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June 22, 2017

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Dear Sir:

Please find attached:

"Reply to a Notice of Nonconformance"
(99901476/2017-201)

Sincerely,

Daniel T. Bolling
Product Assurance Manager

Cc: Chief
Quality Assurance Vendor Inspection Branch 2
Division of Construction Inspection and Operational Programs
Office of New Reactors

IE09
NRO

L&S Machine Co., L.L.C.
709 Donohoe Rd
Latrobe, PA. 15650
Phone: 724-837-5500
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www.lsmachineco.com

L&S MACHINE CO., L.L.C.

Letter No. LSM-LTR-17-03

June 2, 2017

Attention: **John P. Burke, Chief**

Address: Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection and Operational Programs
Office of New Reactors

Subject: **Response to Notice of Nonconformances 99901476/2017-201-01 & 02 for Nuclear Regulatory Commission Inspection Report of L&S Machine Company No. 99901476/2017-201.**

References:

1. **Nuclear Regulatory Commission, Vendor Inspection Report, "Inspection Report No. 99901476/2017-201"**

Dear Mr. Burke,

L&S Machine Co LLC. (L&S) acknowledges receipt of NRC Letter dated May 4, 2017 transmitting the NRC Inspection Report, 99901476/2017-201, from March 20 -23, 2017 of L&S Machine. The NRC Inspection of L&S was an extremely thorough examination of the L&S Quality Program. We greatly appreciate the NRC Inspection team's time, effort, and support during this period; and we kindly thank them for their comments, observations, and suggestions as for how L&S can continuously improve its Quality Program.

L&S is extremely committed to complying with the provisions of 10 CFR 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and 10 CFR 21, "Reporting of Defects and Noncompliance". As such, we are taking the results of this inspection seriously and are taking the appropriate actions necessary to address the deficiencies noted.

Please find attached our responses to NON 99901476/2017-201-01 and NON 99901476/2017-201-02. L&S respectfully requests the NRC to consider our responses, Attachments 1 and 2 as satisfactorily addressing the concerns raised.

Should you have any questions with regard to the attached responses, please do not hesitate to contact me at (724) 837-5500.

Sincerely,

** Electronically Approved in L&S Machine Co. Q-Pulse

Daniel T Bolling
Quality Assurance Manager
L&S Machine Co., L.L.C.

Attachments:

1. L&S Response to Notice of Nonconformances 99901476/2017-201-01
2. L&S Response to Notice of Nonconformances 99901476/2017-201-02

CC:

Robert Dinardi / L&S Machine
Russell Lion / Tioga Pipe
David Smathers / L&S Machine

Attachment 1: L&S Response to Notice of Nonconformances 99901476/2017-201-01

NRC Notice of Nonconformance 99901476/2017-201-01 states:

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part, that "... 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."

Criterion XVI, "Corrective Action," 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 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."

Contrary to the above, as of March 23, 2017, L&S failed to establish measures for source evaluation and provide objective evidence of quality furnished by a contractor or subcontractor. Also, L&S failed to ensure that conditions adverse to quality are promptly identified and corrected. Specifically, L&S closed out corrective action report (CAR) NC621 on October 16, 2015 without completing the corrective actions to evaluate all suppliers prior to designating them on the Approved Supplier List (ASL). Subsequently, L&S added Tooling Specialist Inc. (TSI) as a safety-related approved supplier on their ASL and issued a safety-related purchase order (PO) to TSI on October 19, 2015 for the procurement of coordinate measuring machine (CMM) inspection services. However, the initial audit to qualify TSI on the ASL was not conducted until February 1, 2017. As a result of L&S' inadequate corrective actions to evaluate and qualify its suppliers, L&S failed to verify that TSI's quality assurance program was qualified to perform safety-related CMM inspection services.

L&S Response to required responses:

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

Upon further review of this NON and the L&S Supplier Audit program, L&S must contest the issuance of this condition as a nonconformance. In that, at the time of NRC Inspection L&S Quality failed to provide the NRC Inspection Team with the appropriate objective evidence which would have shown the inspection team that L&S had indeed evaluated its suppliers and closed its corrective actions in accordance with established procedures. In addition, L&S has raised an internal CAR, LSM-CAR-17-16, in accordance with our procedure GOP-16.0 to document corrective and follow up actions.

As background and justification for our response; Westinghouse (WEC) Supplier Quality Assessment conducted a triennial audit of L&S in April 2013. One finding issued by WEC to L&S was that L&S was utilizing the WEC Qualified Suppliers List (QSL). L&S responded to the finding by stating L&S was authorized to use the WEC QSL by way of WEC Purchase Orders; and that L&S recognized WEC's desire to no longer continue the practice of sharing its QSL with the supplier base. L&S and WEC Quality groups worked together to develop a plan to transition away from the

WEC QSL to the L&S ASL. This plan was identified on L&S Corrective Action, NC621. The plan and schedule for transitioning was developed and completed as corrective action for NC621 with agreement by WEC Quality; NC621 was updated and corrective actions closed on Oct 24, 2013 with the plan that L&S would be fully self-sufficient and utilizing its ASL by April 2015. Over the next 2 years, L&S revised procedures, developed audit schedules and audit dates, implemented a Quality Management Software (Q-Pulse) for the management of Quality processes, qualification processes, and training for evaluating and monitoring the supplier base; all in support of L&S being able to manage its own supplier base. L&S determined the ASL would consist at the time of 5 suppliers; two (2) qualified to Appendix B / Part 21 and three (3) by commercial grade dedication. Tooling Specialist Inc (TSI) was one of those Appendix B qualified suppliers. On April 28 & 29, 2015 L&S conducted a supplemental audit of TSI using L&S external audit, LSM-EA-15-1. L&S utilized this audit to qualify TSI and add them to the L&S ASL on April 29, 2015. LSM-EA-15-1 included an audit plan and audit checklist specifically developed for the performance of the limited scope of work L&S was to procure from TSI. The scope of work was for CMM measurement and inspection services for safety related components in support of the AP1000 reactor internal components; LSM-EA-15-1 covered the applicable sections of Appendix B and Part 21 for this work. L&S' Lead Auditor closed audit, LSM-15-EA-1, on October 17, 2015. L&S Quality closed Corrective Action, NC621, on October 16, 2015. Subsequently, L&S issued Purchase Order K4606 on October 19, 2015.

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

1. Issued Corrective Action, LSM-CAR-17-16.
2. Review of L&S ASL for suppliers added to ASL without adequate evaluation and assessment. All suppliers on the L&S ASL were qualified or dedicated prior to issuance of any safety related POs.
3. Reviewed a sample of L&S Corrective Action Program CARs from 2014 to 2016 to verify corrective actions were closed appropriately. Evaluation was completed May 26, 2017, results were all CARs reviewed were closed correctly.

(3) The corrective steps that will be taken to avoid further noncompliance:

No further actions are necessary.

(4) The date when the corrective action will be completed:

All actions are complete.

L&S Corrective Action Report, LSM-CAR-17-16, will be completed and closed once NRC acceptance of L&S' responses is received.

Supplemental information for Attachment 1:

L&S MACHINE CO., L.L.C.

Audit Report

Details	
Number LSM-EA-15-1	**Title** Tooling Specialists Inc.
Status Closed	**Calendar** Supplier Audit
Lead Auditor Bolling, Dan	**Total Score With Percentage** 266/268 (99%)

Dates		
Scheduled Start Date 4/28/2015	**Scheduled End Date** 4/29/2015	**Scheduled Duration** 2 Day/s
Actual Start Date 4/28/2015	**Actual End Date** 4/29/2015	**Actual Duration** 2 Day/s
Closed By Bolling, Dan	**Closed Date** 10/17/2016 9:37 AM	

Findings

Overview

L&S Machine conducted a supplemental audit of Tooling Specialists focusing on Requirement 10, Inspection Services at the TSI Latrobe & Kozack Building locations. TSi's QA Manual and quality activities were audited to 10CFR50 Appendix B and NQA-1 2008. TSI inspects L&S Machine's manufactured components for Westinghouse Electric Co., Enclosures (V6-401), at the Kozack building using CMM. One finding was identified, the temp/humidity gage was found to be overdue for calibration. Two observations were noted. The audit revealed that TSI meets the requirements of 10CFR50 Appendix B & NQA-1.

Number Of Non-Conformances	1
Number Of Outstanding Non-Conformances	0
Number Of Observations	2

Number	Details	Type	Status
2	Does the documented program identify the items and activities to which it applies?Yes, compliant TSI QA Manual Revision P, Quality PolicyChecklist:Supplemental Audit of TSI (Tooling Specialist Inc)Question No. 3.1Observation: TSI does not reference Kozack building in their QA Manual.	Observation	na

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3	Is there evidence that personnel performing or managing activities affecting quality have received training in their job responsibilities and authority, general criteria, including applicable codes and standards, regulatory commitments, company procedures and QA program requirements?yes, Compliant. Procedure QP-9.3 R-D Training, QP-9-4 R-D Qualification of Inspection and Test PersonnelMike Brinker is CMM inspector and programmer.Checklist:Supplemental Audit of TSI (Tooling Specialist Inc)Question No. 3.4.1Observation: TSI doesn't specifically state that Mike Brinker is a qualified CMM Programmer thru review of training, education and experience.	Observation	na
LSM-EA-15-1	Are tools, gages, instruments and other M & TE used for activities affecting quality controlled, calibrated at specific periods , adjusted and maintained to required accuracy limits?Partially compliant, CMM & sphere have tags with date calibrated and due dateFinding: Temp/Humidity gage was found to be overdue for calibration, the cal sticker required calibration was due 3/30/2015.Checklist:Supplemental Audit of TSI (Tooling Specialist Inc)Question No. 7.1	Non-Conformance	Closed

Accepted By	Accepted On
Lion, Russell	5/28/2015 2:46 PM

Scope

Type	Description
Supplier	Tooling Specialists Inc.
Area Of Standard	Requirement 1 Organization (NQA-1\Requirement 1 Organization)
Area Of Standard	Requirement 2 Quality Assurance Program (NQA-1\Requirement 2 Quality Assurance Program)
Area Of Standard	Requirement 6 Document Control (NQA-1\Requirement 6 Document Control)
Area Of Standard	Requirement 8 Identification and Control of Items (NQA-1\Requirement 8 Identification and Control of Items)
Area Of Standard	Requirement 10 Inspection (NQA-1\Requirement 10 Inspection)
Area Of Standard	Requirement 12 Control of Measuring and Test Equipment (NQA-1\Requirement 12 Control of Measuring and Test Equipment)
Area Of Standard	Requirement 13 Handling, Storage and Shipping (NQA-1\Requirement 13 Handling, Storage and Shipping)
Area Of Standard	Requirement 15 Control of Nonconforming Items (NQA-1\Requirement 15 Control of Nonconforming Items)
Area Of Standard	Requirement 17 Quality Assurance Records (NQA-1\Requirement 17 Quality Assurance Records)

Auditor Group

Auditor Name	Note
Bolling, Dan	

Auditee Group

Person Name	Note
Brinker, Michael	
Musiak, Keith	

Additional Information

Audit Classification	Requirement
Nuclear - Safety Related	10CFR 50 Appendix B / NQA-1 1994, 2008 & 2009 (Addenda)

Checklist

Title	Total Score	Completed By	Completed Date
Supplemental Audit of TSI (Tooling Specialist Inc)	266/268 (99%)	Bolling, Dan	4/29/2015 3:27 PM

Attachments

Name
Objective Evidence LSM-EA-15-1
Audit Checklist Review
TSI Audit Summary & CAR

Notes

Created By	Note Text	Date Created
Lion, Russell	TSi responded to CAR LSM-EA-15-1 and corrected the calibration finding. --- RFL added on behalf of Lead Auditor Dan Bolling	6/2/2015
Bolling, Dan	add additional requirements to audit plan	10/17/2016

External Audit

Details

Number	Status	Owner	Raised Date
NC621	Closed	Lion, Russell	6/18/2013

Source	Standard	Target Date
External Audit	NQA-1\Requirement 18 Audits	6/26/2014

Raised By Person	Severity	Raised Against (Department or Supplier)	Fault Category
Lion, Russell	Minor	Quality Assurance	Quality Planning

Audit

Details

Westinghouse Audit WES-2013-065 identified through observation that Westinghouse will begin restricting the use of its Qualified Suppliers List by suppliers. As such, L&S will need to begin qualifying suppliers that were previously qualified through PO transference. L&S and Westinghouse need to establish transition period and guidelines for this change in supplier qualifications

Process	(L/S) Dwg Nbr
Audit	N/A

Document	P/N (WEC)
Subcontractor Qualification and Control	N/A

Closed By	Closed Date	Resolution
Lion, Russell	10/16/2015 11:19 AM	Process Update

Identifying Corrective Action

Target Date	Owner	Closed Date	Closed By
8/30/2013	Lion, Russell	10/22/2013	Lion, Russell

Details

L&S and WEC coordinate to identify the suppliers L&S utilizes Westinghouse QSL, coordinate with WEC to update PO 4500472222 (T&A) to reflect not utilizing WEC QSL, and develop a transition plan with WEC.---------- Oct 21, 2013 ----------L&S and WEC held a meeting on Sept 4, and follow up telecon with the following resolution. Westinghouse will be removing general supplier access to their QSL. The removal will occur sometime in 2014 / 15, L&S agreed and accepted the fact this change will be coming. L&S discussed that sufficient time must be allotted so no adverse impact to L&S will occur. WEC agreed, and stated a schedule will be developed and shared with the supplier base regarding implementation of WEC QSL restriction. L&S corrective actions will be defined and scheduled in the Corrective Action stage. The stage will define the suppliers requiring Audit or Survey, an audit schedule to be developed, and costing plan for implementing an L&S Audit Schedule.Stage is closed 10/22/13 - RFL----------

Actions

L&S MACHINE CO., L.L.C.

Corrective Action

Target Date	Owner	Closed Date	Closed By
10/4/2013	Lion, Russell	10/25/2013	Lion, Russell

Details

Develop audit plan for L&S supplier base reflecting the approved transition plan.
---------- 10-24-13 ----------
Westinghouse (SQA) and L&S held a meeting to discuss the plan to transition from L&S utilizing the WEC QSL. Both parties agreed that prior to the next L&S triennial in April 2016 L&S will have developed and implemented a Supplier Qualification program. The following transition plan was developed and accepted by all:1. L&S will identify the suppliers (Safety Related and Commercially Dedicated) requiring audit / survey under L&S' QA Program. 2. L&S to develop a schedule to conduct the audits and surveys for these suppliers. 3. All suppliers identified will have their scheduled audits / surveys completed by March 2015. 4. WEC will update the L&S SAES once all audits / surveys have been performed April 2015 denoting that L&S must use its own Approved Suppliers List.5. WEC will revise Purchase Orders and SQAR as applicable once the L&S Audits / Surveys are complete and WEC SAES updated.The above transition plan completes the final action associated with SCAR-13-142-M061 so the SCAR may be closed as agreed during the meeting.
---------- End ---------- 10/24/13 RFL

Actions

Follow Up

Target Date	Owner	Closed Date	Closed By
3/31/2015	Lion, Russell	10/16/2015	Lion, Russell

Details

Follow Up - verify audits scheduled and resources available to implement audit plan.----- 4/16/14 ---- Finalized Internal Audit Schedule in Q-Pulse xxxx RFL----- 6/30/2014 ----- L&S Approved Suppliers List generated and finalized into Q-Pulse xxx RFL-----1/7/15 ------ preliminary audit schedule developed for ASL, require supplier confirmation. audit checklist development in process based upon NUPIC checklists. xxxx RFL---- 10/1/15 ---- audit checklist finalized in Q-Pulse Audit Module. ASL complete. Complete and ready for closeout. XXX RFL

Actions

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Attachment 2: L&S Response to Notice of Nonconformances 99901476/2017-201-02

NRC Notice of Nonconformance 99901476/2017-201-02 states:

Criterion XVIII, "Audits," of Appendix B to Title 10 Part 50, states, in part, that "...audits shall be performed in accordance with the written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited."

Subsection 3.18.1.4 of L&S' Quality Assurance Manual, LSM_QAM_001, Revision 10 dated October 15, 2016, states that, "Audits are performed by qualified personnel, independent of the activity being assessed, using written procedures and/or checklists, as appropriate."

Contrary to the above, as of March 23, 2017, L&S failed to ensure that audits were performed by personnel not having direct responsibilities in the areas being audited. Specifically, the NRC inspection team identified that for internal audits conducted between 2013 and 2016 at the L&S facilities located at Latrobe and Marion Center, the Production Assurance Manager and the Director of Quality participated as a member of the audit team and audited areas for which they had direct responsibility.

L&S Response to required responses:

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

The cause for this noncompliance was a function of the Quality Management Team (Director of Quality and Product Assurance Manager) incorrectly assuming they were independent of the areas being audited; in that the Product Assurance Manager was responsible for Criteria 15, Control of Nonconforming Items; and the Director of Quality was responsible for Criteria 16, Corrective Actions. Contrary to this division of responsibility the Director of Quality and Product Assurance Manager both took actions and responsibilities for completing nonconformance reports and corrective action reports thereby removing their independence when performing the internal audits. Neither the Director of Quality nor the Product Assurance Manager recognized this conflict during the planning and execution of internal audits until the NRC Inspection Team identified the conflict.

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

L&S has taken the following actions to correct the defect –

1. Initiated L&S Corrective Action Report: LSM-CAR-17-17
2. Conducted an extent of condition review of internal audits; reviewed all internal audits and audit reports from 2013 to 2016 to determine if any other conditions exist where audit personnel audited the areas in which they were responsible of. L&S identified that the only area where independence was not maintained was for Nonconformance and Corrective Actions between 2014 and 2016.
3. Developed a sampling plan using MIL-STD-105 as a guide for L&S' Nonconformance Reports. The sampling plan covered Nonconformance Reports generated and completed in 2014, 2015, and 2016. L&S employed its 3rd party Lead Auditor to conduct an evaluation of random Nonconformance Reports as identified in the sampling plan with the intent to

ensure the Nonconformance Reports were processed in accordance with L&S' procedures; including any technical justifications, 10CFR 21 evaluations, rework activities, follow up actions, and objective evidence to support closing the Nonconformance Reports. The 3rd party Lead Auditor completed the evaluation and provided L&S with a summary report stating that for the Nonconformance Reports evaluated there were no instances where L&S had incorrectly completed and closed a Nonconformance Report. Based upon the sampling plan developed, L&S can confidently state that even though the Nonconformance program was evaluated by personnel not independent of the Nonconformance activity; the audits were effective in ensuring the Nonconformance program was being properly implemented.

4. Developed a sampling plan using MIL-STD-105 as a guide for L&S' Corrective Action Reports. The sampling plan covered Corrective Action Reports generated and completed in 2014, 2015, and 2016. L&S employed its 3rd party Lead Auditor to conduct an evaluation of random Corrective Action Reports as identified in the sampling plan with the intent to ensure the Corrective Action Reports were processed in accordance with L&S' procedures; including any technical justifications, 10CFR 21 evaluations, corrective action steps, follow up actions, as well as objective evidence to support closing the Corrective Action Reports. The 3rd party Lead Auditor completed the evaluation and provided L&S with a summary report stating that for the Corrective Action Reports evaluated there were no instances where L&S had incorrectly completed and closed a Corrective Action Report. Based upon the sampling plan developed, L&S can confidently state that even though the Corrective Action program was evaluated by personnel not independent of the Corrective Action process; the audits were effective in ensuring the Corrective Action program was being properly implemented.

L&S has completed all corrective actions associated with this condition.

(3) The corrective steps that will be taken to avoid further noncompliance:

L&S has made a business decision that all internal audits would be conducted by a 3rd Party Lead Auditor. In addition, L&S management identified 2 additional personnel (1 from Quality and 1 from Manufacturing) to be trained as auditors to assist with internal auditing thus providing an additional layer of protection to ensure independence when conducting internal audits.

(4) The date when the corrective action will be completed:

All corrective actions have been completed.

L&S Corrective Action Report, LSM-CAR-17-17, will be completed and closed once NRC acceptance of L&S' responses is received.