PENTAS CONTROLS, LLC
Phoenix, Arizona

May 18, 2015

United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-001

Subject: Reply to a Notice of Nonconformance
Reference: Nuclear Regulatory Commission Inspection Report For Pentas Controls, LLC No. 99901456/2015201 and Notice of Nonconformance

In response to the referenced NRC Notice of Nonconformance (NON), Pentas Controls, LLC provides the enclosed reply (Enclosure). In accordance with the instructions specified in the NON, the Enclosure addresses for each 1) the reason for the noncompliance, 2) the corrective steps that have been taken and results achieved, 3) the corrective steps that will be taken to avoid future noncompliance, and 4) the date when the corrective actions will be completed.

Pentas Controls, LLC understands and accepts the NON received from the NRC as a result of the inspection, and in the published Inspection Report. We take this NON seriously and are committed to correcting the identified issues. Actions have been initiated to remedy the specific findings provided and to avoid future noncompliance.

Please contact me if you have any questions or require additional information.

Sincerely,
Pentas Controls, LLC

Robert Prigmore
Quality Assurance Director

RRP/rrp

Enclosure: Reply to NRC Notice of Nonconformance Docket: 99901456 Inspection Report: 2015-201

Cc: Edward H. Roach, Chief
Mechanical Vendor Inspection Branch
Division of Construction Inspection and Operational Programs
Office of New Reactors

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Reply to a Notice of Nonconformance

May 18, 2015

A. Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B, "Quality Assurance Program 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 that, "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

Section 6.3.7, of Pentas Quality Assurance Procedure (QAP) 15.0, "Nonconformance Reporting and Corrective Action," Revision 1 dated April 15, 2014, states that "Upon completion of verification of corrective action, the QA Director shall sign and date the NCR, note the date of closure and shall file the NCR [nonconformance report] as a Quality Record."

Section 6.4.1 of QAP 15.0, states that "Items that have been identified as nonconforming, or potentially nonconforming, shall be segregated from conforming items by physical means or by means of identification."

Section 6.4.3 of QAP 15.0, states that "Where segregation by identification is used, nonconforming items shall be identified with red HOLD tags that are prominently displayed."

Contrary to the above, as of March 13, 2015, Pentas Controls failed to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.

Specifically, the NRC inspection team found:

1. Four items that Pentas approved during final inspection were shipped to customers without verification and/or closure of the nonconforming condition by the QA director, including:

   • NCR 1203-01: A safety-related power supply for the main steam line radiation monitoring system for Exelon Energy

   • NCR 1207-01: A safety-related power supply for the main steam line radiation monitoring system for Calvert Cliffs Nuclear Power Plant

   • NCR 1403-01: A safety-related Berkleonics power supply for Calvert Cliffs Nuclear Power Plant

   • NCR 1408-01: A safety-related GEMAC Dual Alarm Module and a safety-related GEMAC Input Summer Module for Nine Mile Point Nuclear Station

2. A Fluke 87 (ID: PCI-022) Multimeter was found with a red 'Hold tags' attached to it and no NCR was generated when the equipment was removed from service and placed in the designated segregation area. As a result of not generating the NCR Pentas failed to verify where this equipment was previously used and perform an evaluation to validate if the readings provided by the affected equipment still within the calibration range.

3. Approximately 30 items physically located in the designated segregation area did not have 'Hold tags' attached to them or open NCR's to document the nonconforming condition. Many of these items were actually conforming but were stored with nonconforming items in a manner that could allow the inadvertent use or installation of nonconforming items.

This issue has been identified as Nonconformance 99901456/2015-201-01.

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

Pentas Controls accepts this nonconformance and offers the following discussion regarding the reasons for the nonconformance. Pentas Controls initiated Corrective Action Request C1503-01 to address this nonconformance.

With respect to the NCRs, Pentas Controls documents all repair or corrective action activities within each respective Project Traveler. In cases where an NCR has been initiated with respect to a deficient component, or other project related issue, the NCR in some cases has been viewed as "in addition to" the information that will be thoroughly documented in the respective Project Traveler as the project moves forward. In some cases, this has led to NCR's not being updated appropriately for closure in a timely manner.

With respect to PCI-022, this instrument had recently been returned from calibration at the approved Calibration Laboratory. It had not been issued for any project prior to being issued to the technician. Initially powering up the instrument, the technician immediately identified that that the display was erratic. The technician returned the instrument to the Logistics Manager. There was no discussion or communication with respect to initiation of an NCR to track disposition of the erratic display on the instrument.

With respect to the segregation area, the majority of components observed in that area were not nonconforming. Pentas Controls believes the issue to center more in storing conforming, or possible conforming components in that area. At the time of this inspection, the only nonconforming part stored in the segregation area was PCI-022. As noted in the nonconformance, QAP 15.0 provides the instructions for segregation, which was not adequately complied with.

(2) The corrective steps that have been taken and the results achieved.

a. Pentas Controls has initiated a Corrective Action Review Group that includes the QA Director, Logistics Manager, and Engineering Director. This group will meet approximately once a month to review every open NCR and CAR. The purpose will be to provide and enter status updates, determine additional actions that should be performed, determine if

closure is warranted and perform closure actions if possible. The review group has met on one occasion to date with positive results. This effort is to ensure actions are timely, and backlog is minimized.

b. Pentas Controls NCR 1503-05 was initiated to document the problem with PCI-022. This NCR will remain open until as found calibration results are received from the calibration laboratory, and document the verification that this instrument was not used in any shop activities subsequent to the last calibration.

c. The nonconforming part segregation area has been firmly established, with no conforming parts stored or remaining in this area.

(3) The corrective steps that will be taken to avoid noncompliances.

a. The Corrective Action Review Group will continue to meet and review all open NCR/CARs each month. It is anticipated that this will prevent any instances of components being shipped with related NCRs remaining open.

b. Training sessions will be conducted with all personnel to reiterate the importance of documenting deficiencies in NCRs or CARs.

(4) The date when corrective action will be completed.

All corrective actions will be implemented by August 18, 2015.

B. 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."

Section 6.2.1 of Pentas QAP 16.0, "Corrective Action," Revision 1 dated June 9, 2013, states that "Conditions adverse to quality, including significant conditions adverse to quality, shall be identified promptly and corrected as soon as practical."

Contrary to the above, as of March 13, 2015, Pentas failed to establish measures to ensure that conditions adverse to quality were promptly identified and corrected. Specifically, for the sample of open corrective action requests (CARs) selected, the NRC inspection team noted that CARs had not been promptly corrected, including:

- C1311-01: NUPIC audit finding (VA 13223-01) documenting a recurrence of not having a basis for selecting critical characteristics when conducting commercial grade dedication. This CAR has been open for 16 months.

• C1311-03: NUPIC audit finding (VA 13223-05) documenting a recurrence that recorded test data was not aligned with the established acceptance criteria. This CAR has been open for 16 months.

• C1402-07: An internal audit finding documenting a recurring failure to conduct surveys of suppliers. This CAR has been open for 15 months.

This issue has been identified as Nonconformance 99901456/2015-201-02

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

Pentas Controls will also address the corrective action issues identified in this nonconformance in Corrective Action Request C1503-01.

While Pentas Controls accepts this nonconformance, the Pentas Controls takes exception to the characterization of the three Correction Action Request examples identified in the Nonconformance. The nonconformance states that CAR's C1311-01, C1311-03, and C1402-07 document a "recurrence" of a deficiency. This wording implies that the problems were previously identified which in turn would imply that previous corrective actions were ineffective.

A review was conducted of NUPIC Audit, VA 13223, November 4-8 2013, Pentas Controls Internal Audit 2014-01, February 3-7 2014, NUPIC Audit CENG 22994, May 2-9 2011. Audit 13223 identified these issues with no mention that the issues were repeat occurrences. There is no evidence or indication of any problems being previously identified with respect to bases for selecting critical characteristics, dedication test data/order alignment, or commercial grade surveys of suppliers. As these issues were not previously identified, Pentas Controls believes these CARs do not constitute a recurrence of a previously identified problem, or ineffective corrective actions.

With respect to CARs C1311-01 and C1311-03, the two issues were identified during the aforementioned NUPIC audit. As a result of the concern, Pentas Controls committed to review every Commodity Test Dedication Evaluation (CTDE) and Equivalency Evaluation, and revise any of these documents that: 1) required additional bases, or: 2), required reorder of the test steps. Since this required a review of over 600 documents, NUPIC agreed that Pentas Controls would conduct reviews for each document prior to use, revise if necessary prior to use. The Pentas Controls Engineering Director created two (2) separate data bases to track completion of reviews and revisions.

Subsequently, the NUPIC Lead Auditor performed a follow-up review for closure of the audit findings, which is documented in Duke Energy letter dated 4/22/2014. The two findings that were internally documented in the respective CARs were closed with the following statements:

> *The Engineering Director has reviewed all Equivalency Evaluations to identify those that require updating with improved justifications. PCI maintains several hundred Equivalency Evaluations. The Director has created spreadsheets identifying those Equivalency Evaluations that will require revision, as well as identifying those that are*

*currently acceptable (example attached).Each Equivalency Evaluation requiring revision **will be** revised prior to its use. The spreadsheets will be used to track these revisions to completion.*

*Pentas Controls is in the process of revising all of their CTDE Procedures and Commodity Test Data Sheets to align with the sequence steps for testing and recording the data. Since PCI has numerous CTDE testing procedures, they have created a log to show which has been revised. PCI will continue to revise the CTDE procedures as required for new commodities needed to be dedicated. The PCI CTDE Log **will be** updated in include the revised procedures when reviewed and approved for usage.*

NUPIC considered this a longer term project, to review/revise over 600 documents, so was satisfied with the process for the project, and closed the findings. However, Pentas Controls elected to use the CARs to track the review/revision activities to completion. Further, Pentas Controls has determined that completion of this project has been less than timely, and is devoting additional resources for completion. Pentas Controls will continue to track progress of this project with these CARs, and will update the CARs each month to monitor progress. The CARs will be closed when the review/revision project can be verified as complete.

C1402-07 was initiated during the internal audit, 2014-01 February 4-7 2014, because the Lead Auditor felt that wording within QAP 7.5, "Commercial Grade Surveys", required surveys of all suppliers, regardless of whether or not the supplier provided Safety or Quality related parts, components or services. This was not the intent of the procedure. Subsequently, the QAP 7.5 was revised on April 15, 2014 to clarify when and for what purpose a commercial grade service would be performed. In addition to this, recommendations were included to consider relocating portions of QAP 7.5 to other procedures, and deleting QAP 7.5, since at present Pentas Controls does not maintain any Quality Suppliers on the Approved Suppliers list that would necessitate performance of a Commercial Grade Survey.

Since this decision was not felt to be a high priority, closure of this CAR lacked timeliness, and did not meet expectations.

(2) The corrective steps that have been taken and the results achieved.

a) C1402-07 is now closed. QAP 7.5, "Commercial Grade Surveys", will be retained and utilized in the event Pentas Controls deems a Commercial Grade Survey necessary for acceptance of Quality or Safety Related parts or services.

b) The Corrective Action Review Group has been implemented to review every open NCR and CAR on an approximate monthly basis. The first group meeting has occurred with positive results. This group will review every open NCR and CAR on an approximate monthly basis to update, determine additional actions needed, or close as appropriate.

(3) The corrective steps that will be taken to avoid noncompliances.

a) With the implementation of the Corrective Action Review Group, it is anticipated that no noncompliances with respect to promptness or timeliness of Corrective Actions, or closure of CARs, will reoccur.

b) With additional resources assigned, we expect the CTDE and Equivalency Evaluation will be completed in a more timely manner.

(4) The date when corrective action will be completed.

Corrective actions will be complete by August 18, 2015.

C. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components."

Section 6.3, "Commodity Dedication Plan," of QAP-7.3, "Commercial Grade Dedication," Revision 2 dated September 6, 2013, states, in part, that the Commodity Dedication Specification Plan lists all critical characteristics for the applicable commodity type, and lists the attributes to be verified for the critical characteristics. The verification shall provide reasonable assurance that the correct commodity type with the proper values has been selected for use.

Contrary to the above, as of March 13, 2015, Pentas Controls failed to establish adequate measures for the selection and review for suitability of application of materials that are essential to the safety-related functions of the structures, systems, and components.
Specifically,

1. Pentas' EQ# X17-004, "Equivalency Evaluation for NLI 913189-A Firing Board w/ Terminal strip," identified FR-4 board as an acceptable alternative for the original glass epoxy substrate. Duane Arnold purchase order (PO) 0232796 for seismically qualified safety-related Pentas Controls PCI-913189-A1 firing board and terminal strips identified the board material as FR-4. Pentas' Commodity Dedication Plan Specification Data Sheet (CSN) M02, "Commodity Type Description: Circuit board," for PO 0232796 identified the acceptance method for board material as Hipot testing. The Hipot testing performed by Pentas did not verify the chemical composition of the board material and no laboratory testing was performed to verify the board's chemical composition. CSN M02 acceptance method for board material did no provide reasonable assurance the circuit board material was FR-4 board as required by PO 0232796.

2. Pentas' EQ# X17-004 identified tin/lead plating as an acceptable alternative for the plating material. Duane Arnold PO 0232796 identified tin/lead as the plating material for circuit boards traces and pads. Pentas' CSN M02 for PO 0232796 identified the acceptance method for plating material as conductivity testing. The conductivity testing performed by Pentas did not verify the chemical composition of plating material and no laboratory testing

was performed to verify the plating material chemical composition. CSN M02 acceptance method for plating material did not provide reasonable assurance the plating material was tin/lead board as required by PO 0232796.

This issue has been identified as Nonconformance 99901456/2015-201-03

(1) The reason for the noncompliance, or if contested, the basis for disputing the noncompliance.

Pentas Controls initiated CAR 1503-07 to address this issue.

FR4 was erroneously identified on the Commodity Test Dedication Data form as an acceptance criteria for laminate material. Laminate material was erroneously listed as the critical characteristic in the Equivalency Evaluation and in the Commodity Test Dedication Evaluation for circuit boards. Dielectric strength should have been listed as the critical characteristic for laminate material for the circuit board. The critical characteristics for the circuit board should have been listed as conductance and dielectric strength of material. The acceptance criteria should have been identified on the form as greater than 2kv per mil for dielectric strength, and less than 0.5 ohms for conductance.

The trace plating material, tin/lead, is described in Pentas Controls Equivalency Evaluation, EQ# X17-004, as the accepted plating material for circuit boards. There does not appear to be a standard requirement contained in any bases documentation requiring dedication to include verification of the chemical constituency of the trace material. The acceptability determination is based solely on the material's conductance. The acceptability of alternative circuit board trace materials, such as gold, platinum and silver, would also be based on the material's conductance within the circuit board. While resistance for these materials would be significantly less than tin/lead, conductance remains as the means to determine acceptability for circuit board dedication.

Pentas Controls has thoroughly reviewed the Duane Arnold PO 02327296 (correction, as there is no Duane Arnold PO 0232796) several times. Pentas Controls could find no request, reference, or description from Duane Arnold in their purchase order for tin/lead plating for the circuit board. Pentas Controls cannot recall ever receiving a specific request from any organization specifying a plating material for circuit boards.

Consequently, the suitability and acceptance of the materials that constitute Pentas Controls circuit boards was appropriately tested and dedicated. However, the Commodity Test Dedication Evaluation and Commodity Test Dedication Data form created discrepancies that led to this nonconformance, and require revision.

(2) The corrective steps that have been taken and the results achieved.

The bases for the critical characteristics for circuit board dedication and acceptability are stated in EPRI NP-5652 and TR-102260, "Plant Engineering: Guidelines for Acceptance of Commercial Grade Items in Nuclear Safety Related Application." This document supports the past and current process for Pentas Controls dedication of printed circuit boards.

The Commodity Test Data Evaluation is in revision for circuit boards to clarify critical characteristics.

(3) The corrective steps that will be taken to avoid noncompliances.

a) The Commodity Test Dedication Evaluation, and the Commodity Test Dedication Data form will be revised to assure circuit board testing and dedication documentation is in compliance with the requirements contained in EPRI NP-5652.

b) Pentas Controls will conduct an extent of condition evaluation to verify that other Commodity's Test Dedication Data forms reflect the appropriate critical characteristics and acceptance criteria for the commodity.

c) Pentas Controls will conduct training on the changes made to the Commodity Test Dedication Evaluation and Commodity Test Dedication Data Form.

(4) The date when corrective action will be completed.

All corrective actions regarding this noncompliance will be completed by October 18, 2015