

Explore the Engineering Edge

**IHI**

**IHI Corporation**

**Nuclear Power Operations**

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United States Nuclear Regulatory Commission

ATTN: Document Control Desk

Washington, D.C. 20555-0001

**Subject: Reply to NOTICE OF NONCONFORMANCE (99901395/2010-201)**

Reference: Letter, R. Rasmussen(NRC) to T. Kuribayashi(IHI), dated October 26, 2010, "NRC INSPECTION REPORT NO. 99901395/2010-201 AND NOTICE OF NONCONFORMANCE".

Dear Sir,

IHI Corporation, Nuclear Power Operations'(hereafter just "IHI") reply to a Notice of Nonconformance is enclosed in Attachment-1. As discussed in the attachment, some of the corrective actions are already completed and others are currently in process. We believe that those corrective actions will prevent further nonconformance in these areas.

Regards,



Takashi KURIBAYASHI

General Manager of Quality Assurance Department

IHI Corporation, Nuclear Power Operations

Enclosure: Attachment-1

cc: Richard Rasmussen

Chief Quality and Vendor Branch 2

Division of Construction Inspection & Operational Programs

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NR0

Attachment-1

IHI reply to NRC Notice of Nonconformance  
NRC Inspection Report No. 99901395/2010-201

**A. Nonconformance 99901395/2010-201-01**

Description

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 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."

Part 21 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 21), "Reporting of Defects and Noncompliance," Section 21.3 of 10 CFR Part 21 (10 CFR 21.3), "*Definitions, Dedication*," states, in part, that the dedication process must be conducted in accordance with the applicable provisions of Appendix B to 10 CFR Part 50 (Appendix B), "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

IHI Procedure IBR A13-30003, "Control Procedure for Dedication of Commercial Grade Item," Revision G, dated September 10, 2010, provides the methods for the dedication of commercial-grade items and/or services used in nuclear safety applications.

IHI Drawing No. 022K095, "Specification of Quality Program (Commercial Grade Item)," Revision 0, dated October 21, 2009, defines the quality assurance requirements for commercial-grade items for the containment vessels for Vogtle Electric Generating Plant, Units 3 and 4.

Contrary to the above, as of September 17, 2010, IHI failed to provide adequate procedural guidance in IBR A13-30003 for the dedication of commercial-grade items.

Specifically:

– IHI procedures such as IBR A13-30003 and IHI Drawing no 022K095 did not provide adequate guidance for including specific provisions or methodology for identification of the critical characteristics and their verification/acceptance methods to be performed during the conduct of the IHI vendor survey specific to the item being dedicated.

- IBR A13-30003 did not include the appropriate definitions from 10 CFR 21.3, "Definitions," applicable to the dedication of commercial-grade items. The NRC inspection team noted that the procedure did not include the correct definitions for "commercial-grade item" and "basic component" and also did not include definitions for "critical characteristics," "dedication," and "dedicating entity," as defined in 10 CFR Part 21.

- IHI procedures, such as IBR A13-30003 and IHI Drawing No. 022K095, did not provide adequate guidance for the development of sampling inspection plans consistent with known industry standards. The NRC inspection team determined that IHI's sampling plan methodology was inconsistent with the guidance described in Electric Power Research Institute (EPRI) 7218, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," dated January 1999, for the use of normal, reduced, or tightened sampling plans. This issue is identified as Nonconformance 99901395/2010-201-01.

IHI's reply to Nonconformance 99901395/2010-201-01

(1) Reason for the noncompliance

IHI's recent manufacturing experiences have been limited to those of ASME stamped items for Non-US customers. Therefore IHI had less experience and practical application concerning dedication of commercial grade items or services in applying the published documents of EPRI Guideline NP-5652, 7218 and Subpart 2.14 of ASME NQA-1a-2009.

IHI had an incomplete understanding of the range of requirement to fully document the dedication of Commercial Grade Items and Services. Additionally, IHI agrees that our internal procedure, IBR A13-30003 "Control Procedure for Dedication of Commercial Grade Item", did not include adequate guidance reflected in EPRI Guideline NP-5652 and 7218 due to our lack of full understanding.

(Evaluation of Impact and Extent)

IHI has plans to dedicate commercial grade items such as rubber gaskets, plastics and carbon moldings for containment personnel airlocks. However, the assembling of airlock mechanical portion has not yet started. Therefore, there is no impact on safety functions of dedicated or to be dedicated commercial grade item. IHI believes that the proposed corrective action will demonstrate the acceptability of planned CGI dedication for basic components

(2) Corrective steps that have been taken and the results achieved

- IBR A13-30003 and IHI Drawing No.5901003-022K095 has been revised to include an amplified guidance for identification of the critical characteristics and their verification/acceptance methods.
- IBR A13-30003 has been revised to include the appropriate definitions from 10 CFR 21.3, "Definitions," applicable to the dedication of commercial grade items.
- IBR A13-30003 has been revised to provide adequate guidance for the development of sampling inspection plans consistent with known industry standards.
- IHI Drawing No.021K672 "CGI dedication procedure for EPDM gasket" and IHI Drawing No.021K678 "CGI dedication procedure for BISHILITE No.1" have been revised to reflect the new requirements of revised IBR A13-30003.
- The dedication process for EPDM, BISHILITE was subsequently performed including re-survey in accordance with the newly revised dedication procedures of 021K672, 021K678.

(3) Corrective steps that will be taken to avoid noncompliance

- QAPD will be revised to be consistent with revised IBRs.
- In addition the above, IHI is now preparing to indoctrinate QA/QC/Design personnel on revised QAPD and IBRs to assure consistent understanding of the updated requirements iterated above.

(4) Date when corrective action will be completed

- January 31, 2011

**B. Nonconformance 99901395/2010-201-02.**

Description

Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states 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. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

IHI is committed to American Society of Mechanical Engineers NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Nonmandatory Appendix 16A-1, which states, in part, that conditions adverse to quality should be reviewed to determine the existence of trends. The significance of identified trends should be classified to determine whether further action is necessary.

Contrary to the above, as of September 17, 2010, IHI failed to review conditions adverse to quality to determine the existence of trends. The NRC inspection team identified 5 instances involving IHI operators failing to appropriately follow procedures that led to nonconforming conditions for US and Chinese components. These 5 instances occurred over a 12 month period.

This issue is identified as Nonconformance 99901395/2010-201-02.

IHI's reply to Nonconformance 99901395/2010-201-01

(1) Reason for the noncompliance

Commitment to criterion 16A-1 of NQA-1-1994 was added to our QAPD by the revision on August 27, 2010 reflecting the customer's comments in a recent review, IHI had been preparing the issuance of a related procedure document and implementation process of Trend Analysis of Nonconformity Reports, but failed to complete the actions before our recent NRC inspection.

(Evaluation of Impact and Extent)

Each nonconformance in our system has been identified, evaluated and dealt with the documented IHI procedure in appropriate manners. Therefore, even though

nonconformances have been cited as recurring, there is no impact on the safety function of our fabricated products.

(2) Corrective steps that have been taken and the results achieved

IBR A13-30007 "Trend Analysis Procedure" has been issued.

(3) Corrective steps that will be taken to avoid noncompliance

Nonconformance Trend Analysis will be implemented in accordance with new procedure IBR A13-30007 and identified adverse trends documented and addressed as needed.

(4) Date when corrective action will be completed

- January 31, 2011