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U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555-0001

Re: Inspection Report 9901477/2017-201
Reply to a Notice of Nonconformance 99901477/2017-201-01

This letter is in regard to Swagelok Company's Nuclear Regulatory Commission Inspection Report No. 99901477/2017-201. Below is a discussion of relevant criteria, procedures, and findings and an explanation of actions that Swagelok is implementing to avoid non-conformances in the supplier approval process.

Quality Assurance Criteria and Swagelok Quality Assurance Manual:

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" (the "Criterion") 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."

In furtherance of the Criterion, Section 7-200 ("Supplier Evaluation and Selection") of Swagelok's Quality Assurance Manual, Revision G, dated January 1, 2016, states, in part, that

"All suppliers are evaluated based on the effect of the purchased items, source material, or service on the final product to determine their ability to meet specified technical and quality requirements. This includes suppliers who maintain an ASME Quality System Certificate or N type Certificate. The evaluation includes: (1) An on-site survey/audit; (2) An assessment of the supplier's quality performance, including recent history of producing similar products, and (3) Quality program, including records and documented objective evidence of effective implementation."

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The NRC Inspection Findings:

An NRC inspection team reviewed Swagelok's subcontracting processes in light of the Criterion. In April 2017, the NRC inspection team provided its report, which concluded that Swagelok did not have adequate measures for source evaluation and selection of contractors and subcontractors and had not established adequate measures to obtain objective evidence of quality furnished by the contractors or subcontractors. Specifically, the NRC inspection team determined that:

- Swagelok procured heat treating services as safety-related without a supplier audit to verify and document the effectiveness of the suppliers quality program to meet the requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21.
- Swagelok purchased safety-related material (raw material) and services (e.g. machining, deburring, grinding, cutting, and testing) without sufficient measures to ensure that these suppliers had implemented the requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21. Specifically, the evaluation of Swagelok's Appendix B to 10 CFR Part 50 and 10 CFR Part 21 programs and associated implementing procedures did not provide documented objective evidence to demonstrate compliance with the requirements passed down through procurement documents. In addition, Swagelok's audits of these suppliers did not verify that they had imposed and verified the necessary controls, including the applicable regulatory and technical requirements, on their sub-suppliers.
- Swagelok's commercial-grade surveys of suppliers of commercial machining and heat treating services did not provide adequate documented objective evidence to demonstrate that the process and controls of the selected critical characteristics identified in the Swagelok technical evaluation were adequately controlled and the components would perform their intended safety function. Verification of the control of critical characteristics supports the basis for the selection of the sample testing population for the material's chemical composition and mechanical properties to complete the acceptance testing as part of Swagelok's dedication process.

Reason for Non-Compliance:

On March 23, 2017, based on preliminary feedback from the NRC team provided prior to the issuance of its April report, Swagelok opened corrective actions CA170323001 and CA170323002. Pursuant to these corrective actions, Swagelok conducted root cause analysis and found the following:

- Swagelok conducted an on-site audit was performed at the heat treating supplier's facility to verify the supplier's quality program met the requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21. The audit identified deficiencies in the supplier's quality program which required a follow-up audit. A follow up was not performed due to an error in the supplier addition process which allowed purchase orders to be sent to the supplier without completion of the follow up audit.
- Swagelok performs on-site audits of all suppliers of safety-related materials and services. The completed audit checklists did not contain adequate objective evidence of the suppliers' implementation of 10 CFR Part 50, Appendix B and 10 CFR Part 21. The current audit checklist does not provide specific guidance to the audit team on what objective evidence to record during the audit.
- Swagelok's commercial grade survey plans and reports list the critical characteristics required to be controlled by the supplier. The completed survey checklists did not contain adequate objective evidence of the suppliers' controls implemented to control the identified critical characteristics. The current audit checklist does not provide specific guidance to the audit team on what objective evidence to ask during the audit.

Corrective steps that have been taken and the results achieved:

Swagelok takes safety and compliance seriously and has fully cooperated with the NRC inspection team. As noted above, Swagelok began addressing issues preliminarily raised by the NRC team even before the team issued its April report. Since receipt of the report, Swagelok has taken the following actions:

1. Swagelok has evaluated its approved suppliers list to determine if any current suppliers can be evaluated using a commercial grade survey to support commercial grade dedication of the materials or services they provide. This evaluation has determined that several suppliers can provide commercial grade items and need not be qualified as suppliers of safety-related items and services.
2. Swagelok is developing more prescriptive supplier audit and survey checklists and evaluating the procurement requirements provided to suppliers of safety-related and commercial grade items and services.

Corrective steps that will be taken to avoid further noncompliance:

In addition to the actions described above, Swagelok will implement the additional measures described below:

1. Swagelok will complete follow up audit of the heat treating supplier and revise the supplier addition process to require the approved suppliers list be updated and reviewed prior purchase orders being sent to a new supplier.
2. Swagelok will require suppliers of safety-related items and services to review their quality programs and verify they fully comply with 10 CFR Part 50, Appendix B, 10 CFR Part 21, and Swagelok's procurement requirements.
3. Swagelok will implement the new supplier audit and survey checklists and provide training to lead auditors and auditors on using the new checklists and documenting objective evidence.

Date corrective actions will be completed:

December 1, 2017

Swagelok is committed to closing out these items and implementing improvements to its supplier approval.

Sincerely,



David H. Peace