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11 Oct 18

US Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTN: Document Control Desk

SUBJ: Reply to a Notice of Nonconformance

Ref: Inspection Report NO.99900345/2018-201
Notice of Nonconformance dated Sept. 11, 2018

Dear Ms. Kavanagh,

This letter is intended to supply responses to the subject Inspection Report and the nonconformance(s) documented therein.

Nonconformance 99900345/2018-201-01

Respectfully, the nonconformance cites failures more in regards to meeting specific ASME Code requirements, rather than Appendix B Criterion. HTI is not aware of a specific requirement that requires "the quality manual to contain additional attachments or appendices to address the gaps between a Quality Systems Program based on ISO 9001:2008 and ASME NCA-3800/4200 or even 10CFR50 Appendix B. The cited nonconformance fails to provide examples of specific gaps that exist in the supplier's manual relative to meeting ASME NCA-4253. HTI acknowledges that the subject supplier's Quality System Manual does not contain all applicable requirements of ASME NCA-4253 but maintains it does provide the major basis of the quality program as required by NCA-4253.1(a). The manual is implemented by separately written procedures as required by NCA-4253.1(b), therefore HTI maintains that the requirements of NCA-4253 are met. HTI will verify that the QA Manual for all Material Organizations currently qualified by HTI adequately addresses the applicable requirements of NCA-3800/4200.

The subject audit was conducted over two days looking at objective evidence of implementation of both their manual and numerous procedures critical to satisfactory material such as, welder and weld procedure qualification, weld filler material control, traceability and material test reports. During this audit, HTI material was witnessed being processed including the implementation of the nonconformance process. Although the audit checklist did not contain sufficient evaluation to support the conclusions of adequate implementation of certain areas of the supplier's Quality System Program in accordance with ASME NCA-3800, those areas were in fact evaluated and found to meet NCA-3800 requirements. Additional objective evidence is contained in the audit package in the form of: various procedure reviews, welder qualification, weld procedure qualification, calibration, CGD of calibration service, weld filler metal control, traceability which represents evaluation of those areas required of a material manufacturer. Procedure FBC/CFR21 rev. 1 documents their 10CFR21 program.

Receipt inspection performed at HTI verified the dimensional configuration. Although not required by the ASME Code or the customer's purchase order, the item was hydro-tested without repair by HTI. Furthermore, annual evaluations of this long-standing non-QSC supplier (as required by NCA 3842.2) continue to be performed which includes supply of material samples that verify conformance with material specifications correlating to the suppliers CMTR. This supplier has provided material suitable for the basic component as provided by HTI.

Based on the above discussion, there is no impact on the current or other material manufactured by the supplier.

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could be independently reviewed and determine that acceptable material had been provided to HTI without further input by the lead auditor. This audit will be redone with an expected date of 2 November 2018. Any other audits performed by that lead auditor will be reviewed and revised accordingly.

HTI has documented this nonconformance on HTI CAR P1101.

Nonconformance 99900345/2018-201-02

HTI is not aware of a specific document identifying that "10CFR50 Appendix B as being applicable" is specifically required to be identified on purchase orders. HTI believed we were adequately identifying requirements based on requiring the item or service to be provided in accordance with the program audited by HTI and then also specifically identifying that 10CFR21 applied to the order. Previous audits by independent contracted lead auditors or by other organizations had not identified this as a requirement.

HTI initiated specifically referencing both 10CFR 50 Appendix B and 10CFR21 as being applicable on purchase orders for material, items and services when this was identified during the Inspection.

HTI has identified no impact to previous supplied material, items or service due to this nonconformance.

HTI documented this nonconformance on HTI CAR A1102

Nonconformance 99900345/2018-201-03

- 1) HTI had attempted to document both a CGD survey and a limited scope audit from the ASME Code perspective on a single document. It is acknowledged that clear distinctions were not made to the critical characteristic versus other programmatic controls HTI reviewed. In the specific example of suppliers providing a machined component, the single attribute from the identified critical characteristic for Method 2 "commercial grade survey" is material control. The critical characteristic of material control is based on the supplier performing no activity that would affect the HTI provided and previously accepted material. The controls and processes that would affect the material remain the same whether we are in the CGD survey or ASME limited scope audit realm. Existing surveys will be reviewed individually to determine what additional action(s) need to be taken and documents revised accordingly. Going forward these activities will be documented on separate forms.

HTI has identified there is no impact to any product shipped.

HTI has documented this nonconformance on HTI CAR P1106

- 2) HTI does not agree with the wording "without reviewing the suitability of the material or assuring that the material conformed to the purchase order requirements of the customer". A survey was conducted prior to the CGD plan being formally issued which HTI acknowledges is not the proper sequence of events. The onsite survey was to determine that the supplier could maintain heat/lot traceability. Although the survey report was not adequately documented, the survey did determine that a program was in place that provided traceability. That program was identified on the PO to the supplier and the documentation required by the PO was received. Material was purchased after the survey was conducted.

An action during the survey, was that HTI identified two spools of material that was to be purchased. As part of the complete dedication plan requirements, a sample was taken from each of the two spools for independent testing at HTI's approved supplier. The material sample taken while onsite was tested by HTI's approved testing supplier. The test verified that the material specification requirement was met. No material was used prior to this independent test.



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This weld filler material was used on a single customer PO for a safety related part. The customer was notified of this condition. Three of four pieces on the order had shipped to the customer but none of the parts had been put into service. All parts were segregated at the customer while HTI supplied the customer with all requested documentation. The customer has accepted HTI's response and the remaining part has shipped to the customer. The remaining weld filler material held in quarantine by HTI remains on nonconformance until the plan and survey have been properly documented and Commercial Grade Dedication is completed.

HTI has documented this nonconformance on HTI CAR A1103

Nonconformance 99900345/2018-201-04

HTI does not accept this nonconformance.

The dead weight tester operating range with the high pressure piston installed per the manufacturer's instruction manual, is 75 to 10,000 psi. The identified 1,000 psi was simply the low point of a multi-point test verifying the tester's operating range. All test points were within the manufacturer's specification.

To re-affirm the cited hydrotest as valid, HTI had the dead weight tester recalibrated with 75 psi as the low test point using the high pressure piston. Additionally, HTI had our approved calibration supplier calibrate each of HTI's analog gages. These are direct read gages and there are no adjustments that can be made. All were found to be within the tolerance required which validates that the dead weight tester had provided an acceptable test to the 0-400 psi gage cited in the nonconformance.

There is no impact to any item that has been supplied by HTI.

HTI has documented this nonconformance on HTI CAR P1111

Nonconformance 99900345/2018-201-05

- 1) We believe this has been addressed in nonconformance -03 part 2 above.
- 2) HTI does not accept this part of the nonconformance.

The reported conflict involves two completely different activities or functions that the QA Manager performed as part of his individually held qualifications and his defined job responsibilities. The first activity was conducting a nondestructive examination as a Level II examiner. As an examiner the qualification record was signed by the appointed Level III subcontractor and the President who assumed the responsibilities of the QA Manager. As a Level II examiner there was no oversight required by any other personnel. The signing of the data report by the QA Manager was carrying out his responsibility of verifying or attesting that all Code required activities had been met. To maintain that those activities were inspection of his own work would preclude the QA Manager from signing a data report or Certificate of Compliance because as a qualified lead auditor he audited the supplier or that he signed the purchase order to the supplier involved in the item being shipped. This has never been an industry accepted position and has never been identified previously during any type of survey or audit.

HTI maintains there is no impact to product shipped.

- 3) HTI does not accept this part of the nonconformance as written. In the attachment to the report identifying all records reviewed, the single job traveler UN10222-1-6 for part 01-403-636 is listed on page 4 and appears to be the basis for this part of the nonconformance. The report identifies that the QCI issued material on July 10 and identifies the specific material. The HTI job tracking program, which a welder is required to log into, to track earned hours, identifies that welding was done on July 10 -12th.



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There is a violation of HTI procedure MFS -1 in that the specific time was not noted. The MFS-1 procedure, as written, would require the time to be noted in all cases. The intent had been to address the concern of SMAW materials being exposed too long prior to use. There is also discussion in section 7.1.4 that identifies for covered electrodes, only a sufficient quantity for 4 hours is to be taken at one time. It further states that any electrodes outside the oven for more than 4 hours are to be returned to the oven for 24 hours. Procedure MFS-2 that was also reviewed, contains the same requirement. It is our belief that the 4 hour limit HTI has imposed represents one half of the generally accepted industry practice regarding covered electrodes exposure to the atmosphere. There is no identified violation in a QCI identifying ahead of time what material is to be used. There is no mention in the report of the time frame and concern in regard to covered electrodes. In subsequent discussions with the welder and QCI neither could recall the NRC Inspector inquiring or otherwise trying to determine their knowledge of the time frame or any concern regarding covered electrodes. The Inspector apparently did not question whether or not covered electrodes had ever been scrapped because of the time of exposure. The weld materials identified are bare wire product forms and not subject to the concern of moisture absorption. Procedures MFS-1 and MFS-2 will be revised to more clearly reflect HTI requirements.

There is no documented citation of any welding materials issued over a weekend either with or without QA/QCI release. During the normal work week there is QA coverage for the first 1 ½ hours of the second shift. Earlier this year, there was a four month period where a QCI was moved to second shift to support production requirements. Weekend coverage, when required, is provided by all personnel that are needed. The statement "...welding of safety-related components performed during night shift and on weekends was conducted without QA or QCI present..." is not supported. In the issuance of materials, in general, there is no impact with materials being identified ahead of actual welding. The potential for the use of covered electrodes has been mitigated by limiting the time to one half of industry practice and documented training of Welders and QCIs.

The job identified, UN10222, per the customer PO was to be built in compliance to ASME Code Section III Sub-section ND requirements but is neither Code stamped nor safety related. When our customers order items in that manner, HTI makes no further distinction to documentation that is provided to the shop floor employees for processing.

HTI has determined there is no product impact to the job specifically identified or other safety related items shipped by HTI.

This nonconformance is documented on HTI CAR P1107.

We believe these responses adequately address the non-conformances identified. Please advise if any of the actions taken to address the non-conformances are to be submitted to the Inspection Team for follow-up and closure.

Sincerely,

Douglas J. Roszman
Q. A. Manager

C2: Ms. K. Kavanagh, Chief
Quality Assurance Vendor Inspection Branch -2
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