CAR 635 stated that the root cause of this nonconformance was that Conval procedure QP-0015, dated September 25, 2003, should have had a place for a review to determine if a CAR was required. CAR 635 stated that the corrective action to address the nonconformance and to preclude recurrence was to revise QP-0015 to address nonconformances and subsequent corrective actions, as required by Appendix B to 10 CFR Part 50 and applicable ASME Codes.

The inspectors reviewed the latest revision to QP-0015 and found that words were added to adequately address "Parts and Components" and require nonconforming conditions to be captured in a document, such as a reject tag, to identify the condition adverse to quality. Conval added requirements to review nonconformances for the need to initiate a CAR and to evaluate 10 CFR Part 21 applicability. Conval modified the reject tag to add a signature space labeled "Reviewed for Corrective Action" for the QA manager's signature. While this provides verification that the need for corrective action for a nonconforming material, part, or component has been considered, the reject tag fails to provide verifiable evidence that a review for 10 CFR Part 21 applicability has been performed. Consequently, the reject tag does not provide the basis for a decision that an evaluation of the deviation under 10 CFR Part 21 is not necessary (i.e., an explanation of why Part 21 does not apply to the rejected item).

This issue has been identified as an example of Violation 99901367/2009-201-01.

In Conval's letter dated December 13, 2007, Conval identified its corrective action for Nonconformance 99901367/2007-201-2c as a revision to QP-0015 to include "control of nonconforming processes that are adverse to quality." The inspectors reviewed the subsequent and most recent revisions to QP-0015. The inspectors identified that while nonconforming processes and activities were added to Section 1.0, "Purpose," the body of the procedure, Section 4.0, "Procedure," did not give guidance for the identification, documentation, evaluation, or disposition of nonconforming processes or activities.

Conval's failure to establish an acceptable procedure to identify, document, and correct nonconformances in material, parts, and components and the activities and processes related thereto, as required by Criterion XV of 10 CFR 50, Appendix B, has been identified as Nonconformance 99901367/2009-201-02. Furthermore, Conval's failure to implement an effective corrective action program to correct the issues identified Nonconformance 99901367/2007-201-2c and to complete actions documented in Conval's letter to the NRC has been identified as an example of Nonconformance 99901367/2009-201-03.

During the August 2007, inspection, the inspectors identified that Conval's corrective action procedure, QP-0016, was deficient; however, QP-0016 was not identified as an inadequate procedure because the NRC inspectors identified that Conval would have to revise the procedure in parallel with QP-0015 to bring Conval into compliance with Appendix B of 10 CFR 50. A specific deficiency noted in the report was that QP-0016 specified that the QA Manager was responsible for generating all CARs; however, to achieve compliance with Appendix B to 10 CFR 50, anyone who identifies a condition adverse to quality must be able to document it. The NRC inspectors found that the most recent revision of QP-0016 at the time of the inspection (dated May 27, 2008) still specifies that the QA Manager is responsible for generating all CARs, and there is no other method for other employees to identify, report, or document conditions adverse to quality. Conval's failure to include individuals other than the QA Manager in the corrective action program has been identified as Nonconformance 99901367/2009-201-04.

c. Conclusions

Except for the examples identified in Violation 99901367/2009-201-01, Nonconformance 99901367/2009-201-02, Nonconformance 99901367/2009-201-03, and Nonconformance 99901367/2009-201-04, the NRC inspectors concluded that the corrective actions Conval implemented in response to Nonconformance 99901367/2007-201-2c were acceptable.

6. ENTRANCE AND EXIT MEETINGS

On April 21, 2009, the NRC inspectors discussed the scope of the inspection with Frank Siver, CEO; Donald L. Curtin, President; and other members of Conval management and staff. On April 22, 2009, the NRC inspectors presented the inspection results and observations during an exit meeting with Frank Siver, CEO; Donald L. Curtin, President; and other Conval management and engineering staff. A list of entrance/exit meeting attendees is included as an attachment to this report.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND KEY PERSONS CONTACTED

<u>NAME</u>		<u>TITLE</u>	<u>ENTRANCE</u>	<u>EXIT</u>	<u>INTERVIEWED</u>
Brian S. Nichols	Conval	Quality Assurance Manager	√	√	√
Frank A. Siver	Conval	Chairman & CEO	√	√	
Donald L. Curtin	Conval	President – General Manager	√	√	
Charles A. Sumner	Conval	Vice President Engineering	√	√	√
Dudley D. Williams	Conval	Vice President & Controller	√	√	
Austin C. Wilkie	Conval	Inside Sales & Marketing Manager	√	√	
John Volungis	Conval	Operations Manager	√	√	
Jeremiah J. O'Callaghan, P.E.	Conval	Senior Engineer			√
Greg Winston	Conval	Quality Assurance Specialist			√
Brian Ryder	Conval	Inspector Lead			√
Wesley Deschaine	USNRC	Inspector	√	√	
Sabrina Cleavenger	USNRC	Lead Inspector	√	√	
Garrett Newman	USNRC	Inspector	√	√	

2. INSPECTION PROCEDURES USED

Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors."

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance."

3. LIST OF ITEMS OPEN, CLOSED AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901367/2007-201-I	Closed*	NOV	Violation of 10 CFR Part 21
99901367/2007-201-1	Closed	NON	Criterion V
99901367/2007-201-2a	Closed*	NON	Criterion V
99901367/2007-201-2b	Closed	NON	Criterion III
99901367/2007-201-2c	Closed*	NON	Criterion V, XV, and XVI
99901367/2009-201-01	Opened	NOV	Violation of 10 CFR Part 21
99901367/2009-201-01	Opened	NON	Criterion III and V
99901367/2009-201-02	Opened	NON	Criterion XV
99901367/2009-201-03	Opened	NON	Criterion XVI
99901367/2009-201-04	Opened	NON	Criterion V and XVI

* Violation or Nonconformance has been closed but a related finding has been opened due to (1) a failure to implement adequate corrective actions to resolve all issues identified in the initial finding, (2) new inadequacies that were identified as a result of the corrective actions performed by the vendor, or (3) a failure to implement corrective actions as defined in the vendor's response letter to the NRC's most recent inspection report, Notice of Violation, and/or Notice of Nonconformance.