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January 05, 2015

U.S. Nuclear Regulatory Commission
ATTENTION: Document Control Desk
Washington, D.C. 20555

SUBJECT: Reply to a Notice of Nonconformance cited in NRC Inspection Report No. 99901441/2014-202,
Dated December 05, 2014

Attached please find our responses and corrective actions taken to address Nonconformances 99901441/2014-202-01 and 99901441/2014-202-02 cited in NRC Inspection Report Number: 99901441/2014-202.

QualTech NP Huntsville Operations is committed to maintain compliance in accordance with Title 10 of the Code of Federal Regulations (10 CFR) Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

We appreciate the time and effort of the NRC inspection team and will utilize the information obtained to help improve our processes.

Objective evidence for corrective actions taken can be provided upon request. If there are any questions or comments please contact me.

Sincerely,

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Nonconformance 99901441/2014-202-01

- A. Criterion III, "Design Control," of Appendix B states, in part, that, "Measures shall be established for the selection and review of suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components."

Contrary to the above, the NRC Inspection Team identified three examples where there was an inadequate review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of structures, systems, or components (SSCs).

- QualTech failed to adequately identify and review critical characteristics for the dedication of a pinch valve liner in commercial dedication report EGS-TR-HC-1535-01. Specifically, QualTech did not evaluate critical characteristics such as porosity, surface finish, and structural integrity which would affect the ability of the pinch valve liner to perform its intended safety function.
- QualTech failed to ensure that material requirements listed in purchase order (PO) 4700664988 for two safety relief valves were met. Specifically, QualTech failed to verify that the: body and bonnet material was bronze; disc and spring material was stainless steel; nozzle material was bronze; and seal and O-ring material was Teflon as required by the PO.
- QualTech failed to ensure that item specifications required in Customer POs were met. Specifically, QualTech failed to ensure that item specifications, such as original equipment manufacturers, were met in accordance with PSEG POs 00643044 and 4500746367 to maintain equipment qualification. In addition, the NRC inspectors noted that for a transistor in PO 4500746367, the PO required Microsemi as the OEM, the test report identified Westinghouse as the OEM, and the pictures taken by QualTech at receipt inspection showed what appeared to be Solid State Inc. as the OEM.

Response

QualTech NP, Huntsville Operations accepts the nonconformance and investigations /corrective actions taken are as follows:

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The reason for the nonconformance

It was determined that for the first example the basic cause was the improper use a generic dedication procedure and associated Project Summary Sheet. Specifically, the procedure was for a complete valve assembly and not just the valve liner, therefore, it did not properly define critical characteristics specific to the liner. When Engineering generated the Project Summary Sheet using the generic dedication procedure all of the critical characteristics were either not defined or were incorrectly identified as not applicable without justification.

It was determined that the basic cause for example two was that during the order entry review QualTech NP did not request clarification for the revised extended item description. Specifically, the customer added additional description for materials (body and bonnet material is bronze, disc and spring material is stainless steel, nozzle material is bronze, and seal/o-ring material is teflon) that was not called out in the original order nor addressed in the previous dedication or qualification report.

It was determined that the cause of example three was inadequate order entry review and improper technical reviews for the final documentation and reports.

Corrective action steps that have been taken and the result achieved

For example one additional critical characteristics were defined (e.g. dimensions, hardness and visual inspection of surface finish) and a comparison was made between two production liners returned from OPPD and the originally qualified seismic specimen. The results confirmed that the production liners were consistent with the seismic specimen and that failure to perform the additional testing did not result in a deviation from the original qualified item.

For example two it was determined that the only corrective action needed was to clarify by revision to the Certificate of Compliance that no additional material testing was performed to verify the body and bonnet material is bronze, disc and spring material is stainless steel, nozzle material is bronze and seal/o-ring material is teflon). Review of customer purchase order 4700664988 confirmed that the customer requested certification to the original purchase order and dedication/seismic report. Based on failure modes and critical characteristics (operability, structural integrity, and pressure boundary integrity) defined in the original report it was determined that verification of seat material, shell integrity, seat leakage, set point, and seismic testing confirmed acceptability for the intended safety function.

For example three it was confirmed that the supplied item was the same part number with the same form, fit and function, however, the manufacturer was incorrectly identified. The Certificate of Compliance was revised to document the discrepancy concerning the part

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manufacturer. Further, the customer provided clarification that as long as the part number has not changed and the form/fit/function of the part remains the same, an alternate manufacturer can be used.

Corrective steps that will be taken to avoid future nonconformances

An extensive training was held with all engineering staff on the proper use of generic dedication procedures and how to properly define and document critical characteristics for acceptance. The training also stressed the importance of the Engineering Verifier properly reviewing the document to determine technical adequacy.

Additional training concerning order entry review will be completed. This training will address the need to verify all technical requirements imposed by the customer purchase order are properly implemented and any discrepancies or technical issues are properly resolved in writing prior to completion of the order. This includes item description issues like that identified in example two and three above.

For example three all future Certificates of Compliance for commercially dedicated items will include the identification of the manufacturer.

Extent of condition evaluation is being performed and will be completed by February 03, 2015.

Date when corrective actions will be completed

Identified corrective actions are complete with two exceptions

1. The additional training will be completed by January 30, 2015.
2. Extent of condition evaluation will be complete by February 03, 2015.

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- B. Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50 states in part that, "A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed on accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. Test results shall be documented and evaluated to assure that test requirements have been satisfied."

Contrary to the above, the NRC inspection team identified three examples where test requirements were not satisfied and there was no documentation of evaluations for these test deviations.

- QualTech failed to document and evaluate a change in test configuration that affixed a power supply, VGA extender, and USB extender to the shaker table rather than the rear of the mounting plate as required for PO 19-25392.
- QualTech failed to document and evaluate pressure drops during a design basis event (DBE) / high energy line break (HELB) test that went below the test requirements specified in EGS-TR-HC521.
- QualTech failed to document and evaluate test requirements for PO 00151667 for pinch valves. Specifically, there was a PO requirement to pressurize the shell to test pressure 225 pounds per square inch (psi) during the seismic test, but the test procedure only pressurized to 80 psi. Additionally, during the hydrostatic and seat leakage tests, QualTech did not provide ranges to account for instrument uncertainty and did not record the actual gage readings during the test. Also, QualTech did not document the air pressure applied to the valves during the seat leakage test. Finally, there was no documentation of the actual test configuration used to perform the hydrostatic and leak tightness tests.

Response

QualTech NP, Huntsville Operations accepts the nonconformance and investigations /corrective actions taken are as follows:

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The reason for the noncompliance

For example one it was determined that the cause of the nonconformance was a lack of objective evidence documenting the customer expectations and necessary changes made during the test program. The intent of the customer was to install the power supply, VGA extender and USB extender to the shaker table, behind the mounting plate. This was confirmed based on customer witness verification and subsequently documented by the customer.

For example two it was determined that the pressure was identified as a goal and not a requirement. The actual requirement was to maintain temperature which was met for the entire test. To clarify, the customer did not provide any pressure requirements so QualTech created a reference line based on saturated conditions at the applicable temperatures for information. The customer has since provided some minimum pressure requirements which were met or exceeded during the entire test.

For example three it was determined that several errors were made in the test procedure. First, the test pressure for seismic testing incorrectly identified the seat leakage test pressure of 80 and not the shell test pressure of 225 psig as required by the customer purchase order. Second, no tolerances for test pressures were provided. Third, Actual test pressures were not required to be recorded. Fourth, although there was a written description of the test set up in the test procedure and photographs from the seismic test report that provided some evidence of test configuration no detailed documentation of actual test configuration was provided.

Corrective action steps that have been taken and the result achieved

For example one the testing was confirmed to be valid and documentation was generated by the customer to accept the test configuration.

For example two the test results were found to be acceptable as documented.

For example three to confirm that the seismic test at 80 psig with a shell test before and after the seismic test at 225 psig is acceptable, the customer has been contacted to request acceptance of the seismic test at 80 psig and based on their response we will either document their acceptance in the dedication package or if requested will perform a new seismic test at the higher pressure of 225 psig.

For the remaining issues in example three it has been confirmed that testing and test equipment was acceptable and valid test results were achieved even though documentation

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was very weak or inadequate. QualTech NP acknowledges that this is not an industry best practice and all future dedication and qualification procedures shall specify applied ranges and require that the actual test values shall be recorded on the data sheets. The procedure is being revised to properly define the test pressure of 225 psig, the tolerance required for pressure tests, the need to record actual test pressures, and to add test configuration.

Corrective steps that will be taken to avoid future nonconformances

An extensive training was held with all engineering staff on the proper translation of technical requirements contained in design documents, including customer purchase orders and specification, into supporting or subsequent technical documents. The training also stressed the importance of the Engineering Verifier properly reviewing applicable documents to determine technical adequacy.

All engineering and lab inspection/test personnel were trained on the requirements of QualTech NP, Huntsville Operations SOP 15.1, Rev. H. This included instances that occurred requiring the generation of a Notice of Anomaly. The training also emphasized the importance of generating a Notice of Anomaly to officially document any deviation/anomaly even if the customer witness is present and requests the change.

Additional training will be conducted for all engineering and quality personnel concerning order entry review. This training will address the need to verify all technical and quality requirements imposed by the customer purchase order are properly implemented and any discrepancies or technical issues are properly resolved in writing prior to completion of the order. This includes test program issues like that identified in example one above. Also training for all engineering, lab technicians and quality personnel will be performed to document that for all dedication and testing activities it is mandatory that: tolerances be provided for test parameters such as temperature, pressure and dimensions; that actual readings must be recorded (no yes/no is allowed without actual readings also being recorded); and testing that requires a "test setup" or assembly of a test fixture must include a drawing or sketch of test configuration.

Extent of condition evaluation is being performed and will be completed by February 03, 2015.

Date when your corrective action will be completed

Identified corrective actions are complete with three exceptions.

1. The additional training will be completed by January 30, 2015.
2. Seismic testing at 225 psig will be performed by January 23, 2015 unless concurrence is received from the customer that 80 psig is acceptable.
3. The extent of condition evaluation will be complete by February 03, 2015.