



November 30, 2021

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

cc: Chief, Quality Assurance and Vendor Inspection Branch,
Division of Reactor Oversight, Office of Nuclear Reactor
Regulation

Subject: Reply to a Notice of Nonconformance

Reference NRC Inspection Report No. 99900905/2021-201
Nonconformance 99900905/2021-201-01
Nonconformance 99900905/2021-201-02

Dear Sir/Madam:

NTS Huntsville, AL has reviewed Nonconformance 99900905/2021-201-01 and Nonconformance 99900905/2021-201-02 and is enclosing response to said nonconformances.

Should there be any questions or need for additional information, NTS will be pleased to provide the same. I may be contacted by phone at (256) 716-4329, or by email at fred.jefferson@nts.com.

Sincerely yours,

NTS, Huntsville Operations

Fred Jefferson
Manager, Quality Assurance

Attachment: Response to Notice of Nonconformance

Distribution: Eric Loucks, Gary Dennis

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NRR

RESPONSE TO NRC NOTICE OF NONCONFORMANCE
Inspection Report 99900905/2021-201, dated November 19, 2021

Nonconformance 99900905/2021-201-01

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the NTS Huntsville (hereafter referred to as NTS) facility in Huntsville, AL, from October 18, 2021 through October 22, 2021, NTS did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon NTS by its customers or NRC licensees.

- A. 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.* The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Section 3.0, "Supplier Evaluation Methods," of NTS' Quality Assurance Procedure (QAP) HSV 7-1, "Supplier Evaluation and Approved Suppliers List," Revision 7, dated June 7, 2021, states, in part that "[...] an initial on-site audit of the supplier's Quality Assurance Program is conducted. Subsequent on-site audits are conducted on a triennial basis."

Contrary to the above, as of October 22, 2021, NTS failed to establish adequate measures for source evaluation and selection to verify the effectiveness of the control of quality by contractors and subcontractors to assure that purchase services conform to the procurement documents. Specifically, NTS did not perform an on-site commercial grade survey of a supplier of calibration services to determine the adequacy of the supplier's quality controls to ensure that the critical characteristics of the calibration services continue to be acceptable. Instead, NTS performed a fully remote commercial grade survey of the calibration supplier.

This issue has been identified as Nonconformance 99900905/2021-201-01.

RESPONSE TO NRC NOTICE OF NONCONFORMANCE
Inspection Report 99900905/2021-201-01, dated November 19, 2021

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

NTS Response:

The apparent cause is that the vendor was not allowing on-site surveys due to COVID 19 concerns.

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

NTS Response:

The vendor was listed on NTS' approved suppliers list for calibration services based on their ISO/IEC 17025:2017 accreditation and the May 2021 remote survey. NTS performed a review of the purchase orders issued to vendor since the May 2021 survey was conducted. All purchase orders issued to the vendor required the vendor to perform calibration services to their ISO/IEC 17025:2017 accreditation. No purchase orders were issued to the vendor that required calibration services to be performed to survey requirements.

- (3) The corrective steps that have been taken to avoid noncompliance.

NTS Response:

The Commercial Grade Survey of this vendor was not required because of the vendor's ISO/IEC 17025:2017 accreditation. NTS has removed the reference to the remote survey from their Approved Suppliers List.

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

NTS Response:

The above action is complete.

RESPONSE TO NRC NOTICE OF NONCONFORMANCE
Inspection Report 99900905/2021-202-02, dated November 19, 2021

B. 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."

NTS' QAP HSV 16-1, "Corrective Preventive Action Program," Revision 3, dated June 15, 2020, provides for the identification and problem reporting, investigation of the problem for cause, reporting of the corrective actions, including the results of those actions, and evaluation of the effectiveness of the corrective action.

Contrary to the above, as of October 22, 2021, NTS failed to promptly correct conditions adverse to quality. Specifically, NTS failed to implement corrective actions to address Nonconformance 99900905/2015-202-01 as documented in Corrective/Preventive Action Report (CPAR) No. 15-019. Both NTS's official response to the NRC and CPAR No. 15-019 stated that NTS would establish a formal written procedure with data sheets for the performance of routine pre-test and post-test verification checks (spanning) of test equipment. In addition, NTS stated that it would retrain personnel on the specific Criterion XI, "Test Control," and Criterion V, "Instructions, Procedures, and Drawings," of Appendix B to 10 CFR Part 50 to ensure future processes are properly documented. During the inspection, the NRC inspection team identified that NTS closed CPAR No. 15-019 and did not have any objective evidence that a formal procedure was written or that NTS personnel were trained.

This issue has been identified as Nonconformance 99900905/2021-201-02.

RESPONSES TO NRC NOTICE OF NONCONFORMANCE
Inspection Report 99900905/2021-201-02, dated November 19, 2021

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

NTS Response:

The noncompliance was apparently caused by a failure of quality management to properly review the objective evidence prior to closing CPAR No. 15-019.

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

NTS Response:

NTS has issued CPAR No. 21-031 to document this noncompliance. The corrective action for the new CPAR is to write a procedure that addresses the activities being performed and to train appropriate personnel to the procedure. Since the checks were generally being performed based on engineering judgement and were not required to validate test results, no further action is deemed necessary as a result of this noncompliance.

- (3) The corrective steps that have been taken to avoid noncompliance.

NTS Response:

NTS quality management will follow-up on the CPAR No. 21-031 and verify objective evidence prior to closing the CPAR No. 21-031.

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

NTS Response:

These activities shall be completed no later than January 28, 2022.