



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

January 9, 2019

Mr. Douglas Roszman  
Quality Assurance Manager  
Hayward Tyler, Inc.  
480 Roosevelt Hwy  
Colchester, VT 05446

SUBJECT: RESPONSE AND REVISION TO NOTICE OF NONCONFORMANCE  
CONTAINED IN NUCLEAR REGULATORY COMMISSION INSPECTION  
REPORT 99900345/2018-201

Dear Mr. Roszman:

I am responding to your letter dated October 11, 2018 (Agencywide Documents Access Management System (ADAMS) Accession No. ML18291A926), in which you disputed Nonconformances 99900345/2018-201-04 and 99900345/2018-201-05 as identified in the Notice of Nonconformance (NON) attached to Inspection Report No. 99900345/2018-201 (ADAMS Accession No. ML18250A302). The U.S. Nuclear Regulatory Commission (NRC) staff identified these NONs during an inspection conducted from July 16-20, 2018, at your facility in Colchester, VT. The NONs described examples where Hayward Tyler, Inc. (HTI) was not fully implementing its quality assurance (QA) program in the areas of control of measuring and test equipment, and corrective action. We are also responding to concerns raised in your letter about the basis for NONs 99900345/2018-201-01 and 99900345/2018-201-02.

With regard to NON 99900345/2018-201-04, which concerned HTI's failure to establish adequate controls to ensure that the pressure gages used in hydrostatic testing of safety-related components were properly calibrated, the NRC identified that the pressure gages were being tested/calibrated using a dead weight tester whose calibrated range was outside the range of the pressure gages. Your letter, while disputing the NON, did not dispute the fact that the dead weight tester's calibrated range at the time of the inspection was outside the range of the pressure gages. You also indicated in your letter that subsequent to the inspection you re-calibrated the dead weight tester to a range within the range the of the pressure gages being tested.

The NRC staff conducted an independent review of the information provided in your letter dated October 11, 2018, and has concluded that NON 99900345/2018-201-04 remains valid for the reasons presented in the enclosed evaluation (Enclosure 1). While the corrective actions taken subsequent to the inspection to recalibrate the dead weight tester to a range that covers the subject pressure gages appear to be adequate, at the time of the inspection this had not been done, and previous to this issue being identified by the NRC, pressure gages were being calibrated with a dead weight tester whose calibrated range was not inclusive of the full range of their operation. While the dead weight tester manufacturer's specified operating range may have been within the range of the gages, the operating range and the calibrated range are not

one and the same. The calibrated range of the dead weight tester provides the necessary assurance of the accuracy of the pressure gages used in safety-related applications.

You also disputed NON 99900345/2018-201-05, which concerned three examples where HTI failed to take adequate corrective actions in response to NONs identified in NRC Inspection Report 99900345/01-201 (ADAMS Accession No. ML003770586). Specifically, the NRC identified that HTI failed to take adequate corrective actions for previously identified issues concerning the procurement of material, the independence of the QA director, and control of weld material. With respect to Example 1 of NON 99900345/2018-201-05 (which was also cited as Example 2 of NON 99900345/2018-201-03), your letter states that “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.”” With regard to Example 2 of the NON, your letter provided the rationale as to why you believe that the examples cited in the inspection report did not constitute a lack of independence between quality assurance personnel and those actually performing the work. With regard to Example 3 of the NON, your letter explained why you believe that weld material was in fact being properly controlled and that all weld material being utilized for safety-related work was verified as acceptable by quality control prior to use.

With respect to Example 1 of NON 99900345/2018-201-05, we do not agree that HTI implemented adequate controls associated with the procurement of the subject weld wire in accordance with the requirements specified in the customer’s purchase orders. Specifically, HTI did not adequately audit nor obtain a certified material test report from the material’s manufacturer in accordance with the requirements of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code. With respect to Examples 2 and 3 of NON 99900345/2018-201-05, upon further review, and based upon the explanation provided in your letter of October 11, 2018, we agree that these two examples, a nonconformance associated with Criterion XVI of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 did not occur. Consequently, we will be revising NON 99900345-201-05 to include just the one example cited above (Example 1).

In addition to disputing aspects of the two NONs discussed above, you also raised questions regarding the NRC requirements associated with specific portions of NONs 99900345/2018-201-01 and 99900345/2018-201-02. Specifically, with regard to 99900345/2018-201-01, your letter states that, “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 upon ISO 9001:2008 and ASME NCA-3800/4200 or even 10CFR50 Appendix B.”” We agree that there is no specific NRC requirement for a supplier of safety-related materials to have a quality manual that specifically addresses any such gaps; however, the basis of the NON was not so much based upon the gaps in the subject manual but more upon the lack of objective evidence associated with HTI’s audit of the subject supplier and the inability of the NRC inspectors to obtain auditable information regarding the scope and depth of the audit that was performed. We have revised NON 99900345-201-01 to clarify the issue (Enclosure 2).

With respect to NON 99900345/2018-201-02, your letter stated that “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.” We do not agree, Criterion IV of Appendix B to 10 CFR Part 50 specifically states that ... “Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for

procurement of material, equipment, and services, whether by the applicant or by its contractors or subcontractors.” The NRC’s position on this subject is further explained in NRC Regulatory Guide 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21” which endorses Nuclear Energy Institute (NEI) 14.09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1, February 2016 (ADAMS Accession No. ML16054A825).

The bases for the NRC’s conclusions regarding this matter are provided in Enclosure 1 to this letter. We have no further questions or comments at this time and may review the implementation of your corrective actions during a future NRC inspection to determine whether full compliance has been achieved and maintained.

In accordance with 10 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 ADAMS, accessible from the NRC site at <http://www.nrc.gov/readingrm/adams.html>.

Should you have any additional questions, please contact Greg Galletti of my staff at 301-415-1831.

Sincerely,

*/RA/*

Timothy J. McGinty, Director  
Division of Construction Inspection  
and Operational Programs  
Office of New Reactors

Docket No.: 99900345

Enclosures:

1. NRC Evaluation and Conclusion for NONs 99900345/2018-201-01, 02, 03, 04, and 05.
2. Notice of Nonconformance (Revised)

SUBJECT: RESPONSE AND REVISION TO TWO NOTICES OF NONCONFORMANCE  
CONTAINED IN NUCLEAR REGULATORY COMMISSION INSPECTION  
REPORT 99900345/2018-201 Dated: January 9, 2019

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

### **Statement of Nonconformance 99900345/2018-201-01 (original)**

Criterion VII, "Control of Purchased Material, Equipment, and Services" 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, "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."

Subsection NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code 2015 Edition, 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 [...] (b). The Quality System Manual (NCA-4253.1) shall be the party's guide for surveying and auditing the qualified Material Organization's continued compliance with the accepted Quality System Program.

Subsection NCA-4253.1, "Quality System Manual," in Section III of the ASME B&PV Code, 2015 Edition, states, in part, that, "The Quality Program shall be described and summarized in a Quality System Manual that shall be a major basis for demonstration of compliance with the rules of this Section."

Contrary to the above, as of July 20, 2018, HTI failed to establish adequate measures for source evaluation and selection of contractors and subcontractors to ensure that purchased material, equipment, and services conformed to procurement documents. Specifically, the U.S. Nuclear Regulatory Commission (NRC) inspection team determined that HTI failed to adequately qualify a material organization (MO) (i.e. castings) as an approved supplier in accordance with the requirements of NCA-3842.2. The NRC inspection team identified several instances in which the audit checklist did not provide sufficient objective evidence to support the conclusion that the MO had met the controls and applicable requirements of subsection NCA-3850, "Quality System Program Requirements." Furthermore, the NRC inspection team reviewed the quality manual of the MO to independently verify whether it met the applicable requirements of NCA-3800. The quality manual did not contain additional attachments or appendices to address the gaps between a Quality Systems Program based on the International Organization for Standardization (ISO) 9001:2008, "Quality Management System – Requirements" and an ASME B&PV NCA-3800 Quality Systems Program.

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

In its response to the NRC, HTI stated that "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 upon ISO 9001:2008 and ASME NCA-3800/4200 or even 10CFR50 Appendix B.""

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

The NRC staff has evaluated HTI's response and has concluded that Nonconformance 99900345/2018-201-01 occurred as stated in our letter dated September 11, 2018. The basis for this determination is as follows:

The NRC staff considered available regulatory guidance, the NRC inspection report, HTI's response, and held additional discussions with HTI management. While we agree that there is no specific NRC requirement for a supplier of safety-related materials to have a quality manual that specifically addresses any such gaps, the basis of the NON was not so much based upon the gaps in the subject manual but more upon the lack of objective evidence associated with HTI's audit of the subject supplier and the inability of the NRC inspectors to obtain auditable information regarding the scope and depth of the audit that was performed. NON 99900345-208-201-01 has been revised to clarify the issue (Enclosure 2).

### **Statement of Nonconformance 99900345/2018-201-02 (original)**

Criterion IV "Procurement Document Control," states, in part that, "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether by the applicant or by its contractors or subcontractors."

Contrary to the above, as of July 20, 2018, HTI failed to include the applicable regulatory requirements in its safety-related procurement documents for material and services procured as basic components to safety-related equipment which is necessary to ensure that adequate quality assurance is suitably included or referenced. Specifically, HTI did not impose the requirements of Appendix B to 10 CFR Part 50 in its safety-related procurement documents for materials and services procured as basic components. Procurement documents shall specify compliance with the requirements of Appendix B to 10 CFR Part 50 to ensure that adequate quality assurance is applied and passed down to the sub-suppliers.

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

In response to the nonconformance, HTI stated that 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.'"

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

The NRC staff has evaluated HTI's response and has concluded that NON 99900345/2018-201-02, occurred as stated in our letter dated September 11, 2018. The basis for this determination is as follows:

The NRC staff considered the available regulatory guidance, the NRC inspection report, HTI's response, and held discussions with HTI management. The NRC staff does not agree with HTI's contention that Appendix B requirements are not required to be specified on purchase orders for safety-related items and services. Criterion IV of Appendix B to 10 CFR Part 50 specifically states that ... "Measures shall be established to assure that applicable regulatory requirements [emphasis added], design bases, and other requirements which are necessary to

assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether by the applicant or by its contractors or subcontractors.”

In addition, the NRC’s position with regard to procurement documents are addressed in NRC Regulatory Guide 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21.” This regulatory guide endorses Nuclear Energy Institute (NEI) 14.09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Revision 1, February 2016 (Agencywide Document Access Management System (ADAMS) Accession No. ML16054A825). Specifically, paragraph 6.5 of NEI 14-09 states, “For nuclear power plants, the applicable quality assurance requirements for procuring basic components are specified in 10 CFR Part 50, Appendix B. Specifically, Criterion IV, “Procurement Document Control” of Appendix B requires that purchasers contractually impose Appendix B quality assurance requirements on suppliers supplying safety-related materials, parts and services. Thus, for procurements of basic components, which impose 10 CFR Part 21 requirements on suppliers, the procurement documents should also impose the applicable Appendix B quality assurance requirements on the supplier.”

#### **Statement of Nonconformance 99900345/2018-201-03 (original)**

Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 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.”

Contrary to the above, as of July 20, 2018, HTI failed to establish measures to assure that services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. Specifically, the NRC inspectors determined that:

1. HTI performed limited-scope audits of its commercial supplier’s QA program rather than commercial-grade surveys, to verify how the identified critical characteristics were controlled, specific to the service procured (i.e. machining services).
2. HTI procured welding material from a commercial supplier, in October 2017 and used the commercial welding material in safety-related applications without reviewing the suitability of the material or assuring that the material conformed to the purchase requirements of the customer.

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

HTI did not dispute Example 1. With regard to Example 2, HTI stated that “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.”” In its letter, HTI explained that a survey was conducted prior to procuring the subject material and that samples of the material were also sent out to an independent laboratory for material testing to ensure the relevant material specifications were met.

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

The NRC staff has evaluated HTI's response and has concluded that Example 2 of NON 99900345/2018-201-03, occurred as stated in our letter dated September 11, 2018. The NRC staff considered the available regulatory guidance, the NRC inspection report, HTI's response, and held additional discussions with HTI management. Specifically, the NRC staff considered the additional information provided by HTI, including copies of CMTRs from an approved testing laboratory of weld wire samples taken by HTI from two wire spools at the wire manufacturer (which apparently were not made available for review by the inspectors during the inspection). Based upon the information presented, we still believe that HTI has not provided sufficient documented evidence to confirm the suitability of the weld material in question. While the CMTRs provided address the suitability of the material for the specific samples that were taken, HTI did not provide sufficient documented evidence to demonstrate that the wire spools contained wire that originated from homogeneous source material. The wire manufacturer is only an intermediary processor of the wire and not the provider of the source material, which was an unqualified source material supplier in China. While HTI stated to have also conducted a surveillance of the source material supplier in China, HTI did not provide sufficient documentation to demonstrate that this surveillance occurred and was sufficient to ensure proper material controls were in place to ensure the traceability and homogeneity of the material supplied. The NRC staff also noted that the weld wire was used in ASME B&PV Code-related activities. HTI did not meet the requirements of the ASME B&PV Code for adequately auditing the material supplier in China as a qualified material organization, nor did the CMTRs provided originate from the material's manufacturer, as specified by the Code and detailed in the inspection report.

### **Statement of Nonconformance 99900345/2018-201-04 (original)**

Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, states, in part, that, "measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states, "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. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

HTI's Quality Assurance Manual Section 12, "Control of Measuring and Test Equipment," Subsection 12.3 states, in part, that, "calibration activities will be performed in accordance with written procedures prepared by the QC [Quality Control] inspector and reviewed and approved by the Quality Assurance Director (QAD). These procedures include the basis and method of calibration, allowable tolerance and other controls that assure that M&TE [measuring and test equipment] is properly adjusted at specified period of use intervals." Further, it states, "Pressure gauges used for hydrostatic test will be calibrated against a standard dead weight tester before each test or series of tests. A series is that group of tests using the same gauge, which is conducted within a period not exceeding two weeks. Analog type gauges will have a range of not less than 1½ times nor more than 4 times the test pressure."



Contrary to the above, as of July 20, 2018, HTI failed to establish adequate controls to ensure that the pressure gauges used in hydrostatic testing of safety-related components affecting quality were properly calibrated and adjusted at specified periods to maintain their accuracy within necessary limits using a written calibration procedure. Specifically, the NRC inspection team determined that the pressure gauge used during hydrostatic testing of three ASME Section III safety-related diffusers were not calibrated within the tolerance range of 0-400 pounds per square inch gauge (PSIG) using a standard dead weight tester and calibration procedure. HTI had been calibrating this pressure gauge with a standard dead weight tester and calibrated tolerance range of 1000 to 10,000 PSIG. The pressure gauge was used for hydrostatic testing of safety-related components since September 2015. The validity of such hydrostatic test results are of indeterminate quality.

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

HTI's letter indicated that the dead weight tester in question had an operating range of 75 to 10,000 psi, and that the 1,000 psi reference pointed cited in the inspection report was simply the low-point of a multi-point test. HTI also indicated in its letter that subsequent to the inspection the dead weight tester had been recalibrated to a range within the range of the pressure gages.

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

The NRC staff has evaluated HTI's response and has concluded that NON 99900345/2018-201-04, occurred as stated in our letter dated September 11, 2018. The NRC staff considered the available regulatory guidance, the NRC inspection report, HTI's response, and held additional discussions with HTI management. While the corrective actions taken subsequent to the inspection to recalibrate the dead weight tester to a range that covers the subject pressure gages appear to be adequate, at the time of the inspection this had not been done, and previous to this issue being identified by the NRC, pressure gages were being calibrated with a dead weight tester whose calibrated range was not appropriate. While the dead weight tester manufacturer's specified operating range may have been within the range of the gages, the operating range and the calibrated range are not one and the same, and it is the calibrated range of the dead weight tester that provides the necessary assurance of the accuracy of the pressure gages used in safety-related applications. While we agree that the weights themselves need no further calibration since they themselves are traceable standards, the weights need to work in conjunction with the rest of the system, and the system calibration should be such that it verifies the operation and accuracy of the system over the complete operating range.

### **Statement of Nonconformance 99900345/2018-201-05 (original)**

Criterion XVI, "Corrective Action," of Appendix B, to 10 CFR Part 50, states, in part, 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."

Paragraph 16.1, "Purpose and Scope," Section 16, "Corrective Action," of the "Quality Assurance Manual of Hayward Tyler, Inc.," Edition 7 Revision 0, dated January 7, 2017, states, in part that, "conditions adverse to quality such as repetitive audit findings, failures, malfunctions, deficiencies, defective material/services/equipment and other nonconformances are promptly identified and corrected and the cause is identified and corrected."

Contrary to the above, as of July 20, 2018, HTI failed to promptly identify and correct conditions adverse to quality. Specifically, the corrective actions that were implemented by HTI to address the findings in the 2001 NRC Inspection Report 99900345/2001-201 were ineffective. As a result of the ineffective corrective actions, the NRC inspection team identified the following similar examples:

1. HTI did not ensure that verification of the suitability of material to be used in a safety-related application was verified;
2. The QA director was not independent of work being inspected; and
3. Weld material issued from weld storage by welders for use on safety-related components was not adequately confirmed by Quality Assurance or a Quality Control Inspector.

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

For Example 1 of NON 999000345/2018-201-05, see the NRC staff's response to Example 2 of NON 99900345/2018-201-03 (above). For Example 2 of NON 999000345-2018-201-05, HTI's letter provided rationale as to why HTI believes that the examples cited in the inspection report did not constitute a lack of independence between quality assurance personnel and those actually performing the work. For Example 3 of NON 999000345/2018-201-05, HTI's letter explained why HTI believes that weld material was in fact being properly controlled and that all weld material being utilized for safety-related work was verified as acceptable by quality control prior to use.

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

The NRC staff considered available regulatory guidance, the NRC inspection report, HTI's response, and held additional discussions with HTI management. With regard to Example 1 of NON 99900345/2018-201-05, see the NRC staff's evaluation provided in Example 2 of NON 99900345/2018-201-03, as to why we believe the NON occurred as stated in our letter dated September 11, 2018.

With regard to Example 2 of NON 99900345/2018-201-05, the NRC staff has evaluated HTI's response and has concluded that a lack of independence between the quality assurance personnel and those actually performing the work did not occur. Additionally, for Example 3 of NON 99900345/2018-201-05, the NRC staff agrees that the inspectors did not specifically identify any examples where weld material was being verified after the work was done and that the material verification can be performed at any time prior to the commencement of the weld activities, provided that proper material controls are in place.

Based upon the explanation provided in your letter of October 11, 2018, and supplemental information gathered after the inspection, we agree that for two of the three examples discussed in NON 99900345/2018-201-05, a nonconformance associated with Criterion XVI of Appendix B to 10 CFR Part 50 did not occur. Consequently, this NON has been revised (Enclosure 2).

## NOTICE OF NONCONFORMANCE (REVISED)

Hayward Tyler, Inc.  
480 Roosevelt Hwy.  
Colchester, VT 05446

Docket No. 99900345  
Report No. 2018-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Hayward Tyler, Inc. (hereafter referred to as HTI) facility in Colchester, VT, from July 16, 2018 through July 20, 2018, HTI did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon HTI by its customers or NRC licensees:

### A. Control of Purchased Material, Equipment, and Services:

Criterion VII, "Control of Purchased Material, Equipment, and Services" 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, "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."

Subsection NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code 2015 Edition, 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 [...] (b). The Quality System Manual (NCA-4253.1) shall be the party's guide for surveying and auditing the qualified Material Organization's continued compliance with the accepted Quality System Program."

Subsection NCA-4253.1, "Quality System Manual," in Section III of the ASME B&PV Code, 2015 Edition, states, in part that, "The Quality Program shall be described and summarized in a Quality System Manual that shall be a major basis for demonstration of compliance with the rules of this Section."

Contrary to the above, as of July 20, 2018, HTI failed to establish adequate measures for source evaluation and selection of contractors and subcontractors to ensure that purchased material, equipment, and services conformed to procurement documents. Specifically, the NRC inspection team determined that HTI failed to adequately qualify a material organization (MO) (i.e., castings) as an approved supplier in accordance with the requirements of NCA-3842.2. The NRC inspection team identified several instances in which the audit checklist did not provide sufficient objective evidence to support the conclusion that the MO had met the controls and applicable requirements of subsection NCA-3850, "Quality System Program Requirements."

This issue has been identified as Nonconformance 99900345/2018-201-01.

B. Procurement Document Control:

Criterion IV "Procurement Document Control," states, in part that, "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether by the applicant or by its contractors or subcontractors."

Contrary to the above, as of July 20, 2018, HTI failed to include the applicable regulatory requirements in its safety-related procurement documents for material and services procured as basic components to safety-related equipment which is necessary to ensure that adequate quality assurance is suitably included or referenced. Specifically, HTI did not impose the requirements of Appendix B to 10 CFR Part 50 in its safety-related procurement documents for materials and services procured as basic components. Procurement documents for basic components shall specify compliance with the requirements of Appendix B to 10 CFR Part 50 to ensure that adequate quality assurance is applied and passed down to the sub-suppliers.

This issue has been identified as Nonconformance 99900345/2018-201-02.

C. Control of Purchased Material, Equipment, and Services

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 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."

Contrary to the above, as of July 20, 2018, HTI failed to establish measures to assure that services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. Specifically, the NRC inspectors determined that:

1. HTI performed limited-scope audits of its commercial supplier's QA program rather than commercial-grade surveys, to verify how the identified critical characteristics were controlled, specific to the service procured (i.e., machining services).
2. HTI procured welding material from a commercial supplier in October 2017 and used the commercial welding material in safety-related applications without reviewing the suitability of the material or assuring that the material conformed to the purchase requirements of the customer.

This issue has been identified as Nonconformance 99900345/2018-201-03.

#### D. Control of Measuring and Test Equipment

Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, states, in part that, "measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50, states, "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. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

HTI's Quality Assurance Manual Section 12, "Control of Measuring and Test Equipment," Subsection 12.3 states in part that, "calibration activities will be performed in accordance with written procedures prepared by the QC [Quality Control] inspector and reviewed and approved by the Quality Assurance Director (QAD). These procedures include the basis and method of calibration, allowable tolerance and other controls that assure that M&TE [measuring and test equipment] is properly adjusted at specified period of use intervals." Further, it states, "Pressure gauges used for hydrostatic test will be calibrated against a standard dead weight tester before each test or series of tests. A series is that group of tests using the same gauge, which is conducted within a period not exceeding two weeks. Analog type gauges will have a range of not less than 1½ times nor more than 4 times the test pressure."

Contrary to the above, as of July 20, 2018, HTI failed to establish adequate controls to ensure that the pressure gauges used in hydrostatic testing of safety-related components affecting quality were properly calibrated and adjusted at specified periods to maintain their accuracy within necessary limits using a written calibration procedure. Specifically, the NRC inspection team determined that the pressure gauge used during hydrostatic testing of three ASME Section III safety-related diffusers were not calibrated within the tolerance range of 0-400 pounds per square inch gauge (PSIG) using a standard dead weight tester and calibration procedure. HTI had been calibrating this pressure gauge with a standard dead weight tester and calibrated tolerance range of 1000 to 10,000 PSIG. The pressure gauge was used for hydrostatic testing of safety-related components since September 2015. The validity of such hydrostatic test results are of indeterminate quality.

This issue has been identified as Nonconformance 99900345/2018-201-04.

#### E. Corrective Action

Criterion XVI, "Corrective Action," of Appendix B, to 10 CFR Part 50, states in part 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."

Paragraph 16.1, "Purpose and Scope," Section 16, "Corrective Action," of the "Quality Assurance Manual of Hayward Tyler, Inc.," Edition 7 Revision 0, dated January 7, 2017, states, in part that, "conditions adverse to quality such as repetitive audit findings, failures,

malfunctions, deficiencies, defective material/services/equipment and other nonconformances are promptly identified and corrected and the cause is identified and corrected.”

Contrary to the above, as of July 20, 2018, HTI failed to promptly identify and correct conditions adverse to quality. Specifically, the corrective actions that were implemented by HTI to address the findings in the 2001 NRC Inspection Report 99900345/2001-201 were ineffective. As a result of the ineffective corrective actions, the NRC inspection team identified the following similar examples:

1. HTI did not ensure that verification of the suitability of material to be used in a safety-related application was verified. Specifically, HTI procured welding material (weld wire) from a commercial supplier in October 2017 and used the commercial material in safety-related applications without reviewing the suitability of the material or assuring that the material conformed to the purchase requirements of the customer. While HTI obtained Certified Material Test Reports (CMTRs) for the material) taken from each of two spools of wire, HTI did not provide sufficient documented evidence to demonstrate that the weld wire spools contained wire that originated from homogeneous source material.
2. Deleted
3. Deleted

This issue has been identified as Nonconformance 99900345/2018-201-05.

Dated this the 11th day of September 2018.