



March 20, 2024

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

Kerri Kavanagh, Chief
Quality Assurance Vendor Inspection Branch
Division of Research Oversight
Office of Nuclear Reactor Regulation

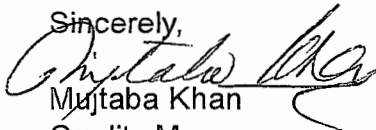
Subject: Reply to a Notice of Nonconformance
Docket No: 99902119
Reference NRC Inspection Report No. 99902119/2024-201
Non-conformance 99902119/2024-201

Dear Sir/Madam:

Hanna Cylinders has reviewed NRC Inspection Report No. 99902119/2024-201 and is enclosing responses to said non-conformances.

Should there be any questions or need for additional information, Hanna Cylinders will be pleased to provide information as needed. I can be contacted by phone at 1 (847) 287-5954 or by email at mkhan@hannacylinders.com.

Sincerely,


Mujtaba Khan
Quality Manager
Hanna Cylinders

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Attachments: Attachment 1: Corrective Action Reports – CAR# 2024-13,14,15,16
Attachment 2: Supporting Document – Revised procedures.
Attachment 3: Supporting Document – QA Alert
Attachment 4: Supporting Documents – Training Record

Hanna Cylinders Response
NRC Notice of Nonconformance Inspection Report 99902119/2024-201, Dated March 4,
2024

Nonconformance 99902119/2024-201

A. This issue has been identified as Nonconformance 99902119/2024-201-01.

Criterion II "Quality Assurance Program," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of the Federal Regulations (10CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states in part, that "the program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. "Section 2.5 "Indoctrination and Training," of Hanna's Quality Assurance Manual (QAM) Revision 2, dated July 25, 2023, "Quality Assurance Program," states in part, that "personnel performing work determined to be within the scope of the Hanna Cylinders quality assurance program are to be given appropriate indoctrination and training prior to independently performing those activities, ... All indoctrination and training shall be documented. ... Hanna Cylinders shall maintain records of relevant authorizations, competence, training, qualifications, skills, and experience for those assigned to perform testing, inspection, and safety-related activities. These records shall be readily available and include the basis on which any authorization or competencies are confirmed. "Section 5.4.6 of Hanna's procedure QA-1, "Training and Qualification," revision 4, dated September 5, 2023, states "Refresher indoctrination/training may be held periodically for the purpose of reviewing the Quality Assurance Program and its revisions. Documentation of refresher training shall be retrained." Section 5.6.3 states "All training records are maintained by the Quality Manager and are to be reviewed and updated as necessary to ensure they remain accurate. Although it is not their direct responsibility the employee and their supervisor(s) should request updates/revisions when needed. "Contrary to the above, as of January 12, 2024, Hanna failed to provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. Specifically, Hanna failed to provide objective evidence that personnel performing activities affecting quality were adequately indoctrinated and trained. Hanna was unable to provide indoctrination and refresher training records from 2020 to present.

B. This issue has been identified as Nonconformance 99902119/2024-201-02.

Criterion VII "Control of Purchased Material, Equipment, & Services," of Appendix B to 10 CFR Part 50, 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."

Hanna's QAM, Section 4.4, states that "an approved supplier list comprised of sources approved by Hanna shall be maintained electronically by the QA Department." Section 4.4.12, states "purchase orders shall not be issued to a proposed supplier not included in the approved supplier list until notification is received from Quality Manager that the supplier is qualified and approved." Section 4.4.5, states that "approved suppliers shall be surveyed/audited onsite on a triennial basis, as a minimum and qualified by Hanna QA department using a QA survey/audit checklist by auditors assigned by the QA Manager."

Contrary to the above, as of January 12, 2024, Hanna failed to assure that purchased materials and services conform to procurement documents through 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. Specifically, (1) Safety related services were procured from a supplier to perform internal audits for 2022 and 2023, however there was no objective evidence that the supplier had been audited prior to adding them to the Approved Supplier List (ASL). (2) At least three commercial suppliers were added to the ASL without Hanna performing a survey and qualification of the suppliers. (3) Hanna procured parts from at least two suppliers that were not on the ASL and Hanna did not take measures to control the items under its quality assurance program.

C. This issue has been identified as Nonconformance 99902119/2024-201-03.

Criterion XII "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, states in part, that "measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specific periods to

maintain accuracy within necessary limits. "Hanna's QAM, Section 12.3.2 states "All measuring, and test equipment shall be properly maintained, identified, and controlled. "Section 6.6 of Hanna's procedure QA-8, "Calibration and Control of M&TE," Revision 10, dated October 21, 2023, states "The M&TE Calibration Log will be maintained by the Quality Technician. This log will contain a list of all devices, their ID numbers, date of last calibration, location of item, and next scheduled calibration date." Section 6.10 states "Any device failing to meet calibration standards will be immediately removed from service." Section 11.1 states "If equipment is found to be of nonconformance, personnel shall inform the Quality Manager and issue an M&TE NCR, QA-DOC-31." Section 11.4 states: "If test or measuring equipment is found to be out of calibration or tolerance an extent of condition review will be performed to ensure that no safety-related materials have been measured or tested with the equipment in question." Contrary to the above, as of January 12, 2024, Hanna failed to assure that gages used in activities affecting quality are properly controlled. Specifically, Hanna failed to adequately control measuring and test equipment (M&TE) and perform an extent of condition review for M&TE that was found to be out of calibration or tolerance, as described by the following examples:

- Two ring gages (TR-309 & 340) were found to be out-of-tolerance in June 2023, however, Hanna did not perform an extent of condition review to ensure that these gages were not used to measure or test safety-related material. The NRC inspection team identified that TR-340 was used for a safety-related job that Hanna shipped in July 2022.*
- One vernier caliper (VNR-76) could not be found. No extent of condition review was performed.*
- Two plug gauges (PG713 & PG714) were not being controlled on the M&TE log.*
- One vernier caliper (VNR-190) was past its calibration due date and in a segregation area on the floor but not tagged.*

D. This issue has been identified as Nonconformance 99902119/2024-201-04.

- 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."*
- Section 5.5 of Hanna's procedure QA-18, "Corrective Action Procedure", Revision 3, dated October 17, 2023, states that "CARs are*

to be completed six months after the date initiated. If additional time is required, a one-month extension may be granted but must be documented with written approval by the engineering manager."

Section 5.6 states that "following the resolution of the CAR, a 30-day follow-up may be scheduled to check and ensure that the corrective action is being performed and/or is being shown to be effective."

- *Contrary to the above, as of January 12, 2024, Hanna failed to promptly identify and correct conditions adverse to quality. Specifically, Corrective Action Reports (CARs) 2023-31, 32, 33 were issued on May 25, 2023, and remained open; CAR 2023-30 was closed without completing the corrective action to develop a procedure for controlling.*
- *Items with a shelf-life; at least three CARs between April 2023 and August 2023 had*
- *open effectiveness reviews beyond the established 30-day follow-up period; and CARs 2023-34, 35, 36 were issued in June of 2023, subsequently closed, and had no evaluation of the effectiveness of the CARs.*

Hanna Cylinders Response
NRC Notice of Nonconformance Inspection Report 99902119/2024-201, Dated March 4,
2024

Hanna Cylinders acknowledges Nonconformance 99902119/2024-201(1)

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

- 1) Regarding NON 99902119/2024-201, Hanna Cylinders acknowledges that there were occurrences of the failure to provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. Specifically, Hanna failed to provide objective evidence that personnel performing activities affecting quality were adequately indoctrinated and trained. Hanna was unable to provide indoctrination and refresher training records from 2020 to present.

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

- 1) Internal Corrective Action # 2024-12, initiated 3/27/2024.
 - a. Failure to provide objective evidence that personnel performing activities were adequately indoctrinated and training.
 - i. Hanna has established a training program roadmap 2024-2025 for all Hanna employees to address the lack of training issue.
 - ii. Hanna employees have been retrained and displayed competence of adherence to the new process.

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

- 1) Quality Manager to monitor the training effectiveness on a quarterly basis.
- 2) Implement a tracking system to monitor the training status and effectiveness.

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

- 1) All Corrective Actions identified in the Hanna Cylinders response will be completed by May 24, 2024.
 - A. 2024-12: Completed
 - B. 2024-13: Due May 24, 2024
 - C. 2024-14: Completed
 - D. 2024-15: Completed

Hanna Cylinders acknowledges Nonconformance 99902119/2024-201(2)

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

- 1) Regarding NON 99902119/2024-201(2), Hanna Cylinders acknowledges that there were occurrences of the failure to provide measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, they did not conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection.

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

- 1) Internal Corrective Action # 2024-13, initiated 3/27/2024
 - a. Lack of understanding of QAM section 4 by Hannas Quality team.
 - i. The Quality Manager and Quality Administrator have been retrained and have displayed competence in adhering to the new process.
 - b. Purchase orders were being made to non-approved suppliers.
 - i. The quality team has updated and is maintaining the approved supplier list electronically.
 - ii.

2) The corrective steps that will be taken to avoid further noncompliance.

- 1) Hanna will develop a commercial grade audit plan to conduct the required audits and evaluations on all ASL suppliers.

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

- 1) All Corrective Action's identified in the Hanna Cylinders response will be completed by May 24, 2024.
 - A. 2024-12: Completed
 - B. 2024-13: Due May 24, 2024
 - C. 2024-14: Completed
 - D. 2024-15: Completed

Hanna Cylinders acknowledges Nonconformance 99902119/2024-201(3)

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

- 1) Regarding NON 99902119/2024-201(3), Hanna Cylinders acknowledges that there were occurrences of the failure to properly take measures to establish that tools, gages, instruments, and

other measuring and testing devices used in activities affecting quality were maintained and calibrated.

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

- 1) Internal Corrective Action #2024-14, initiated 3/27/2024
 - a. Hanna has provided training to all relevant staff on the Calibration procedure and M&TE log and they have displayed competence in this area.
 - b. Hanna has issued a QA alert.
 - c. Hanna has updated the M&TE log to be current and up to date.

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

- a. A monthly review of M&TE logs will be performed by the Quality Manager.
- b. A periodic audit to verify the calibration system effectiveness will be done.

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

- 1) All Corrective Actions identified in the Hanna Cylinders response will be completed by May 24, 2024.
 - A. 2024-12: Completed
 - B. 2024-13: Due May 24, 2024
 - C. 2024-14: Completed
 - D. 2024-15: Completed

Hanna Cylinders acknowledges Nonconformance 99902119/2024-201(4)

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

Regarding NON 99902119/2024-201(3), Hanna Cylinders acknowledges that there were occurrences of the failure to properly close Corrective Actions of assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

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

Internal Corrective Action # 2024-15, initiated 3/27/2024

- a. Hanna has performed a thorough review of the CAR log for CARs left open, effectiveness reviews left open and incomplete evaluations of effectiveness.
- b. Hanna has been reviewing the CAR log monthly.
- c. Hanna is actively completing/closing all CARs which were previously neglected.

(3) The Corrective steps that will be taken to avoid further noncompliance.

- 1) Hanna will provide refresher training on QA-18 for all relevant staff.
- 2) Establish CAR metric- CAR closure rate to monitor and track the closing status.
- 3) Quality manager will monitor the training effectiveness on a quarterly basis.

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

- 1) All Corrective Actions identified in the Hanna Cylinders response will be completed by May 24, 2024.
 - E. 2024-12: Completed
 - F. 2024-13: Due May 24, 2024
 - G. 2024-14: Completed
 - H. 2024-15: Completed