U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

Inspection Report

Docket No.: 71-0947

Report No.: 71-0947/2022-201

Enterprise Identifier: I-2022-201-0014

Certificate Holder: Orano-Transport Logistics International, Inc.
8161 Maple Lawn Blvd, Suite 480
Fulton, MD 20759

Facility: Container Products
Corporation 112 North
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NC 28406

Inspection Dates: February 22–May 20, 2022

Inspectors: Jeremy Tapp, Transportation and Storage Safety Inspector, Team Leader Jon Woodfield, Transportation and Storage Safety Inspector
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Inspection and Oversight Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

EXECUTIVE SUMMARY

Orano-Transport Logistics International, Inc.
NRC Inspection Report 71-0947/2022-201

On February 22 through 24, 2022, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Container Products Corporation (CPC) facility in Wilmington, NC. The CPC is under contract with Orano-Transport Logistics International, Inc. (TLI) to fabricate important-to-safety (ITS) components of the Versa-Pac transportation packaging under Certificate of Compliance (CoC) 71-9342.

The purpose of the inspection was to verify and assess the adequacy of TLI's compliance with the NRC requirements for the design, modification, fabrication, assembly, testing, and procurement of Versa-Pac components. TLI is the holder of the CoC and designer of the Versa-Pac transportation packaging.

Management Controls

- The team determined that the quality assurance (QA) controls at CPC were generally adequate. The team concluded that CPC conducts its activities associated with QA organization independence and QA responsibilities in accordance with their Quality Assurance Manual (QAM). (Section 1.1)

- The team concluded that CPC has an adequate nonconformance control program in place to ensure compliance with the applicable regulations and quality assurance program (QAP) requirements. (Section 1.2)

- The team identified CPC's corrective action program (CAP) as an area for improvement as evidenced by the issue identified and described in this report. The team identified one Severity Level IV violation of 10 CFR 71.133, "Corrective action" for CPC's failure to take adequate corrective actions from an issue identified during the previous inspection to ensure that suppliers on its Qualified Suppliers List (QSL) received a triennial inspection as required by the QAM and that the QSL was maintained current with qualified vendors. (Section 1.3)

- The team concluded that CPC was effectively implementing its document and records control program and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. (Section 1.4)

- The team found that for the audits reviewed, CPC conducted the audits with qualified personnel independent of the areas being audited and evaluated the applicable functional areas of the QAP. (Section 1.5)

Design Controls

- The team concluded that CPC was effectively implementing their design control program. (Section 2.1)

Fabrication Controls

- The team determined that the procurement controls were adequate, and CPC was generally effective in implementing their procurement program. (Section 3.1)
- CPC's implementation of fabrication controls for fabrication and assembly, including material storage, was assessed to be adequate. (Section 3.2)
- The team assessed that CPC had adequate controls for inspection of the Versa-Pac and it was generally being inspected per approved QA procedures and fabrication specifications by qualified personnel. (Section 3.3)
- The team concluded that the measuring and test equipment (M&TE) quality procedure being implemented at CPC provided adequate guidance for M&TE calibration and use, and CPC adequately implemented M&TE calibration, tracking, and use requirements. (Section 3.4)

REPORT DETAILS

1. Management Controls

1.1 Quality Assurance Policy

a. Inspection Scope

The team reviewed the Container Products Corporation (CPC) Quality Assurance Manual (QAM), Revision 24 and the associated Quality Control Operating Procedures (QCOPs) and Department Procedures to assess the effectiveness of the quality assurance program (QAP) implementation. The team conducted reviews of CPC's quality program, policies, and procedures, to determine whether activities subject to 10 CFR Part 71 were adequately controlled and implemented under CPC's QAM.

Specifically, the team reviewed the QAP authorities and responsibilities to determine if they were clearly defined and documented, and the quality assurance (QA) organization functioned as an independent group.

b. Observations and Findings

The team assessed that CPC had a QAP and implementing procedures in place that were generally effective in conducting activities in accordance with their QAM. No issues of significance were identified.

c. Conclusions

The team determined that the QA controls at CPC were generally adequate. The team concluded that CPC conducts its activities associated with QA organization independence and QA responsibilities in accordance with their QAM.

1.2 Nonconformance Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that CPC effectively implemented a nonconformance control program in accordance with the requirements of 10 CFR Part 71 and CPC's nonconformance procedures. The team requested the Discrepancy Report (DR), CPC's term for a nonconformance report, logbook for the current batch of 25 Versa-Pac's being fabricated and found that no DRs had been written. Therefore, the team assessed CPC's nonconformance controls process.

The team reviewed the following Section of the CPC QAM, Revision 24, and QCOPs:

- QAP-1015, "Non-Conforming Items," Revision G
- QCOP-2030, "Discrepancy Reports," Revision 8
- QCOP-2050, Supplier Discrepancy Report, Revision 1

b. Observations and Findings

The team assessed that CPC had adequate procedures and controls in place for dispositioning and tracking DRs to closure. No issues of significance were identified.

c. Conclusions

The team concluded that CPC has an adequate nonconformance control program in place to ensure compliance with the applicable regulations and QAP requirements.

1.3 Corrective Actions Controls

a. Scope

The team reviewed selected records and interviewed personnel to verify that CPC effectively implemented a CAP in accordance with the requirements of 10 CFR Part 71 and CPC's corrective action procedures. The team requested the CPC corrective action report (CAR) logbook for the current batch of 25 Versa-Pac's being fabricated and found that no CARs had been written. Therefore, the team assessed CPC's CAR control process.

The team reviewed the following Section of the CPC QAM, Revision 24, and QCOP:

- QAP-1015, “Corrective Action,” Revision J
- QCOP-2031, “Corrective Action Report,” Revision 0

Additionally, the team included a review of CAR 2019-03 that was opened during the previous 2019 NRC inspection to determine whether the corrective actions taken to address the issues were appropriate and was closed out in a timely manner in accordance with CPC procedures.

b. Observations and Findings

The team assessed that CPC had adequate procedures and controls in place for identifying and writing CARs, documenting corrective action(s) taken, performing a root cause evaluation for significant conditions adverse to quality, documenting actions taken to prevent recurrence, performing CAR closure verification, and tracking CARs to closure.

During the review of the corrective actions taken to close CAR 2019-03, dated March 4, 2019, that was opened during the previous 2019 inspection to correct several issues identified by the NRC, the team noted that corrective actions were taken with respect to CPC’s failure to perform two supplier audits at the three-year frequency established in CPC procedures to keep the suppliers on CPC’s QSL. The CAR stated that the corrective action taken was to update the QSL to address this. For the action to prevent recurrence, the CAR only states to see the revised QSL dated February 6, 2019. The team reviewed the most recent QSL dated April 26, 2021, and the latest supplier audit schedule provided by CPC. The team identified that Airgas Performance Plus Division had not been audited since November 14, 2016, and Branham Corporation had not received an audit since being added to the QSL on August 23, 2018. Both remained on the QSL and the QSL stated that their qualification basis was by audit.

The team determined a violation of 10 CFR 71.133, “Corrective action” occurred in that CPC took inadequate corrective actions during the previous inspection to ensure that applicable suppliers on its QSL received a triennial audit as required by the CPC QAM Section QAP-1007, and that the QSL was maintained current with qualified vendors. At the time of the inspection, Airgas Performance Plus Division and Branham Corporation had not been audited in the past three years and remained on the QSL. 10 CFR 71.133 “Corrective action” states, in part, that the certificate holder (CPC represents the Certificate of Compliance (CoC) holder TLI) shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition.”

Contrary to the above, CPC took inadequate corrective action from the 2019 inspection as documented in CAR 2019-03 to preclude repetition of suppliers not being audited triennially in order to keep the supplier on the QSL. Specifically, Airgas Performance Plus Division and Branham Corporation have not been audited in the past three years but remained on the QSL.

The team dispositioned the violation using the traditional enforcement process in Section 2.3 of the Enforcement Policy. The team determined the violation was more-than-minor safety significance in accordance with Inspection Manual Chapter (IMC) 0617, "Vendor and Quality Assurance Implementation Inspection Reports," Appendix E, "Minor Examples of Vendor and QA Implementation Findings," Example 16.a; because the adverse condition recurred. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. CPC and TLI entered the issue into their CAPs under CAR # 2022-08 and 1215, respectively. This violation is being cited in the enclosed Notice of Violation (Notice). **(71-0947/2022-201-01)**.

c. Conclusions

The team identified CPC's CAP as an area for improvement as evidenced by the issue identified and described above. The team identified one violation of NRC requirements concerning the failure by CPC to take adequate corrective actions from an issue identified during the previous inspection to ensure that suppliers on its QSL received a triennial inspection as required by the QAM and that the QSL was maintained current with qualified vendors.

1.4 Documentation Controls

a. Scope

The team reviewed CPC's documentation and records control program and quality procedures to assess the effectiveness of controls established for the approval, issuance, use, and revisions of quality documents. The team also reviewed a sample of CPC documents (instructions, procedures, records, drawings, and specifications) to verify how CPC developed and controlled quality related documents. Specifically, the team reviewed a sample of controlled QAMs and quality procedures, controlled copy distribution lists, receipt records of updated quality manuals, and fabrication drawing hard copies distributed to various CPC departments, among the sample of documents reviewed. The team reviewed the following Sections of the CPC QAM, Revision 24, and Department Procedure:

- QAP-1006, "Document Control," Revision J
- QAP-1017, "Quality Assurance Records," Revision J
- 1002, Engineering Department Procedure, Revision 9

The team also interviewed QA personnel regarding document and record controls. The team interviewed the QA Manager regarding responsibilities for 1) controlled quality procedures including access, revisions, and distribution; and 2) final document package development, among the interviews performed.

b. Observations and Findings

The team assessed that CPC had adequate and effective controls established by their implementing procedures for the approval, issuance, use, storage, and revision of quality documents and records. No issues of significance were identified.

c. Conclusions

The team concluded that CPC was effectively implementing its document and records control program and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements.

1.5 Audit Program

a. Scope

The team reviewed selected records and interviewed personnel to verify that CPC effectively implemented an internal audit program in accordance with the QAM and the applicable requirements of 10 CFR Part 71. The team reviewed the qualifications, training records, and annual evaluations for CPC's Quality Assurance Manager and external auditor to determine if they met the requirements stated in the QAM.

The team reviewed the audit schedule and internal audits performed since the previous 2019 initial inspection to determine if they were performed in accordance with the QAM, if CPC identified deficiencies, and whether CPC addressed these deficiencies within their CAP. The team reviewed the following Sections of the CPC QAM:

- QAP-1002, "Quality Assurance Program," Revision O
- QAP-1018, "Audits," Revision K

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

The team found that for the audits reviewed, CPC conducted the audits with qualified personnel independent of the areas being audited and evaluated the applicable functional areas of the QAP.

2. Design Controls

2.1 Design Development

a. Scope

The team reviewed the design control Section of the CPC QAM and applicable implementing quality procedures to verify that CPC properly implemented their design control program. Specifically, the team reviewed the design control process between the CoC holder TLI and the fabricator CPC.

The team focused its review on the translation of the TLI design specification and licensing drawings to the CPC fabrication drawings and the controls that were in place. The team reviewed a sampling of CPC fabrication drawings for the Versa-Pac assembly and piece parts. The team verified that the fabrication drawings developed by CPC had received the proper CPC and TLI review and approvals.

The team reviewed the following sections of the CPC QAM, Revision 24, and Department Procedure:

- QAP-1003, “Design Control,” Revision H
- QAP-1005, “Instructions, Procedures & Drawings,” Revision D
- 1002, Engineering Department Procedure, Revision 9

b. Observations and Findings

The team assessed that CPC was following its engineering procedures, as applicable, to ensure that fabrication drawings and any associated specifications were consistent with the TLI licensing drawings approved by the NRC, and design requirements/commitments as documented in the Versa-Pac CoC. The team also determined that the design document approvals were performed as required. No issues of significance were identified.

c. Conclusions

The team concluded that CPC was effectively implementing their design control program.

3. Fabrication Controls

3.1 Procurement Controls

a. Scope

The team reviewed CPC's procurement of ITS materials and services, which included the review of procurement documents, drawings and procedures, and receipt inspection records. The team reviewed the following sections of the CPC QAM, QCOP and Department Procedure associated with procurement:

- QAP-1004, "Procurement Document Control," Revision J
- QAP-1007, "Control of Purchased Items & Services," Revision M
- QCOP-1001, "Material Receipt Inspection," Revision 22
- 1004, Purchasing Department Procedure, Revision 11

The procedures were reviewed to verify if they were being properly implemented. The team also reviewed CPC's QSL, dated April 26, 2021, to determine if materials and services were being procured from qualified suppliers and the suppliers were being acceptably qualified.

The team selected a sample of qualified suppliers and ITS materials for review. The sample included sheet steel, weld wire, hardware, gasket material, and nondestructive examination (NDE) services.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

The team determined that the procurement controls were adequate, and CPC was generally effective in implementing their procurement program.

3.2 Fabrication and Assembly

a. Scope

The team reviewed records associated with fabrication of the Versa-Pac packagings as well as material storage controls to verify that the fabrication and storage processes were properly controlled and implemented. Although there was no ongoing fabrication or assembly activities while the team was onsite, the facility was toured to assess material storage controls and fabrication controls for those Versa-Pac's on the shop floor at the time of the inspection. The team reviewed the following sections of the CPC QAM, QCOPs and Department Procedure associated with procurement:

- QAP-1008, "Identification and Control of Materials, Parts, and Components," Revision E
- QAP-1013, "Handling Storage and Shipping," Revision E
- QAP-1014, "Inspection, Test, and Operating Status," Revision E
- QCOP-1010, "Shelf Life Verification," Revision 9
- QCOP-2003, "Tagging Procedure," Revision 5
- QCOP-2029, "Shipping, Handling, and Storage," Revision 4
- 1001, Manufacturing Department Procedures, Revision 1

A sample of travelers for Versa-Pac's currently being fabricated and three that were completed were reviewed to verify that fabrication and test activities were accomplished and appropriately documented according to controlled drawings and quality procedures.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

CPC's implementation of fabrication controls for fabrication and assembly, including material storage, was assessed to be adequate.

3.3 Test and Inspection

a. Scope

The team reviewed CPC processes and procedures that address inspection of the Versa-Pac packaging. The team focused on the magnetic particle inspection (MT) NDE that was ongoing during the onsite inspection. The team observed MT being performed on Versa-Pac welds and interviewed personnel involved in the activity. The team reviewed the qualifications of the individual performing the MT NDE. The team also reviewed a sample of completed MT records from previous inspection activities on the Versa-Pac's being fabricated. The team reviewed the following sections of the CPC QAM and the NDE service provider's procedure:

- QAP-1009, "Control of Special Processes," Revision G
- QAP-1010, "Inspection," Revision E
- SSPC-ASME-MT1, "Magnetic Particle Inspection Procedure," Revision 2

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

The team assessed that CPC had adequate controls for inspection of the Versa-Pac and it was generally being inspected per approved QA procedures and fabrication specifications by qualified personnel.

3.4 Tools and Equipment

a. Scope

The team reviewed selected M&TE and reviewed records and procedures to assure that equipment used in activities affecting quality were properly controlled and calibrated. The team reviewed the following Section of the CPC QAM and QCOP:

- QAP-1012, "Control of Measuring and Test Equipment," Revision H
- QCOP-2011, "Control of Measuring and Test Equipment," Revision 1

Specifically, the team reviewed the calibration records with respect to the light meter used to ensure the flashlight used during the MT inspections observed exceeded the minimum footcandle requirement.

b. Observations and Findings

No issues of significance were identified.

c. Conclusions

The team concluded that the M&TE quality procedure being implemented at CPC provided adequate guidance for M&TE calibration and use, and CPC adequately implemented M&TE calibration, tracking, and use requirements.

4. Entrance and Exit Meeting

On February 22, 2022, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Andrew Langston and other members of the TLI and CPC staff. On February 24, 2022, the NRC inspection team presented the inspection results and observations during an onsite preliminary exit meeting. On May 20, 2022, the NRC inspection team conducted a final telephone conference exit with Andrew Langston and other members of the TLI and CPC staff. Section 1 of the attachment to this report shows the attendance for the entrance and exit meetings.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

Name	Title	Affiliation	Entrance	Exit
Jeremy Tapp	Inspection Team Leader	NRC/DFM	X	X
Jon Woodfield	Inspector	NRC/DFM	X	X
Aaron Thomlinson	QA Engineer	NRC/DFM	X	
Andrew Langston	Director, Engineering and Packaging Services	TLI	X	X
Alex Jones	Chemical Engineer	TLI	X	X
Tom Barron	Designate, QA	TLI		X
Dwight Campbell	President	CPC	X	
Tammy Thurston	QA Manager	CPC	X	X
Brian Schave	QC Supervisor	CPC	X	
Katie Fletcher	Sales	CPC	X	
Alex Thomas	Buyer	CPC	X	
Rhonda Hahn	Engineering	CPC	X	

2. INSPECTION PROCEDURES USED

IP 86001	Design, Fabrication, Testing, and Maintenance of Transportation Packagings
NUREG/CR-6407	Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety
NUREG/CR 6314	Quality Assurance Inspections for Shipping and Storage Containers

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
71-0947/2022-201-01	Opened	NOV	Inadequate corrective actions to prevent recurrence of failure to perform triennial audits of suppliers

4. LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
CAP	Corrective Action Program
CAR	Corrective Action Report
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CPC	Container Products Corporation
DR	Discrepancy Report
IP	Inspection Procedure
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
MT	Magnetic Particle Inspection
NDE	Nondestructive Examination
Notice	Notice of Violation
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QAM	Quality Assurance Manual
QAP	Quality Assurance Program
QCOP	Quality Control Operating Procedure
QSL	Qualified Suppliers List
TLI	Orano-Transport Logistics International, Inc.

5. DOCUMENTS REVIEWED

Certificate holder and fabricator documents reviewed during the inspection were specifically identified in the Report Details above.