Conval INC.

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December 13, 2007

United States Nuclear Regulatory Commission
Document Control Desk
Washington, DC 20555
Copy To:
Mr. John Nakoski
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Subject: 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.

Attention: Mr. John Nakoski, Chief Quality and Vendor 2, Office of New Reactors

Dear Mr. Nakoski,

Notice of Violation 99901367/2007-201-I

1) Reason for the Violation:

Longstanding language contained in Conval's 10 CFR Part 21 procedure, CP-0240, had been imprecise, inconsistent and incomplete since the first issuance of the procedure in 1990. There had been an apparent lack of understanding of the specific and exact definitions contained in 10 CFR Part 21, and as a consequence, the text contained in the resultant CP-0240 misapplied the Part 21 concepts as they related to Conval's applicable activities.

Furthermore, the language in the old procedure failed to recognize the variety of issues that could affect quality relative to 10 CFR 50, Appendix B and 10 CFR Part 21 definitions. Consequently proper compliance with 10 CFR 21 was not exercised.

2) Corrective Steps Taken:

In order to provide adequate guidance to document, evaluate and report all conditions adverse to quality to the appropriate personnel, the NRC and licensees, Conval's CP-0240 procedure which governs compliance with 10 CFR Part 21 has been rewritten and now incorporates the following:

A. Definitions contained in CP-0240 are now precisely equivalent to those contained in 10 CFR 21.

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C. Language was added to distinguish *Commercial Quality Components*—a Conval definition of non-nuclear related parts, from *Commercial Grade Items*—a 10 CFR 21 definition. CP-0240 makes it clear that *Commercial Grade Items* designated for dedication are subject to the requirements of 10 CFR 21, and it further eliminates former confusing language in that regard.

D. The misuse of the terms, "defect", "deviation" and "failure to comply" has been corrected.

E. CP-0240 now requires 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 21.

F. Records retention practice has been restated in CP-0240, Section 7, Records to conform with 21.51(a) and 21.51(b) of 10 CFR 21.

G. CP-0240 now requires that conditions or circumstances relating to a basic component that are adverse to quality reported on Corrective Action Requests undergo a screening to determine 10 CFR Part 21 applicability.

3) Corrective Steps That Have Been Taken To Avoid Further Violations:

As noted above, CP-0240 has been revised. Conval's management team is in the process of training all Conval employees in the new procedure. The Corrective Action Request form, FQ-044, is being revised to require a Part 21 judgment on all issues involving CAR's. The Corrective Action Request database is similarly being revised to include 10 CFR Part 21 applicability screening.

Conval senior, engineering and quality assurance staff are currently working to the new CP-0240 process, though official transmittal within Conval's Quality Management System has not occurred.

4) Dates Corrective Action Will Be Completed:

All issues associated with this Notice of Violation, including forms, databases, procedure transmittals and training will be completed by January 11, 2008.

Notice of Nonconformance 99901367/2007-201-1

1) Reason for the Nonconformance: Inspector did not follow the requirements of the procedure for inspection sample size.

2) Corrective Steps Taken:
The lot of material that was accepted as a result of the nonconforming sample size had been released to production by the time that the audit occurred therefore it was not possible tor e-sample the lot. During final inspection of completed items critical dimensions will be inspected. Final inspection will occur as the parts are produced.

3) Corrective Steps That Have Been Taken To Avoid Further Nonconformances:
Inspectors assigned to complete inspection activities in accordance with QP-003 have received refresher training focusing on selecting the proper sample size. This training was completed on Nov. 29, 2007

4) Dates Corrective Action Will Be Completed:
Nov. 29, 2007

Notice of Nonconformance 99901367/2007-201-2a

1) Reason for the Nonconformance:

Definition contained in procedure QP-0006 is incorrect.

2) Corrective Steps Taken:
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. Revision to be completed by Dec. 31, 2007

3) Corrective Steps That Have Been Taken To Avoid Further Nonconformances:

Procedure CP-0009 titled Quality System Management Reviews will be revised to include a review of 10 CFR 21 and associated Conval procedures on an annual basis to ensure continued compliance.

4) Dates Corrective Action Will Be Completed:
Dec. 31, 2007

Notice of Nonconformance 99901367/2007-201-2b

1) Reason for the Nonconformance:

The current procedure had been in use for a number of years and was thought to be in compliance. Good engineering practice was used to perform and check analyses. However each analysis was not fully verified and validated as specifically required.

2) Corrective Steps Taken:

Procedure EP-0012 was revised October 25, 2007, to clearly define the requirements specified in 10CFR50 Appendix B. Each analysis that is performed on a nuclear component or product is logged for complete traceability. The analysis is then independently verified by a person deemed technically competent by the Engineering Manager. The analysis is further validated by another technically qualified person. All verification and validation activities are logged.

3) Corrective Steps That Have Been Taken To Avoid Further Nonconformances:

All engineering personnel will be trained in the proper use and implementation of the re-written version of EP-0012.

4) Dates Corrective Action Will Be Completed:

Training will be completed by December 31, 2007.

Notice of Nonconformance 99901367/2007-201-2c

1) Reason for the Nonconformance:
Rejection system as implemented is oriented towards the control of items.

2) Corrective Steps Taken:
Procedure for the control of nonconformance will be revised to include control of nonconforming processes that are adverse to quality and bring the nonconformance system into full compliance with 10CFR 50 App. B, revision to be completed by Dec. 31, 2007

3) Corrective Steps That Have Been Taken To Avoid Further Nonconformances:

The quality manual will be revised to include the requirements of 10CFR50 App. B for nonconformances at the next revision. This revision is planned to be completed by June 1, 2008.

4) Dates Corrective Action Will Be Completed:
Dec. 31, 2007 and June 1, 2008

Thank you for your consideration.

Very truly yours,

CONVAL, INC.

Brian S. Nichols
Quality Assurance Manager

Cc: F. Siver, Chairman, CEO, Conval
D. Curtin, President Conval
D. Williams, Vice President Finance, Conval
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