

January 23, 2014

EA-2013-205

Mr. Kirt Richardson, Quality Assurance Manager  
Babcock & Wilcox Canada Ltd.  
581 Coronation Boulevard  
Cambridge, Ontario, Canada, N1RV3

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT  
NO. 99900067/2013-201 RESPONSE TO DISPUTED NOTICE OF  
NONCONFORMANCE

Dear Mr. Richardson:

I am responding to your letter dated August 29, 2013, in which you disputed Nonconformance 99900067/2013-201-03 as identified in the Notice of Nonconformance (NON) attached to the Inspection Report 99900067/2013-201. The subject nonconformance was identified by the Nuclear Regulatory Commission (NRC) staff during an inspection conducted June 3 – 6, 2013, at your Babcock & Wilcox Canada (BWC) facility. The nonconformance involved BWC's failure to adequately qualify a material organization as an approved supplier in accordance with the requirements of NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of the American Society of Mechanical Engineers Boiler & Pressure Vessel Code.

In your letter, you disputed NON 99900067/2013-201-03 stating that: (1) the audit file including the check list used, which was based on the requirements of NCA 3850, as well as the auditor's qualifications were presented to the inspection team; and (2) not having a copy of the Bruck Quality Manual on hand was not a nonconformance in itself.

The NRC staff has independently reviewed the information provided in your letter of August 29, 2013, and has concluded that the nonconformance occurred as stated in the NON of July 16, 2013. The bases for the NRC conclusions regarding this matter are provided in the enclosure to this letter. You are requested to respond to this letter within 30 days and should follow the instructions specified in the NON, dated July 16, 2013.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC site at <http://www.nrc.gov/readingrm/adams.html>.

K. Richardson

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Should you have any additional questions, please contact Yamir Diaz-Castillo of my staff at 301-415-2228.

Sincerely,

**/RA/**

Michael C. Cheok, Director  
Division of Construction Inspection  
and Operational Programs  
Office of New Reactors

Docket No.: 99900067

Enclosure:  
NRC Evaluation and Conclusion  
for NON 99900067/2013-201-03

K. Richardson

- 2 -

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**/RA/**

Michael C. Cheok, Director  
Division of Construction Inspection  
and Operational Programs  
Office of New Reactors

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NRO-001

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## **NUCLEAR REGULATORY COMMISSION'S EVALUATION AND CONCLUSION**

### **Statement of Nonconformance 99900067/2013-201-03**

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, states, in part, that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Subsection NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of the American Society of Mechanical Engineers Boiler & Pressure Vessel (ASME B&PV) Code Section III, states, in part, that "Evaluation of a Material Organization's Quality System Program by parties other than the Society, as provided by NCA-3820(b), shall be performed in accordance with the requirements of (a) through (i) below. [...] (a) The Quality System Program shall be surveyed, accepted, and audited by the party performing the evaluation on the basis of its compliance with the applicable material requirements of this Section and the requirements of NCA-3850."

Contrary to the above, as of June 6, 2013, BWC failed to adequately qualify a material organization as an approved supplier in accordance with the requirements of NCA-3842.2. Specifically, BWC inadequately qualified Bruck GmbH as a Qualified Material Organization based on Bruck's International Organization for Standardization (ISO) 9001:2008, "Quality Management System (QMS) - Requirements," Quality Systems Manual.

### **Specific Basis for Disputing the Nonconformance**

In response to the nonconformance, BWC stated that it evaluated Bruck GmbH per NCA 3842.2. The response also stated that the audit file included a check list that was based on the requirements of NCA 3850, and that the auditor's qualifications were presented to the inspection team. BWC feels that there is no nonconformance in this instance. BWC also stated that it did not have a copy of Bruck's Quality Manual on hand, which is not a nonconformance in itself.

### **NRC Evaluation of Vendor's Response**

The NRC staff has carefully reviewed BWC's response and has concluded that Nonconformance 99900067/2013-201-03 occurred as stated in our letter dated July 16, 2013. The NRC staff's basis for this determination is as follows:

The NRC staff did receive the checklist used by the auditor to verify Bruck GmbH's compliance with the requirements of Section NCA-3850, as required by Subsection NCA 3842.2 (a). The NRC staff also reviewed the qualifications of the auditor who performed the audit of Bruck GmbH and found no issues with the auditor's qualifications.

In order to qualify Bruck GmbH as a material organization, BWC must ensure that Bruck GmbH's Quality System's Program meets the requirements of Section NCA-3850 of the ASME

Enclosure

Code, as required by Subsection NCA 3842.2 (a). Specifically, Subsection NCA-3442.2 (a) states: “The Quality System Program shall be surveyed, accepted, and audited by the party performing the evaluation ***on the basis of its compliance with the applicable material requirements of this Section and the requirements of NCA-3850.***” During this evaluation, the NRC staff carefully reviewed the audit checklist to verify whether it provided sufficient objective evidence to support the conclusion that Bruck GmbH’s quality program met the different requirements of NCA-3850. The NRC inspection team identified several instances in which the audit checklist did not provide sufficient objective evidence to support the conclusion that Bruck GmbH had met the applicable checklist requirements. Specifically, the inspection team noted several instances where certain checklist requirements were marked as being “Satisfactory;” however, there was no additional information provided with the checklist to support the BWC auditor’s conclusion that the NCA-3850 requirement was met. Furthermore, the NRC staff noted that the auditor’s findings were often cited against the requirements of ISO 9001:2008 and not against the requirements of NCA-3850.

The NRC staff also noted that Bruck GmbH’s Quality Systems Program is based on ISO 9001:2008. Although the ASME B&PV Code allows for the qualification of material organizations by Certificate Holders, the material organizations’ Quality Systems Program must meet the requirements of NCA-3800, “Metallic Material Organization’s Quality System Program.” During the inspection, the NRC inspection team requested that BWC provide a copy of Bruck GmbH’s quality manual to independently verify that it met the requirements of NCA-3800 or that it at least contained additional attachments or appendices that would address the gap between a Quality Systems Program based on ISO 9001:2008 and an ASME B&PV NCA-3800 Quality Systems Program. Although BWC was not able provide the NRC inspection team a copy of Bruck GmbH’s quality manual, the NRC staff did not consider this issue as part of its basis for issuing the Nonconformance, as stated by BWC in its response dated August 29, 2013.

### **NRC Conclusion**

Based on its review, the NRC staff has determined that BWC failed to meet the requirements of Criterion VII of Appendix B to 10 CFR Part 50 and Subsection NCA-3842.2 of the ASME Code when it audited Bruck GmbH’s Quality Systems Program. For the above reasons, the NRC concludes that Nonconformance 99900067/2013-201-03 occurred as stated in the Notice of Nonconformance dated July 16, 2013.