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LTR-NRC-24-27

July 15, 2024

Subject: Reply to Notice of Nonconformances Cited in NRC Inspection Report No. 99900404/2024-201 Dated June 18, 2024

Westinghouse Electric Company LLC (Westinghouse) acknowledges receipt of NRC Inspection Report Number 99900404/2024-201 and Notice of Nonconformances (NONs), dated June 18, 2024. Westinghouse is taking appropriate actions to resolve the NONs and is committed to compliance with the provisions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocess Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities.”

Details of the corrective actions associated with these NONs are attached to this letter.

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Nonconformance 99900404/2024-201-01

Criterion VII, "Control of Purchased Material, Equipment, and Services," 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 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."

W2-9.4-101, "Control of Purchased Items and Services," Revision 8.1, Section 4.5.3, states, in part, that "Westinghouse methods to accept an item or service from a supplier shall be a supplier certificate of conformance, source verification, receiving activities, receipt inspection, or post-installation test at the nuclear facility site, or a combination of these methods." Section 4.5.3.1 of W2-9.4-101, states that "where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements (e.g., certificate of conformance) shall be available at the nuclear facility site prior to installation or use."

Contrary to the above, as of May 10, 2024, WEC failed to ensure that purchased material, equipment, and services from Liberty Electronics conform to the purchase order (PO) requirements. Specifically, WEC did not provide sufficient objective evidence to demonstrate that the requirements imposed in PO 4500858963 for procured calibration services and recording of inspection, measurement and test equipment used were satisfied.

Westinghouse Response:

Westinghouse has created issue report IR-2024-6678 in its Corrective Action Program to track the issue and completion of corrective actions.

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

   Westinghouse acknowledges objective evidence was not concisely documented or readily available to demonstrate how the requirements, as documented in CDI-4057, for the procurement of calibration services and the recording of inspection, measurement and test equipment were satisfied based on the supplier evaluation records presented for Liberty Electronics. The analysis for IR-2024-6678 identified the following causes of the noncompliance:

   - Supplier Quality Assessment (SQA) inadequately documented the evidence and supporting detail within the supplier evaluation records (e.g. checklist, report, Supplier Assessment Evaluation Summary) to resolve the gap between Liberty's QA Program and the requirements defined within CDI-4057 holistically. Specifically, SQA narrowly focused on documenting the justification to confirm the acceptance criteria was being met, as it related to the services being provided, rather than

documenting the evidence in how Liberty's QA Program and process controls provides reasonable assurance to meet the critical characteristics.

- The resulting issue(s) of the commercial grade survey (WES-2023-102) were ineffectively processed in accordance with the requirements established within QA-7.22, "Commercial Grade Survey (CGS) Process", Revision 1.1 dated 3/31/22. Through discussion with the Westinghouse Lead Auditor, inadequate assumptions were made when processing the deficiency with Liberty's QA Program which resulted in the compensatory measures on the QSL to be inadvertently removed. In addition, the Lead Auditor failed to issue a discrete issue against CDI-4057. These processing deficiencies are attributable to ambiguity with the requirements established in QA-7.22 as it relates to maintaining compensatory measures for programmatic deficiencies identified during the CGS process until Westinghouse Engineering has full resolved the CDI discrepancies.

Although Westinghouse acknowledges that objective evidence was not concisely documented within the supplier evaluation records for the programmatic controls implemented through Liberty's QA Program, Westinghouse has confirmed sufficient evidence exist to demonstrate that critical characteristics for PO 4500858963 have been satisfied and there is no impact to the items and/or services provided.

The proposed corrective actions to address the aforementioned causes are detailed in Section 3 of this response.

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

a. **March 2020 –** CAP IR-2020-4474 was initiated due to gap between Liberty's QA Program and CDI-4057 Revision 12. Based on the input documented by Westinghouse Engineering in IR-2020-4474, SQA issued the following procurement restrictions and compensatory measures on Liberty's Westinghouse QSL listing:
   i. Liberty Electronics shall utilize the QA Program, Liberty Electronics, Inc. Quality Manual AS9100D, dated 7/18/2019, approved by Westinghouse. Changes to the Liberty Electronics QA Program manual shall be submitted for review prior to implementation on Westinghouse contracts.
   ii. For all Westinghouse work, Liberty Electronics shall implement a process that ensures that changes to Liberty's procurement documents are treated in the same manner as the original document. No Westinghouse items can be shipped until programmatic implementation is verified by Westinghouse Quality.
   iii. Liberty Electronics shall segregate all product, material, and calibrated equipment used to fulfill Westinghouse orders. No Westinghouse items can be shipped until programmatic implementation is verified by Westinghouse Quality.
   iv. For any calibration, Liberty Electronics shall ensure use of suppliers that are ANSI/ISO/IEC 17025 accredited as evidenced by certificate from an ILAC MRA approver and that published scope of the accreditation is current and covers the contracted services, including necessary measurement parameters, range, and uncertainties.

v. No Westinghouse items can be shipped until programmatic implementation is verified by Westinghouse Quality.
vi. Purchase Orders to suppliers providing calibration services to Liberty Electronics shall include the following:
    1. Requirement that the lab shall use its ANSI/ISO/IEC 17025 accredited quality program.
    2. Additional technical requirements imposed by Westinghouse as a result of the technical evaluation and identified in the Westinghouse PO, such as tolerances, accuracies, ranges over which the item is to be calibrated, specific industry standards to be used, etc.
    3. Requirement that the supplier reports as-found calibration data when calibrated items are found to be out-of-tolerance.
    4. Requirement that the laboratory identifies which equipment and standards were used in the calibration.
vii. No Westinghouse items can be shipped until programmatic implementation is verified by Westinghouse Quality.
viii. Liberty Electronics shall record all IM&TE utilized during inspections and tests for Westinghouse product. No Westinghouse items can be shipped until programmatic implementation is verified by Westinghouse Quality.

b. **April 2021** – Westinghouse SQA performed an in depth evaluation of the deficiencies from the 2020 commercial grade survey (WES-2020-015) which confirmed compensatory measures could be removed with the exception of the following restrictions which were maintained until March 2023:
    i. For any calibration, Liberty Electronics shall ensure use of suppliers that are ANSI/ISO/IEC 17025 accredited as evidenced by certificate from an ILAC MRA approver and that published scope of the accreditation is current and covers the contracted services, including necessary measurement parameters, range, and uncertainties.
    ii. Purchase Orders to suppliers providing calibration services to Liberty Electronics shall include the following:
        1. Requirement that the lab shall use its ANSI/ISO/IEC 17025 accredited quality program.
        2. Additional technical requirements imposed by Westinghouse as a result of the technical evaluation and identified in the Westinghouse PO, such as tolerances, accuracies, ranges over which the item is to be calibrated, specific industry standards to be used, etc.
        3. Requirement that the supplier reports as-found calibration data when calibrated items are found to be out-of-tolerance.
        4. Requirement that the laboratory identifies which equipment and standards were used in the calibration.
    iii. Liberty Electronics shall record all IM&TE utilized during inspections and tests for Westinghouse product. No Westinghouse items can be shipped until programmatic implementation is verified by Westinghouse Quality.

c. **April 2023** – SCAR# IR-2023-2884 was issued and drove resolution of the programmatic gaps identified against the requirements within CDI-4057 Revision 13 and Liberty's QA Program. Liberty took the following actions to resolve the deficiencies which were reviewed and approved within the Westinghouse corrective action program:
   i. Liberty's Procurement Quality Requirement document, PQR-417 was updated to include the following requirements:
      1. *"Purchase Orders to suppliers providing calibration services to Liberty Electronics shall include the following: (A) Requirement that the lab shall use its ANSI/ISO/IEC 17025 accredited quality program, (B) Additional technical requirements imposed by Westinghouse as a result of the technical evaluation and identified in the Westinghouse PO, such as tolerances, accuracies, ranges over which the item is to be calibrated, specific industry standards to be used, etc., (C) Requirement that the supplier reports as-found calibration data when calibrated items are found to be out-of-tolerance. (D) Requirement that the laboratory identifies which equipment and standards were used in the calibration."*
   ii. Liberty implemented system barriers within their eRouter/eChecklist system to require a specific step for recording measuring test equipment utilized throughout the production lifecycle.

d. **June 2023 – April 2024** – Westinghouse Supplier Quality Americas (SQ Americas) and Supplier Performance Engineering (SPE) organizations performed a total of nine (9) quality and technical surveillances to verify adequate implementation of Liberty's QA Program and it's conformance to the requirements within Westinghouse PO# 4500858963:
   i. TSR-23-7 Rev. 0 dated 6/12/23 - Technical surveillance was carried out which focused on randomly sampling cables, power supplies, and fan assemblies for the Limerick project to confirm conformance against Westinghouse approved drawings.
   ii. TSR-23-9 Rev. 0 dated 6/29/23 - Technical surveillance was carried out document the first article inspection on the Power Distribution Panel (10173D15G02 Rev. 3) which in addition covered pull tests being performed by Liberty.
   iii. TSR-23-12 Rev. 0 dated 08/09/23 - Technical surveillance was carried out which focused on the workmanship and conformance to Westinghouse drawings of cables, power supplies, fan assemblies, termination units, and CIM harps being provided for the Limerick project.
   iv. QSR-23-482 Rev. 0 dated 11/06/23 - Quality surveillance was performed to verify sub-assemblies conformed to the quality requirements defined in QSP-218 Rev. 14, WNA-WI-00256-GEN Rev. 3, and WNA-PQ-00308-GEN Rev.1. SQ America's performed 100% visual inspection and quality assurance data package (QADP) reviews which included validating measuring and test equipment was calibrated and identified within the records.
   v. TSR-23-14 Rev. 5 dated 12/06/23 - Technical surveillance was carried out to document the workmanship and testing of the CIM Harp Assembly - AF1

Modem (Part #s: 10173D36G14 & 10173D36G15) against Westinghouse procurement requirements.

vi. QSR-24-11 Rev. 0 dated 01/05/24 – Quality surveillance was performed to verify cabinet PN 10173D36G15 conformed to the quality requirements defined in QSP-218 Rev. 14, WNA-WI-00256-GEN Rev. 3, and WNA-PQ-00308-GEN Rev.1. SQ America's performed 100% visual inspection resulting in the observation of IPC-620 defects and process indicators.

vii. QSR-24-106 Rev. 0 dated 01/05/24 – Quality surveillance was performed to verify sub-assemblies conformed to the quality requirements defined in QSP-218 Rev. 14, WNA-WI-00256-GEN Rev. 3, and WNA-PQ-00308-GEN Rev.1. SQ America's performed 100% visual inspection and quality assurance data package (QADP) reviews which included validating measuring and test equipment was calibrated and identified within the records. Acceptance was documented in QR-23-545 and QR-23-541.

viii. QSR-24-110 Rev. 0 dated 02/26/24 – Quality surveillance was performed to verify sub-assemblies conformed to the quality requirements defined in QSP-218 Rev. 14, WNA-WI-00256-GEN Rev. 3, and WNA-PQ-00308-GEN Rev.1. SQ America's performed 100% visual inspection and quality assurance data package (QADP) reviews which included validating measuring and test equipment was calibrated and identified within the records.

ix. QSR-24-122 Rev. 0 dated 02/29/24 – Quality surveillance was performed to verify cabinets and sub-assemblies conformed to the quality requirements defined in QSP-218 Rev. 14, WNA-WI-00256-GEN Rev. 3, and WNA-PQ-00308-GEN Rev.1. SQ America's performed 100% visual inspection and quality assurance data package (QADP) reviews which included validating measuring and test equipment was calibrated and identified within the records. Observed and verified the program implementation for calibrated tooling and test equipment.

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

The following actions will be taken as part of CAP IR-2024-6678:

a. Conduct stand-down with supplier quality auditors to ensure consistency when processing deficiencies identified during the commercial grade surveys process and the level of specificity required when documenting the objective evidence.

b. Complete an extent of condition of the Westinghouse QSL and define additional corrective actions based on the results. Extent of condition will focus on determining if any additional commercial grade surveys performed over the last three (3) years may have been impacted in a similar manner.

c. Revise QA-7.22, "Commercial Grade Survey (CGS) Process", to clarify the requirements for maintaining compensatory measure on the QSL until Westinghouse Engineering has

full resolved any of the discrepancies with the CDI or the supplier has modified their QA Program controls.

d. Perform limited scope commercial grade survey (CGS) of Liberty Electronics to reconcile the lack objective evidence documented within WES-2023-102.

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

a. The stand-down will be completed by July 18, 2024.

b. The extent of condition of the Westinghouse QSL and definition of additional corrective actions based on the results will be completed by August 16, 2024.

c. The revision of QA-7.22, "Commercial Grade Survey (CGS) Process", will be completed by September 6, 2024.

d. The limited scope commercial grade survey (CGS) of Liberty Electronics will be completed by August 30, 2024.

Nonconformance 99900404/2024-201-02

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."

W3-5.1-101, "Westinghouse Corrective Action Program Procedure," Revision 10.0, Section 4.1.3 states, that "Condition Adverse to Quality (CAQ) shall be promptly identified and corrected."

Contrary to the above, as of May 10, 2024, WEC failed to correct conditions adverse to quality. Specifically, WEC closed Corrective Action Program-Issue Report (CAP-IR)-2023-3864 and CAP-IR-2023-11754 without adequately correcting the conditions adverse to quality identified in these CAP-IRs.

Westinghouse Response:

Westinghouse has created issue reports IR-2024-5058, IR-2024-5561, IR-2024-6149, and IR-2024-6685 in its Corrective Action Program to track the issue and completion of corrective actions.

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

The Westinghouse Corrective Action Program (CAP) requires issues identified to have the following elements, as applicable. These elements include a corrective action plan, actions to address problem, actions to address cause(s), actions to address extent of condition, actions to

address extent of cause, and preventive actions. Westinghouse failed to fully meet these programmatic requirements for the subject CAP issue reports IR-2023-3864 and IR-2023-11754.

CAP IR-2023-3864 was processed by the issue owner with focus on addressing the technical concerns but failed to effectively evaluate and address the systemic issues. The issue owner failed to fully understand or implement the procedural requirements prescribed by W2-5.1-101 for processing CAP IR-2023-3864. This resulted in the issue owner closing the CAP issue report without conducting a causal analysis, extent of condition, and extent of cause nor including the required objective evidence.

CAP IR-2023-11754 was processed by the issue owner with a focus on the logistical issues associated with the release of a design change to a vendor for production services. The decision to revert to an earlier baseline was made for commercial reasons but the actions needed were never fully implemented. The issue owner failed to recognize the planned actions were not fully implemented and closed the CAP prematurely without the required objective evidence to support the closure. This was a result of the issue owner not fully understanding or implementing the procedural requirements prescribed by W2-5.1-101 for processing CAP IR-2023-11754.

These process deficiencies are attributed to an inadequate understanding of the procedural requirements for the processing of CAPs due to unfamiliarity with process expectations and failure to implement human performance principle for procedural adherence.

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

Two CAPS have been issued to address the inadequate closure of IR-2023-3864 and IR-2023-11754. CAP IR-2024-5561 has been assigned to address the noncompliant conditions associated with CAP IR-2023-3864, and CAP IR-2024-5058 has been assigned to address CAP IR-2023-11754.

CAP IR-2024-5058 – actions that have already been completed:

- The action has been completed which was to distribute the problem statement and expectations for CAPs closeout to the CEG/Duke Project Portfolio group for immediate prevention of additional CAPS from the group being closed out without proper action or objective evidence. The action has since been closed with the provided objective evidence that includes the follow-up group meeting minutes and email providing distribution to the CEG/Duke Project Portfolio department. This action was completed on July 9th, 2024.

- Introduce a temporary additional final QA approval of ICS CAPS in the closure workflow to better monitor/control CAP closure quality while actions are put in place to ensure CAP owners obtain refresher training. This action was completed on July 12th, 2024.

CAP IR-2024-5561 – an activity that have already been completed:

- A preliminary extent of condition was conducted on May 20th, 2024, to assess other potential improper CAP closures. As a result of the preliminary findings, an interim activity has been established that a mandatory final review by Global I&C Quality will be assigned to all CAPs assigned to issue owners within GICP.

- CAP IR-2024-6149 was created on June 5th, 2024, to perform supplemental actions to evaluate the extent of condition. This includes an action to perform a comprehensive evaluation of CAP closure by issue owners within Global Instrumentation and Control Production and IV&V (GICP).

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

Note, Westinghouse issued CAP IR-2024-6685 as an overarching CAP to address the NRC NON, 99900404/2024-201-02 - Inadequate Corrective Action Closures.

The actions assigned to CAP IR-2024-6685 to avoid further noncompliance include:

a. Develop refresher training, including CAP Closeout Checklist, and implement to both GIC and ICS teams. Training is being developed for roll out to GICP via IR-2024-6149. This action is to ensure this training and additional checklist is also rolled out to ICS (both PM and Customer Solutions).

b. Similar action to GIC Action #3 from IR-2024-6149, ensure ICS Americas PM managers perform a sample of their teams CAPS using the developed closeout checklist to validate improved first pass quality.

c. Actions for EoC/EoCa investigations are in place for both IR-2024-5561 and IR-2024-5058. This action is to review the results of those investigations and report conclusions and tracking mechanisms for any additional action needed.

The actions assigned to CAP IR-2024-5058 to avoid further noncompliance include:

a. Perform and document Extent of Condition evaluation to determine if other CAPS with the same owner as IR-2023-11754 may have similar deficiencies and perform Extent of Cause to ensure Limerick Project Medium CAPS or Low CAPS with CAQ (Condition Adverse to Quality) classification have not been closed out by individuals lacking refresher training or knowledge of expected closure evidence. If additional findings are identified, the action requires that the owner and direct supervisor/manager/director of the CAP be notified to assess if further action is needed specific to those CAPs. Provide summary Extent of Condition/Cause results and email notifications (if any) as objective evidence.

b. Perform Extent of Cause to ensure other PMs in the CEG/Duke department have not closed CAPS without appropriate actions or objective evidence. Assess any findings to determine if additional actions are needed to ensure those issues are fully resolved. Provide results of EoCa evaluation and assessment of actions needed for any findings.

The actions assigned to CAP IR-2024-5561 to avoid further noncompliance include:

a. Perform a causal analysis, extent of condition, extent of cause and assign additional actions as required to ensure compliant closure of CAP IR-2023-3864.

b. Address the lack of procedural compliance to W2-5.1-101 for the closure of IR-2023-3864. This includes conducting a causal analysis, extent of condition, extent of cause and assigning actions to ensure programmatic compliance for the systemic causes in CAP IR-2023-3864.

c. Develop/execute refresher training with the Electrical Technicians and Quality Control personnel while reviewing the lessons learned associated with IR-2023-3864 including review of reading tolerance ranges.

The actions assigned to CAP IR-2024-6149 to avoid further noncompliance include:

a. Develop refresher training on proper CAP closure.

b. Create a checklist to aid issue owners in ensuring programmatic compliance for CAP closure.

c. Communicate to the GICP managers to perform a sample review of their teams CAPs using the developed checklist to improve first pass quality.

d. Perform and document Extent of Condition evaluation to determine if other CAPs within the last three years with the same owner as IR-2024-3864 may have similar deficiencies. Additionally, the Extent of Condition will include a sample of CAPs owned by other GICP issue owners to determine if there are similar deficiencies.

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

- CAP IR-2024-6685 - The overall CAP closure is to be completed by December 17th, 2024.
  Action a. – Planned completion date, September 10th, 2024
  Action b. – Planned completion date, September 10th, 2024
  Action c. – Planned completion date, December 4th, 2024

- CAP IR-2024-5058 – The overall CAP closure is to be completed by November 16th, 2024.
  Action a. – Planned completion date, August 15th, 2024
  Action b. – Planned completion date, September 10th, 2024

- CAP IR-2024-5561 – The overall CAP closure is to be completed by September 17th, 2024.
  Action a. – Planned completion date, August 30th, 2024
  Action b. – Planned completion date, August 30th, 2024

Action c. – Planned completion date, July 26th, 2024

- CAP IR-2024-6149 – The overall CAP closure is to be completed by December 2nd, 2024.
  Action a. – Planned completion date, August 30th, 2024
  Action b. – Planned completion date, July 31st, 2024
  Action c. – Planned completion date, August 30th, 2024
  Action d. – Planned completion date, October 31st, 2024