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June 26, 2009

United States Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555

Copy To:
Mr. John A. Nakoski
Mail Stop T-7F3
Washington, DC 20555

Subject: NRC Inspection Report No. 99901367/2009-201
Notice of Violation 99901367/2009-201-01
Notice of Nonconformance's 99901367/2009-201-01, 99901367/2009-201-02, 99901367/2009-201-03, and 99901367/2009-201-04.

Reference: Reply to a Notice of Violation & Reply to Nonconformances

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

Dear Mr. Nakoski,

Conval has reviewed the information contained in your letter dated May 27, 2009 documenting the Inspection performed at Conval's Somers, CT facility on April 21 and 22, 2009 and provides the following reply:

Notice of Violation 99901367/2009-201

1) Reason for the Violation:
Conval's interpretation of the definitions of deviation and defect as defined in 10 CFR Part 21 was incorrect. Conval understood "failure to comply" as included in the term deviation and defect and did not understand the correct use of failure to comply as a separate term.

Conval felt that reviewing the Reject Tag for corrective actions was adequate as it was implied that it included a review of the need for evaluation under Part 21.

2) Corrective Steps Taken and Results Achieved:
Procedure CP-0240 has been significantly revised to comply with the very specific language of the current version of 10 CFR Part 21. Included in the revision is the proper use of the terms "defect", "deviation" and "failure to comply". These terms have been incorporated into a revised procedure to clearly specify that deviations and other defined circumstances shall be evaluated, and that only defects and failures to comply will be reported to the NRC, should they prove to be a substantial safety hazard based on our evaluation. All terms have been defined precisely per Part 21, and in addition a definition has been added for Failure to Comply.

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Extreme care has been taken to ensure that all definitions have been correctly used and invoked throughout the new procedure. The revision is dated June 24, 2009 and was issued on June 25, 2009. The result is that Conval has a procedure that accurately reflects the requirements of 10 CFR Part 21 that will serve as a basis for training of individuals and for evaluating deviations and failures to comply.

The Reject Tag form will be revised to include a space for the Quality Assurance Manager to document a review of the nonconformance to determine if an evaluation is required under 10 CFR Part 21. QP-0015 has been revised to specify the nature and extent of this review. Reject Tags processed between Feb. 8, 2008 and until the updated Reject Tags have been fully implemented will be reviewed by the Quality Assurance Manager for evaluation under 10 CFR Part21 and this review will be documented in writing on the individual Reject Tag. QP-0015 has also been revised to permit this as an optional measure as required.

3) Corrective Steps That Have Been Taken To Avoid Further Violations:
Key management personnel have been involved in preparing procedures for implementation of 10 CFR Part 21 requirements and have studied the Part 21 document in detail. This involved the President, Vice President Engineering, Quality Assurance Manager and Sales Supervisor. This group met several times to assure that all aspects of the procedure were being correctly reviewed and revised. Training sessions for all Conval personnel are being scheduled to train all personnel on the newly revised procedures.

The Reject Tag form is being updated to include space for documenting a review for Part 21 evaluation.

4) Date When Full Compliance Will Be Achieved:
Revision of procedure CP-0240 was completed on June 24, 2009 and issued on June 25, 2009. Training of Conval personnel in CP-0240 will be completed by July 31, 2009.

Procedure QP-0015 was revised on June 24, 2009 and issued on June 25, 2009. Training of affected personnel will be completed by July 31, 2009, Quality Department personnel will be trained by June 31, 2009.

The Reject Tag will be revised no later than June 30, 2009 and implemented immediately. In the interim The Quality Assurance Manager shall document his review of the Reject Tag for evaluation under Part 21 in writing. Full compliance will be completed once the existing Reject Tags are processed through the system and filed. Conval expects this to be complete by July 31, 2009. Review of Reject Tags processed between Feb 8, 2008 and June 24, 2009 will be completed by August 31, 2009.

Notice of Nonconformance 99901367/2009-201-01

1) Reason for the Noncompliance:
Conval incorrectly selected the wrong definition from Part 21 for commercial grade item with the reasoning that the definition selected referred to Conval as it was thought that the phrase "other than nuclear power plants" applied to activities at Conval.

2) Corrective Steps Taken and Results Achieved:
Procedure QP-0006 has been revised to include the correct definition of commercial grade item. Personnel involved in commercial dedication activities have been trained in the changes to QP-0006. The result is that Conval personnel now understand the proper definition of commercial grade items in accordance with 10CFR Part 21.

3) Corrective Steps That Have Been Taken To Avoid Further Noncompliances:
The procedure is now compliant with 10CFR Part 21; current and future training will prevent any further noncompliance.

4) Dates Corrective Action Will Be Completed:
Procedure QP-0006 was revised and distributed on April 21, 2009. Training of Conval personnel will be completed no later than July 31, 2009

Notice of Nonconformance 99901367/2009-201-02

1) Reason for the Noncompliance:
Conval's revision of QP-0015 was not thorough enough to adequately provide guidance to personnel regarding identification, documentation, evaluation, or disposition of nonconforming processes or activities. It was incorrectly assumed that adding the requirement to the Scope of the procedure was sufficient to implement the identification and processing of nonconforming processes and activities.

2) Corrective Steps Taken and Results Achieved:
Procedure QP-0015 has been revised to include instructions throughout the procedure for identifying and documenting nonconforming activities and processes in addition to nonconforming items. Implementing guidance has been added to the Scope, Hold for Rejection Tag, Nonconformances and Material Review Board sections. The result achieved is that under the revised QP-0015 Conval has the ability to consider processes and activities in addition to items when documenting nonconformances due to the increased scope of guidance provided.

3) Corrective Steps That Have Been Taken To Avoid Further Noncompliances:
Procedure QP-0015 is now compliant with all aspects of Appendix B to 10CFR 50. Affected Conval personnel will be trained on the revised procedure. These actions will prevent further noncompliance.

4) Dates Corrective Action Will Be Completed:
Procedure QP-0015 was revised on June 24, 2009 and issued on June 25, 2009. Training of affected Conval personnel will be completed by July 31, 2009, Quality Department personnel will be trained by June 31, 2009.

Notice of Nonconformance 99901367/2009-201-03

1) Reason for the Noncompliance:
a. Conval failed to recognize the correct use of the terms defect, deviation and failure to comply due to incorrect interpretation of 10 CFR Part 21 requirements.

b. During close out of CAR 641 it appears that Conval's letter dated 12-13-07 was not considered and the wrong definition for 10 CFR Part 21 was once again accepted as being correct. The definition that was used and incorrectly accepted in closing out the CAR was derived from NQA-1 (1994). Conval now clearly understands that the definitions provided in 10 CFR Part 21 are the only definitions that are appropriate for use in procedures that implement 10 CFR Part 21.

c. The author of the annual review was remiss in not including an assessment of the latest 10 CFR Part 21 requirements. However, the review for 2009 was not overdue until the end of the second calendar Quarter (June 30) and was completed on June 19, 2009 and included an assessment of 10 CFR Part 21.

d. Conval's revision of QP-0015 was not thorough enough to adequately provide guidance to personnel regarding identification, documentation, evaluation, or disposition of nonconforming processes or activities. It was originally felt that adding the requirement to the Scope of the procedure was sufficient to implement the identification and processing of nonconforming processes and activities.

The **root cause** of this Nonconformance is that the process that Conval implemented to close out certain Corrective Action Requests resulted in incomplete or inadequate actions to resolve the nonconformity.

2) Corrective Steps Taken and Results Achieved:

a. Procedure CP-0240 has been significantly revised to comply with the current version of 10 CFR Part 21. Included in the revision is the proper use of the terms "defect", "deviation" and "failure to comply". The revision is dated June 24, 2009 and was issued on June 25, 2009. The result is that Conval has a procedure that accurately reflects the specific definitions and requirements of 10 CFR Part 21.

b. Procedure QP-0006 has been revised to include the correct definition of commercial grade item. Personnel involved in commercial dedication activities have been trained in the changes to QP-0006. The result is that Conval personnel now understand the proper definition of commercial grade items and have achieved compliance with 10 CFR Part 21.

c. The 2009 review of Conval's 10 CFR 50 App. B quality assurance program was completed on June 19, 2009 and included a review of 10 CFR Part 21 using the version posted on the NRC website. The 2008 review of the 10 CFR 50 App. B quality assurance program was amended on June 19, 2009 to include a comment addressing the lack of 10 CFR Part 21 review during the review process. These reviews have identified all procedures that implement 10 CFR Part 21 requirements and have identified specific points within these procedures that are to be corrected or upgraded and brought into full compliance with current NRC requirements.

d. Procedure QP-0015 has been revised to include instructions throughout the procedure for identifying and documenting nonconforming activities and processes in addition to nonconforming items. Implementing guidance has been added to the Scope, Hold for Rejection Tag, Nonconformances and Material Review Board sections. The result achieved is that under the revised QP-0015 Conval has specific procedures to use in reviewing processes and activities in addition to items when documenting nonconformances, as previously defined by the increased scope of the procedure.

Root Cause: Procedures CP-0240, QP-0006, QP-0015, QP-0016 and the quality program review document have been upgraded to accurately reflect the requirements of the regulation as noted throughout this letter.

3) Corrective Steps That Have Been Taken To Avoid Further Noncompliances:
a. Key management personnel have been involved in preparing procedures for implementation of 10 CFR Part 21 requirements and have studied the Part 21 document in detail. This involved the President, Vice President Engineering, Quality Assurance Manager and Sales Supervisor. This group met several times to assure that all aspects of the procedure were being correctly reviewed and revised. Training sessions for all Conval personnel are being scheduled to train all personnel on the newly revised procedures.

b. Procedure QP-0006 has been revised to include the correct definition of commercial grade item. Personnel involved in commercial dedication activities have been trained in the changes to QP-0006. The result is that Conval personnel now understand the proper definition of commercial grade items in accordance with 10 CFR Part 21.

c. The Quality Assurance Manager is aware of the requirement to include a review of the latest version of 10 CFR Part 21 as part of the Appendix B to 10 CFR 50 quality assurance program annual review. In addition procedure QP-0034 was prepared on May 9, 2009 to identify the reports required to be prepared by the quality department referencing the implanting system, manual or procedure to be followed for the required report.

d. Procedure QP-0015 is now compliant with all aspects of Appendix B to 10 CFR 50. Affected personnel will be trained on the revised procedure. These actions will prevent further noncompliance.

Root Cause: Conval's Corrective Action procedure QP-0016 was revised on June 22, 2009 to address the need for a more focused review of corrective action close out for those CARs associated with Codes, Standards, Regulations or Specification and for the resulting preparation of new or revised procedures. QP-0016 as revised June 22, 2009 requires that an expert in the field review corrective actions taken that are resultant from nonconformances with Codes, Standards, Regulations or Specification. It also requires that the Quality Work Group, consisting of the QA Manager, President, VP Production Control, VP Engineering, Manufacturing Manager and Sales Manager, review new and revised procedures prior to being issued in support of corrective actions.

4) Dates Corrective Action Will Be Completed:
a. Revision of procedure CP-0240 was completed on June 24, 2009 and issued on June 25, 2009. Training of Conval personnel in CP-0240 will be completed by July 31, 2009.

b. Procedure QP-0006 was revised on 4-21-09 and distributed on April 21, 2009. Training of Conval personnel will be completed no later than July 31, 2009

c. The quality assurance program review was completed on June 19, 2009.

d. Procedure QP-0015 was revised on June 24, 2009 and issued on June 25, 2009. Training of Conval personnel will be completed by July 31, 2009, Quality Department personnel will be trained by June 30, 2009.

Root Cause: QP-0016 was revised June 22, 2009. Distribution will be no later than June 30, 2009. Training for Conval personnel responsible to implement QP-0016 will be completed no later than July 31, 2009

Notice of Nonconformance 99901367/2009-201-04

1) Reason for the Noncompliance:
Conval initiates Corrective Action Request with the use of an ACCESS database. The use of this database is limited to ensure the security of data stored therein. The reason that QP-0016 stated that only the Quality Assurance Manager could prepare CARs was to limit access to the database to authorized persons. The intent was not to limit the ability to identify or report conditions adverse to quality to only the Quality Assurance Manager however, QP-0016 was not clear in this meaning.

2) Corrective Steps Taken and Results Achieved:
Procedure QP-0016 was revised on May 15, 2009 to allow any employee to request the initiation of a CAR. This revision was issued on June 1, 2009.

3) Corrective Steps That Have Been Taken To Avoid Further Noncompliances:
Procedure QP-0016 is now compliant with Appendix B to 10 CFR 50. This action will prevent further noncompliance.

4) Dates Corrective Action Will Be Completed:
Training of all Conval employees will be completed by July 31, 2009. Procedure was revised and issued on June 1, 2009. Note: Procedure QP-0016 was further amended on June 22, 2009 as a result of Notice of Nonconformance 99901367/2009-201-03, however changes made previously to address this particular nonconformance have not been changed

Our entire management team has worked diligently to ensure that all relevant procedures have been revised to thoroughly and completely agree with the requirements of the Nuclear Regulatory Commission. We believe that we now understand precisely what these requirements are and that we have succeeded in translating these requirements into a solid quality system by means of clear and complete procedures. We trust that the information we have provided describing our responses to the violation and the non-conformances will meet with your approval.

Please feel free to contact this office should you require additional information or clarification of the information provided.

Thank you for your consideration.
Very truly yours,

Brian S. Nichols
Quality Assurance Manager
Conval, Inc.

Cc: F. Siver, Chairman, CEO, Conval
D. Curtin, President, Conval
D. Williams, Vice President Finance, Conval
M. Hendrick, Vice President Sales and Marketing, Conval
C. Sumner, Vice President Engineering, Conval
I. Makuch, Sales Supervisor, Conval