



**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:

DAHER-TLI  
8161 Maple Lawn Boulevard, Suite 450  
Fulton, MD. 20759

2. NRC/REGIONAL OFFICE

Headquarters  
U. S. Nuclear Regulatory Commission  
Mail Stop 3WFN 14C-28  
Washington, DC 20555-0001

REPORT NUMBER(S) 71-9342/2016-201

3. CERTIFICATE/QAP DOCKET NUMBER(S)

71-0947 and 71-9342

4. INSPECTION LOCATION

Fulton, MD

5. DATE(S) OF INSPECTION

August 15-17, 2016

**CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:**

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☒ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

One Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

Title 10 of the Code of Federal Regulations (10 CFR), 10 CFR 71.137, "Audits", requires, in part, that the certificate holder shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. Contrary to, as of August 17, 2016, DAHER-TLI did not carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and did not determine the effective of the program. DAHER-TLI entered this violation into their corrective action program for resolution.

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**Statement of Corrective Actions**

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Andy Langston		11-08-2016
NRC INSPECTOR	Marlone Davis		11/14/2016
BRANCH CHIEF	Patricia Silva		11/15/16

## INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder	DAHER-TLI 8161 Maple Lawn Boulevard, Suite 450 Fulton, MD 20759
Licensee/Certificate Holder contact and phone number	Mr. Andy Langston Director of Engineering and Packing Services 301-931-5302
Docket No.	71-9342
Inspection Report No.	71-9342/2016-201
Inspection Date(s)	August 15 - 17, 2016 September 27 - 30, 2016
Inspection Location(s)	Transport Logistics International (TLI) Incorporated (Inc.) Fulton, MD.
Inspectors	Marlone Davis, Team Leader, Senior Safety Inspector Jon Woodfield, Safety Inspector Jeremy Tapp, Safety Inspector Sheiba Tafazzoli, General Engineer (Training/Observer)
Summary of Findings and Actions	During the period of August 15 through 17, 2016, the U.S. Nuclear Regulatory Commission (NRC) completed a team inspection at the corporate headquarters located in Fulton, MD. The team discussed the preliminary results of this inspection on August 17, 2016 and conducted a final telephone exit on September 30, 2016. The team identify one violation of NRC requirements in the area of planned and periodic audits. The team dispositioned the violation as a Severity Level IV non-cited violation (NCV), which was consistent with Section 2.3.2 of the NRC Enforcement Policy. TLI acknowledged the violation during a telephone exit on September 30, 2016 and documented this violation in their corrective action program for resolution.
Lead Inspector Signature/Date	Marlone Davis <i>Marlone F. Davis</i> 11/14/2016
Inspector Notes Approval Branch Chief Signature/Date	Patricia Silva <i>[Signature]</i> 11/15/16



## Inspector Notes

On August 15 to August 17, 2016, the U.S. Nuclear Regulatory Commission (NRC) performed an inspection at the Transport Logistics International (TLI) Incorporated (Inc.) corporate headquarters located in Fulton, MD. TLI is a part of the DAHER group, which is a French industrial business (hereafter referred to as DAHER-TLI). The purpose of the inspection was to assess DAHER-TLI's compliance with the provisions of their approved NRC Quality Assurance Program (QAP) for radioactive material packages, the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 21, and 71, and their applicable Certificate of Compliance (CoC). Specifically, the team of NRC inspectors verified the adequacy of activities related to design, modification, fabrication, assembly, testing, procurement, and maintenance of the DAHER-TLI transportation packaging CoC for the Vera-Pac (VP) models.

Century Industry (CI) was the former holder of the applicable CoC and the NRC approved QAP for the radioactive material package designated under docket numbers 71- 9342, and 71-0947, respectively. DAHER-TLI purchased the assets of CI in September 2013 and submitted a Quality Assurance Program Description (QAPD) on February 24, 2014 to replace the QAPD submitted by CI in September 2009. On March 12, 2014, the NRC approved the DAHER-TLI QAPD on NRC Form 311. DAHER-TLI is now responsible for the quality assurance requirements as applicable to design, fabrication, testing, and modification of the Part 71 packaging and manufacturing of the Versa-Pac (VP) models. Following the purchased of CI, DAHER-TLI manufactured an estimated one-hundred VP models over a two-year period from May of 2014 through May 2016. The NRC now has DAHER-TLI registered as CoC holder for the Versa-Pac packaging as follows:

Model #	Package ID#	Docket #	Certificate #
Versa-Pac (VP) -55, VP-55HC, and VP-110	USA/9342/AF-96	71-9342	9342

The team conducted the inspection activity requirements in accordance with NRC Inspection Procedure 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings". The team reviewed selected procedures and records, and interviewed personnel. The team performed a preliminary exit briefing on August 17 at the completion of the inspection week. However, the team needed additional information to complete the inspection. The team conducted the final telephone exit briefing on September 30, 2016. During the telephone exit briefing, the team lead informed DAHER-TLI of the inspection results. The team identify one violation of NRC requirements in the area of planned and periodic audits. The team dispositioned the violation as a Severity Level IV non-cited violation (NCV). The team determined to treat the Severity Level IV violation as a NCV, which was consistent with Section 2.3.2 of the NRC Enforcement Policy. DAHER-TLI acknowledged the information presented and documented the violation in their corrective action program for resolution.

**INSPECTOR NOTES: AS DESCRIBED BELOW, THE TEAM PERFORMED AND DOCUMENTED APPLICABLE PORTIONS OF 02.02 THROUGH 02.10 OF INSPECTION PROCEDURE (IP) 86001 USED FOR THIS LIMITED SCOPE INSPECTION**

**02.02 Verify that the CoC holder's activities related to transportation packaging are being conducted in accordance with the CoC, as well as the NRC-approved QAP, and that implementing procedures are in place and effective.**

The team of NRC inspectors reviewed how DAHER-TLI performed work under its NRC-approved quality assurance program, QAPD1, "Quality Assurance Program Description," Revision 1 and various implementing procedures. The team verified that the quality program authorities and responsibilities were clearly defined and documented, and the quality assurance organization functioned as an independent group. The team reviewed DAHER-TLI graded approach for identifying Vera-Pac Important-to-Safety (ITS) components. The team verified how DAHER-TLI fulfilled these graded quality level requirements in related procurement documents. The team also reviewed a sample of personnel qualifications and training records.

The team assessed that DAHER-TLI had programs and procedures in place and were effective in conducting activities in accordance with the CoC for the Vera-Pac package and the NRC approved QAP. However, the team noted in some instances that it was difficult to determine if individuals completed all training identified in Table 2 of Quality Procedure (QP) 2.0.02, "Indoctrination and Training of Personnel," Revision 1. DAHER-TLI captured this issue in corrective action report (CAR) No. 1136, dated 8/17/2016.

**02.03 Verify that provisions are in place for reporting defects, which could cause a substantial safety hazard, as required by 10 CFR Part 21**

The team reviewed QP-15.0.02, "Reporting of Defects and Noncompliances in Accordance With 10CFR21," Revision 0, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard. The inspectors requested a list of Part 21 evaluations and notifications associated with the fabrication of the Vera-Pac (VP) transportation packaging and interviewed personnel to determine if they were familiar with the implementing procedure QP-15.0.02. The inspectors reviewed other nonconformance and condition reports initiated and dispositioned to determine if those met the criteria of reporting under Part 21. The team also verified that DAHER-TLI complied with the 10 CFR 21.6, "Posting requirements."

Based on the review, the team assessed that provisions were in place for reporting defects that could cause a substantial safety hazard, as required by 10 CFR Part 21. The team noted that there were no defects or Part 21 noncompliance reports identified since DAHER-TLI started fabrication activities on the Vera-Pac models.



#### **02.04 Interview selected personnel and review selected design documentation to determine that adequate design controls are implemented.**

The team interviewed selected personnel to verify the control of all phases of the design process from the onset of the design through the fabrication activities. The team focused its review on the translation of the design specification to the fabrication drawings and the controls that were in place. The team reviewed the DAHER-TLI procedures specifically related to design development, and control of modification activities. The team also reviewed the qualifications of selected engineering personnel. The team focused its review on DAHER-TLI design activities related to Revision 11 of CoC No. 9342 for the Part 71 Versa-Pac packaging models. The team reviewed the following DAHER-TLI procedures and QAPD sections associated with design control and qualification to verify that DAHER-TLI implemented the procedures properly. The procedures are as follows:

- QAPD1, Section 3.1, "Design Control," Revision 1
- QP-3.0.01, "Design Control," Revision. 3
- QP-3.0.03, "Computer Software Control," Revision 2
- QP-3.0.06, "Project Planning," Revision 4
- QP-3.0.07, "Identification of Quality Categories," Revision 1
- QP-2.0.06, "Qualification of Engineering Personnel," Revision 3

For Revision 11 of CoC No. 9342, the team reviewed a modification that added a new 5-inch steel pipe container designated as VP-55-2R. The team verified that DAHER-TLI developed and referenced the applicable drawings in accordance with the CoC. The team reviewed the computer program verification and validation (V&V) documentation for the Monte Carlo N-Particle Transport Code (MCNP) Version 6.1 to determine if DAHER-TLI followed the requirements of QP-3.0.03.

The team also selected two licensing drawings for review to verify that DAHER-TLI adequately translated the design details of the VP models to the associated fabrication drawings. Specifically, the team reviewed licensing drawings VP-55-LD-1, Revision 11 and VP-55-LD-2 Revision 12, and compared the licensing drawing to the related fabrication drawings. DAHER-TLI developed these new fabrication drawings and issued them for approval in February 2016.

The team assessed that overall, DAHER-TLI was effectively implementing its design control program and that implementing procedures were in place and effective in controlling activities in accordance with the applicable regulations and approved CoC. The team concluded that DAHER-TLI processed and developed project plan, computer code V&V, and licensing and fabrication drawings in accordance with the applicable procedures, except in one case. The team identified one minor violation because DAHER-TLI personnel did not follow procedures to perform an adequate review of fabrication drawings against the applicable licensing requirements. This failure to perform the licensing review is a violation of 10 CFR 71.111 for failure to follow procedures. Specifically, work Instruction (WI) 03-02, "Drawing Change Procedure," Rev. 3, Step 3.3, determines if the fabrication drawings are compliant with license documentation. The team dispositioned the violation as minor because DAHER-TLI did not use these drawings to fabricate any VP models and there were no current plans to use the drawings for fabrication. DAHER-TLI entered this issue into their corrective action program as CAR No. 1135, and plan to void the drawings.

## **02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine that design and maintenance activities meet SARP design requirements documented in the CoC**

The team reviewed DAHER-TLI's documentation control program to assess the effectiveness of controls established for the approval, issuance, revision and use of quality documents. The team reviewed QP-6.0.01, "Document Control," Revision 4. The team verified that DAHER-TLI approved the quality documents per procedure by appropriate personnel and the most current version was available for use. The team observed DAHER-TLI's use of electronic computer file folders for procedure control. The team interviewed personnel who used the system regularly to ensure they were knowledgeable of the program requirements and were implementing it as required. The team also verified a sample of controlled documents in the electronic file folders to ensure that the latest revision was available. Additionally, the team reviewed QP-17.0.01, "Quality Assurance Records," Revision 4. The team discussed how DAHER-TLI personnel implemented the applicable regulatory and procedural requirements for quality record control. Specifically, the team discussed how DAHER-TLI personnel stored the quality documents and how long they retained these documents.

Overall, the team determined that DAHER-TLI implemented its document control program, including quality record control, as required by the applicable regulatory and procedural requirements. The team assessed that the procedures provided adequate guidance for the processing of quality document approvals, revisions, and distribution of newly issued documents. The team noted that DAHER-TLI controlled the use in accordance with the applicable requirements and stores two backups of quality records both on-site and at an offsite backup datacenter on a daily basis at a minimum.

## **02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QA Program holder meet the design requirements**

The team reviewed the applicable procedures and historic records to verify that the procurement specifications for materials, equipment, and services received by DAHER-TLI met the design requirements. The team reviewed the following Quality Procedures (QP):

- QP-3.0.07, "Identification of Quality Categories," Revision 1
- QP-4.0.01, "Procurement Document Control," Revision 2
- QP-7.0.01, "Control of Purchased Materials, Equipment, and Services," Revision 4
- QP-7.0.04, "Receiving Inspection," Revision 3
- QP-7.0.05, "Dedication of Commercial Grade Items and Services," Revision 3
- QP-10.0.01, "Inspection," Revision 3

The team reviewed procurement documents of important-to-safety components such as the Versa-Pac packaging drums, fasteners, and welding materials. The team verified that DAHER-TLI implemented appropriate procedures for control of the procurement process. The team assessed the drums, fasteners, and welding materials for compliance with the CoC, Safety Analysis Report, procurement specifications, as well as associated purchase orders. The team also examined a sampling of DAHER-TLI's material receiving records, certificates of conformance or compliance, and certified material test reports.



As a part of the review, the team found the following minor violation associated with the procurement of Category B important-to-safety materials or services from a DAHER-TLI approved supplier list (ASL).

Title 10 CFR 71.111, "Instructions, procedures, and drawings," states, in part, that the certificate holder shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. Contrary to the requirements of 10 CFR 71.111, as of August 17, 2016, the NRC identified that DAHER-TLI did not follow prescribed instructions and procedures for activities affecting quality.

Section 6.1.1, General Requirements, of QP-7.0.01 states, in part, those suppliers used for safety-related and important-to-safety (ITS) quality activities shall be approved by DAHER-TLI based on an audit or survey in accordance with QP-18.0.01, Audits. Once reviewed and found to be acceptable, the supplier shall be added and maintained on an ASL according to Appendix 1. Contrary to the procedure requirement, DAHER-TLI did not perform audits of its important-to-safety (ITS) Safety Category B item suppliers and add them to its ASL while still performing fabrication. The inspectors noted that ITS items and services include all with a Safety Category A classification and those in Category B if designated by engineering or quality.

The team assessed this was a minor violation since NRC Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," states on Appendix A, Page A-2, that Category B quality materials need not be procured from a qualified vendor list. However, DAHER-TLI did not follow their own procedural requirement to address ITS Category B items. In addition, the team identified that DAHER-TLI's QP contained a conflict between two procedures for the need to add ITS category B items to an ASL. In particular, Section 6.3.2 of QP-3.0.07 states, in part, that the procurement of Category B materials need not be from the Approved Suppliers List. This is in direct contradiction to section 6.1.1 of QP-7.0.01, which states that suppliers to be used for safety-related and ITS quality activities shall be approved by DAHER-TLI based on an audit or survey in accordance with QP-18.0.01, Audits. It further states that once reviewed and found to be acceptable, the supplier shall be added and maintained on an ASL in accordance with Appendix 1 of QP-7.0.01.

**02.08 Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner**

The team reviewed selected records and interviewed selected personnel to verify that DAHER-TLI effectively implemented a nonconformance control program, and that personnel completed corrective actions for identified deficiencies in a technically sound and timely manner. Specifically, the team reviewed DAHER-TLI's quality procedures QP-15.0.0, Nonconforming Material, Parts, and Components and QP-16.0.01, Corrective Action. The inspectors reviewed a list of nonconformances, and corrective action reports for the last three years. The team also discussed the nonconformance and corrective actions with the DAHER-TLI staff.

Overall, the team assessed that DAHER-TLI had an adequate nonconformance and corrective action program in place to resolve deficiencies. However, the team noted that a number of the nonconformance reports dispositioned as "Use-as-is" did not have adequate technical justifications. The team assessed that this was a minor violation because it did not affect the function of the component and there was no adverse consequence associated with the nonconformance. Therefore, this violation was not subject to formal enforcement action. DAHER-TLI captured this issue in CAR No. 1137, dated 8/17/2016.

**02.09 Review selected records and procedures, interview selected personnel, and observe selected activities affecting the safety aspects of the packaging to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and quality assurance (QA) staff are cognizant and provide appropriate oversight**

The team reviewed selected records and procedures, interviewed personnel since there was no ongoing fabrication of the VP packaging models. DAHER-TLI completed active production and permanently closed its fabrication facility in Virginia. The team reviewed the applicable procedures and historic records to assess if individuals performed quality-related activities. The team reviewed the following Quality Procedures:

- QP-2.0.02, "Quality Related Indoctrination and Training of Personnel," Revision 3
- QP-2.0.03, "Qualification of Audit Personnel," Revision 2
- QP-2.0.04, "Qualification of Inspection & Test (I&T) Personnel," Revision 2
- QP-2.0.05, "Qualification of Nondestructive Examination (NDE) Personnel," Revision 3

The team also sampled training and qualification records for quality assurance auditors and lead auditors. The team selected two audit personnel records to assess qualification and certification in accordance with the requirements in QP-2.0.03. The team reviewed a sample of certification and qualification records for welders that fabricated the Versa-Pac packagings. In addition, the team performed a sample review of certification records for several Quality Control inspectors and test personnel for nondestructive examinations according to the American Society of Nondestructive Testing in the NDE methods of Visual Examinations and Magnetic Particle Examinations.

The team assessed that DAHER-TLI implemented procedures QP-2.0.04 and QP-2.0.05 for the qualification of personnel and used the proper forms to document the qualification records. The team assessed that personnel were appropriately qualified according to applicable requirements.



**02.10 Verify that audits of the QA Program and activities affecting the safety aspects of the packaging are scheduled, have been performed as scheduled, and that identified deficiencies have been satisfactorily resolved in a timely manner.**

The team reviewed selected audits and interviewed personnel to verify that DAHER-TLI effectively implemented an audit program. The team evaluated the quality and depth of the audits. The team reviewed the DAHER-TLI QAPD and implementing procedures related to performing internal and external audits/surveys of DAHER-TLI suppliers. The team reviewed the following quality procedures:

- QP-2.0.03, "Qualification of Audit Personnel," Revision 2
- QP-18.0.01, "Audits," Revision 3

The team reviewed the qualifications and training records for two DAHER-TLI Lead Auditors to determine if they met the requirements stated in QP-2.0.03. The team reviewed the current DAHER-TLI ASL dated 7/12/2016, Revision 2. The team reviewed the internal audit schedule for the years 2014, 2015, and 2016.

Overall, the team assessed that DAHER-TLI did not perform all internal audits for 2104 and 2015. The team determined that this violated regulation 10 CFR 71.137, "Audits." Title 10 CFR 71.137, "Audits," states, in part, that the certificate holder shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. Contrary to, from September 2014 to August 17, 2016, DAHER-TLI did not perform all the required internal audits for 2014 and 2015. The team noted that this also was contrary to procedure requirements identified in QP-18.0.01. The team dispositioned the violation as a Severity Level IV non-cited violation (NCV). The team decided to treat the Severity Level IV violation as a NCV, which was consistent with Section 2.3.2 of the NRC Enforcement Policy. DAHER-TLI capture this issue in their corrective action program.

In addition, Section 6.9 of QP-18.0.01 contains the following statements to address the management review of the QA program effectiveness:

- management is required to regularly assess the adequacy and effectiveness of the QAP implementation,
- the review, as a minimum, shall contain a review of internal audits (among other things listed in section 6.9), and
- in order to facilitate this review, the Designate of Quality Assurance shall issue an annual report to management and be documented to include management signatures indicating their review.

Title 10 of CFR 71.137 also states, in part, that audit results must be documented and reviewed by management. The team requested to review the annual reports from 2014 and 2015. DAHER-TLI was only able to provide a DAHER-TLI QA Program Effectiveness Report from 2015. The team noted that DAHER-TLI management was not engaged enough and did not regularly assess the adequacy and effectiveness of the DAHER-TLI quality assurance program implementation to realize that internal audits had not been performed in 2014 and 2015.