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May 16, 2016

ATTN: Document Control Desk
Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Changes to the DAHER-TLI QA program for radioactive material packages; §71.106
Reference: No. 0947 Revision 1; Docket No. 71-0947

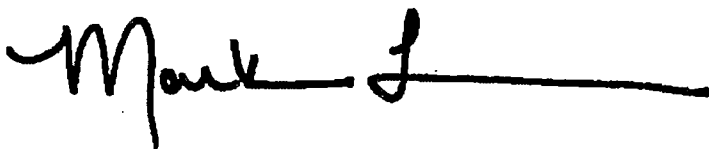
Pursuant to the requirements stated in 10CFR 71.106(b), a quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with §71.1(a).

In accordance with the requirements adopted in §71.106, we are submitting the changes made to our quality assurance program, Document No. QAPD1 Revision 1, date of implementation May 12, 2016. The changes that have been made to the quality assurance program are administrative clarifications, which do not reduce our commitment previously made to the NRC; or changes to provide compliance with the recent amended portion of §71.38 and the addition of §71.106.

All correspondence relative to this application for review shall be sent to:

Mr. Mark Lambert, Managing Director
DAHER-TLI
8161 Maple Lawn Boulevard Suite 450
Fulton, MD 20759

Sincerely,



Mark Lambert
Managing Director, DAHER-TLI

Enclosure: DAHER-TLI QAPD1 Rev. 1

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CHANGES TO THE DAHER-TLI QA PROGRAM FOR RADIOACTIVE MATERIAL PACKAGES; §71.106

DOCKET NO. 71-0947 APPROVAL NO. 0947 REVISION 1

TABLE OF CHANGES – DAHER-TLI QAPD1 REVISION 1 (05-12-2016)			
10CFR71H SECTION REFERENCE	QAPD1 SECTION/ PARAGRAPH REFERENCE	CHANGES	JUSTIFICATION (REASON FOR CHANGE; BASIS FOR CONCLUDING THE CHANGE CONTINUES TO SATISFY 10CFR71H REQUIREMENTS)
§71.101 §71.106	QAPD1	The following provides the changes made to the DAHER-TLI QAPD, Revision 1 dated May 12, 2016	Justification of changes - The revisions identified are for administrative clarification in the DAHER-TLI QA Program. These provide for compliance with the amended portions of 10 CFR 71.38, and the addition of 10 CFR 71.106; or are considered to be editorial in nature. The changes do not reduce any quality commitments made to the NRC by TLI in the previously approved QA Program document.
§71.103	QAPD RI	QAPD1 Approval by Designate, Quality Assurance and Managing Director	Administrative clarification Updated personnel titles to generic organizational positions
§71.103	QAPD INT	Re-wrote last paragraph pertaining to the implementation of the Quality Assurance Program; identifying the Designate, Quality Assurance and Site QA staff and personnel	Administrative clarification Updated personnel titles to generic organizational positions
§71.103	QAPD PS	1 st Para. – Added, “Cleaning”; revised last sentence to coincide with NRC policy on approval prior to implementation	Administrative improvement Administrative clarification of §71.106
		2 nd Para. – Changed to read, “Managing Director” and “Designate, Quality Assurance”, and “Site Quality Assurance”;	Administrative clarification Updated personnel titles to generic organizational positions
		3 rd Para. – changed to read, “Managing Director”;	Administrative clarification Updated personnel titles to generic organizational positions
		4 th Para. – changed to read, “Managing Director”	Administrative clarification Updated personnel titles to generic organizational positions
		Policy Statement signed by the Managing Director	Administrative clarification Updated personnel titles to generic organizational positions
§71.103	Section 1	Change in Management & Organization to coincide with current TLI organization, as follows:	Administrative clarification
		1.2.1 - changed to read, “Managing Director” Added section 1.2.2 “Chief Operating Officer”; re-numbered remaining sections	Administrative clarification Updated personnel titles to generic organizational positions
		1.2.3 – changed to read, TLI Sites”; and “Report directly to Chief Operating Officer”	Administrative clarification Added position function into organization
		1.2.4 - change to read, “Designate Quality Assurance”	Administrative clarification Updated personnel titles to generic organizational positions
		1.2.5 – changed to read, “Site Quality Assurance”, and replaced “division” with “Site”, 5X	Administrative clarification Updated personnel titles to generic organizational positions

CHANGES TO THE DAHER-TLI QA PROGRAM FOR RADIOACTIVE MATERIAL PACKAGES; §71.106

DOCKET NO. 71-0947 APPROVAL NO. 0947 REVISION 1

TABLE OF CHANGES – DAHER-TLI QAPD1 REVISION 1 (05-12-2016)			
10CFR71H SECTION REFERENCE	QAPD1 SECTION/ PARAGRAPH REFERENCE	CHANGES	JUSTIFICATION (REASON FOR CHANGE; BASIS FOR CONCLUDING THE CHANGE CONTINUES TO SATISFY 10CFR71H REQUIREMENTS)
		1.3.2 – changed “Division” to “Site”, 2X	Administrative clarification Updated titles to generic organizational locations
		1.4 – revised “Organizational Chart”	Provides for generic organization
§71.105	Section 2	2.1.1, 6 – added requirements relating to the NRC policy on approval prior to implementation	Administrative improvement Administrative clarification of §71.106
		2.1.1, 7 – added requirements to coincide with NRC amended portions of 10CFR Part 71 Subpart H (i.e., §71.38 and §71.106)	Administrative improvement Administrative clarification of §71.106
		2.1.2 – changed “Division” to “Site”, 2X	Administrative clarification Updated titles to generic organizational positions
		2.2.1 – changed “Quality Assurance” to “DQA”	Administrative clarification Updated titles to generic organizational positions
		Added section 2.4, “Ethics of Company Personnel”	Administrative clarification Added additional employee training requirements
§71.113	Section 6	6.1.3 – changed “Division” to “Site”	Administrative clarification Updated titles to generic organizational locations
§71.115	Section 7	7.1.11 – re-worded sentence to clarify requirement	Administrative clarification Providing for additional verification
---	---	Note: The following requirements in Sections 8 through 15 provide flexibility in manufacturing capabilities either in-house at designated TLI Sites; or the use of approved suppliers:	---
§71.117	Section 8	8.1.1 – added, “in manufacturing and assembly”, and “during maintenance and repair (by TLI and/or approved suppliers)”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER- TLI, or an approved supplier
§71.119	Section 9	9.1.1 – added “and/”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER- TLI, or an approved supplier
§71.121	Section 10	10.1.1 – added, “(performed by TLI; and/or its approved suppliers, contractors, or subcontractors),”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER- TLI, or an approved supplier
		10.1.6 – changed to read, “... (M&TE shall be selected to assure calibration status and of proper ...”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER- TLI, or an approved supplier
§71.123	Section 11	11.1.1 – added, “(performed by TLI; and/or its approved suppliers, contractors, or subcontractors),”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER-

CHANGES TO THE DAHER-TLI QA PROGRAM FOR RADIOACTIVE MATERIAL PACKAGES; §71.106

DOCKET NO. 71-0947 APPROVAL NO. 0947 REVISION 1

TABLE OF CHANGES – DAHER-TLI QAPD1 REVISION 1 (05-12-2016)			
10CFR71H SECTION REFERENCE	QAPD1 SECTION/ PARAGRAPH REFERENCE	CHANGES	JUSTIFICATION (REASON FOR CHANGE; BASIS FOR CONCLUDING THE CHANGE CONTINUES TO SATISFY 10CFR71H REQUIREMENTS)
			TLI, or an approved supplier
		11.1.6 – changed to read, “... (M&TE <u>shall be selected to assure calibration status and of proper</u> ...”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER-TLI, or an approved supplier
§71.125	Section 12	12.1.1 – added, “(performed by TLI; and/or its approved suppliers, contractors, or subcontractors).”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER-TLI, or an approved supplier
§71.127	Section 13	13.1.1 – added, “(performed by TLI; and/or its approved suppliers, contractors, or subcontractors).”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER-TLI, or an approved supplier
§71.129	Section 14	14.1.1 – added, “(performed by TLI; and/or its approved suppliers, contractors, or subcontractors).”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER-TLI, or an approved supplier
§71.131	Section 15	15.1.2 – added, “(performed by TLI; and/or its approved suppliers, contractors, or subcontractors).”	Administrative Clarification Providing for flexibility in manufacturing activities – to be performed by DAHER-TLI, or an approved supplier
		15.2 – added, “Reporting of Defects and Noncompliances”	Administrative Clarification Missing in previous revision
§71.105	Section 19	19.1.4 – added NOTE pertaining to RG 1.28 Rev. 4 requirements as they pertain to the implementation of ASME NQA-1-2008 and NQA-1a-2009 and 10 CFR Part 50 Appendix B	Administrative Clarification Editorial in nature
§71.101 §71.103 §71.105	Section 20	Added – “to demonstrate implementation of the documented QAPD”	Administrative Clarification Editorial in nature
		Added Procedures: QP-0.0.02; QP-3.0.07; QP-19.0.01	Administrative Clarification Terms and Definitions extracted from Procedure No. QP-0.0.01 Formerly Procedure No. QP-7.0.02 Formerly Procedure No. QP-3.0.05
		QP-2.0.02 – added to title, “Quality Related”	Administrative Clarification Editorial in nature
		Deleted Procedures: QP-3.0.02; QP-3.0.04; QP-3.0.05; QP-5.0.01; QP-5.0.02; QP-5.0.03; QP-5.0.04; QP-7.0.02	Administrative Clarification Requirements incorporated into Procedure No. QP-3.0.01 Re-issued as Procedure N. QP-19.0.01 Requirements converted into Work Instructions (pertaining to TLI-ES) Re-issued as Procedure No. QP-3.0.07
		QP-7.0.05 – added to title, “and Services”	Administrative Clarification Missing in previous revision




QUALITY ASSURANCE PROGRAM DESCRIPTION QAPD1


Revision 1

Date of Implementation (for 10 CFR Part 71, Subpart H): May 12, 2016

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	Section:	Title:	Revision:	Date:
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	QAPD RI	Revision Index and QAPD Approval	1	05-12-2016


REVISION INDEX:

Revision:	Date:	Section:	Description:
0	02-20-2014	All	Initial Issue
1	04-28-2016	QAPD RI	QAPD1 Approval by Designate, Quality Assurance and Managing Director
		QAPD INT	Re-wrote last paragraph pertaining to the implementation of the Quality Assurance Program; identifying the Designate, Quality Assurance and Site QA staff and personnel
		QAPD PS	1 st Para. – Added, “Cleaning”; revised last sentence to coincide with NRC policy on approval prior to implementation 2 nd Para. – Changed to read, “Managing Director” and “Designate, Quality Assurance”, and “Site Quality Assurance”; 3 rd Para. – changed to read, “Managing Director”; 4 th Para. – changed to read, “Managing Director” Policy Statement signed by the Managing Director
		Section 1	Change in Management & Organization to coincide with current TLI organization, as follows: 1.2.1 - changed to read, “Managing Director” Added section 1.2.2 “Chief Operating Officer”; re-numbered remaining sections 1.2.3 – changed to read, TLI Sites”; and “Report directly to Chief Operating Officer” 1.2.4 - change to read, “Designate Quality Assurance” 1.2.4 - changed to read, “Managing Director” 1.2.5 – changed to read, “Site Quality Assurance”, and replaced “division” with “Site”, 5X 1.3.2 – changed “Division” to “Site”, 2X 1.4 – revised “Organizational Chart”
		Section 2	2.1.1, 6 – added requirements relating to the NRC policy on approval prior to implementation 2.1.1, 7 – added requirements to coincide with NRC amended portions of 10CFR Part 71 Subpart H (i.e., §71.38 and §71.106) 2.1.2 – changed “Division” to “Site”, 2X 2.2.1 – changed “Quality Assurance” to “DQA” Added section 2.4, “Ethics of Company Personnel”
		Section 6	6.1.3 – changed “Division” to “Site”
		Section 7	7.1.11 – re-worded sentence to clarify requirement Note: The following requirements in Sections 8 through 15 provide flexibility in manufacturing capabilities either in-house at designated TLI Sites; or the use of approved suppliers:
		Section 8	8.1.1 – added, “in manufacturing and assembly”, and “during

	Section:	Title:	Revision:	Date:
	QAPD RI	Revision Index and QAPD Approval	1	05-12-2016

REVISION INDEX:

Revision:	Date:	Section:	Description:
			maintenance and repair (by TLI and/or approved suppliers)"
		Section 9	9.1.1 – added "and/"
		Section 10	10.1.1 – added, "(performed by TLI; and/or its approved suppliers, contractors, or subcontractors),"
			10.1.6 – changed to read, "... (M&TE <u>shall be selected to assure calibration status and of proper ...</u>)"
		Section 11	11.1.1 – added, "(performed by TLI; and/or its approved suppliers, contractors, or subcontractors),"
			11.1.6 – changed to read, "... (M&TE <u>shall be selected to assure calibration status and of proper ...</u>)"
		Section 12	12.1.1 – added, "(performed by TLI; and/or its approved suppliers, contractors, or subcontractors)."
		Section 13	13.1.1 – added, "(performed by TLI; and/or its approved suppliers, contractors, or subcontractors)."
		Section 14	14.1.1 – added, "(performed by TLI; and/or its approved suppliers, contractors, or subcontractors)."
		Section 15	15.1.2 – added, "(performed by TLI; and/or its approved suppliers, contractors, or subcontractors)."
			15.2 – added, "Reporting of Defects and Noncompliances"
		Section 19	19.1.4 – added NOTE pertaining to RG 1.28 Rev. 4 requirements as they pertain to the implementation of ASME NQA-1-2008 and NQA-1a-2009 and 10 CFR Part 50 Appendix B
		Section 20	Added – "to demonstrate implementation of the documented
		QAPD Rev	QAPD"
			Added Procedures: QP-0.0.02; QP-3.0.07; and QP-19.0.01
			QP-2.0.02 – added to title, "Quality Related"
			Deleted Procedures: QP-3.0.02; QP-3.0.04; QP-3.0.05; QP-5.0.01; QP-5.0.02; QP-5.0.03; QP-5.0.04; QP-7.0.02
			QP-7.0.05 – added to title, "and Services"
			NOTE: Justification of changes - The above revisions are for administrative clarification. Provides compliance with the amended portions of 10 CFR 71.38, and the addition of 10 CFR 71.106; or are considered as editorial in nature. The changes do not reduce quality commitments made to the NRC by TLI in the previously approved QA Program document.

	Section:	Title:	Revision:	Date:
	QAPD RI	Revision Index and QAPD Approval	1	05-12-2016

QUALITY ASSURANCE PROGRAM DESCRIPTION- QAPD1 APPROVAL



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Magnan
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Designate, Quality Assurance


Date



Digitally signed by Mark T.
Lambert
Date: 2016.05.17 08:13:06 -05'00'

Managing Director

Date

 DAHER-TLI	Section:	Title:	Revision:	Date:
	QAPD INT	Introduction	1	05-12-2016


Founded in 1988, Transport Logistics International, part of the DAHER Group (DAHER-TLI; or TLI) is uniquely qualified to provide specialized transport of radioactive cargoes. TLI offers a range of services from simple uni-modal transport to multi-modal international transport of all radioactive material.

In addition to managing transportation, TLI provides consulting, engineering, manufacturing, training and other support services to its customers in the nuclear industry; and is committed to offering the highest quality service to its clients.

The DAHER-TLI Quality Assurance Program consists of this QAPD and the associated implementing procedures (Quality Procedures; QP - see Section QAPD 20.0), which are designed and administered to meet the applicable requirements of 10CFR Part 71 Subpart H; 10CFR 50 Appendix B; and ASME NQA-1.

The management of DAHER-TLI is dedicated to offering superior management services and ensuring that the Quality Assurance policy is communicated, understood, and implemented at all levels within the company. All employees are to perform their responsibilities fulfilling the quality assurance requirements, upholding DAHER-TLI's mission of providing specialized transport management services for all forms of radioactive materials while providing excellent customer satisfaction.

The Designate, Quality Assurance (DQA), under the guidance of the DAHER Group Quality Assurance Department, along with Site Quality Assurance staff and personnel will implement the Quality Assurance Program with full approval of the Managing Director and the DAHER-TLI Board.

 DAHER-TLI	Section:	Title:	Revision:	Date:
	QAPD PS	Policy Statement	1	05-12-2016

DAHER-TLI (TLI) is engaged in the business of transportation, engineering, manufacturing, and other safety-related or important-to-safety activities, which includes as required: design, procurement, fabrication, assembly, testing, modification, cleaning, maintenance, repair, and use of radioactive material transportation packages and components. As such, TLI has the obligation and responsibility to protect the health and safety of the public and its employees. TLI has established its Quality Assurance Program (QA Program) to comply with the requirements of 10 CFR71 Subpart H, 10 CFR 50 Appendix B, and ASME NQA-1. In the event that the program reduces the commitment as previously approved by the NRC, the proposed changes shall be reviewed and approved by the USNRC prior to implementation.

The Managing Director of TLI recognizes that the Quality Assurance personnel performing functions affecting quality are to be sufficiently independent of all other functions. The Designate, Quality Assurance (DQA) has been given the full authority and responsibility for establishing and maintaining the QA Program and corresponding implementing procedures, and for the control, administration and enforcement of all sections to maintain full compliance with the QA Program. The DQA has the organizational freedom to: identify quality problems; initiate, recommend, or provide solutions; verify implementation of solutions; and limit or control further processing, or delivery of a nonconforming item or unsatisfactory condition until proper disposition has occurred. Site Quality Assurance personnel act under the authority of the DQA at their assigned location.


The Managing Director of DAHER-TLI retains the overall authority and responsibility for the implementation of the Quality Assurance Program. Each and every employee expected to perform the individual's assigned work activities in accordance with established requirements and policies. The Program ensures that quality is achieved and maintained by those assigned responsibility for performing work, with achievement verified and documented by persons or organizations not directly responsible for performing the work.

When problems or differences of opinion on quality issues cannot be resolved through normal lines of communication, these issues are to be brought to the attention of the Managing Director for resolution. Resolution shall always result in compliance with the applicable code, contract, and/or regulatory requirements as required.

The management of DAHER-TLI is firmly committed to the requirements of this QA Program and total participation of all personnel that represent this company is required.

Managing Director

Date

	Section:	Title:	Revision:	Date:
	QAPD 1.0	Organization and Responsibility	1	05-12-2016

1.1 ORGANIZATION

- 1.1.1 General organization and responsibilities for the establishment and implementation of the Quality Assurance Program (QA Program) are defined and documented, including functional responsibilities, levels of authority, and lines of communication for activities that affect quality; and are described in detail by the implementing procedures (Quality Procedures; QP).

1.2 STRUCTURE

- 1.2.1 Managing Director: Retain the overall authority and responsibility for the implementation of the QA Program, as identified in the Policy Statement. Responsible for the desired end result. Responsible for all activities relating to the operation of TLI. Responsible for ensuring compliance with program, regulatory, and customer related requirements for activities performed in the company operations.
- 1.2.2 Chief Operating Officer: Reports directly to the Managing Director. Responsible for all activities relating to the operation of the TLI Sites
- 1.2.3 Director(s) TLI Sites: Report directly to the Chief Operating Officer. Responsible for all activities and personnel relating to the operation of the TLI Division, and to ensure compliance with program, regulatory, and customer related requirements for activities performed in the division's operation.
- 1.2.4 Designate, Quality Assurance (DQA): Reports directly to the Managing Director. Responsible for the development, implementation and maintenance of the QA Program and implementing procedures. Conducts the annual review and assessment of the QA Program to advise management of its adequacy and effectiveness. The DQA is also responsible for providing administrative and functional guidance to the Quality personnel, and overseeing customer and regulatory audits of the QA Program. The DQA is to be sufficiently independent from the pressures of cost, production, and scheduling. Has the authority to stop production and delivery, and has sufficient authority, access to work areas, and organizational freedom to:
- Identify quality problems;
 - Initiate, recommend or provide solutions to quality problems through designated channels;
 - Verify implementation of solutions;

DAHER-TLI	Section:	Title:	Revision:	Date:
	QAPD 1.0	Organization and Responsibility	1	05-12-2016

- d. Assure that further processing, delivery, or installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

1.2.5 TLI Site Quality Assurance (Site QA): Reports directly to the DQA. As the representative of the DQA, the Site QA is responsible for providing administrative and functional guidance to the Site Quality personnel. Performs the assigned DQA functions at the Site level, as required. Oversees customer and regulatory audits of the QA Program at the assigned Site location.

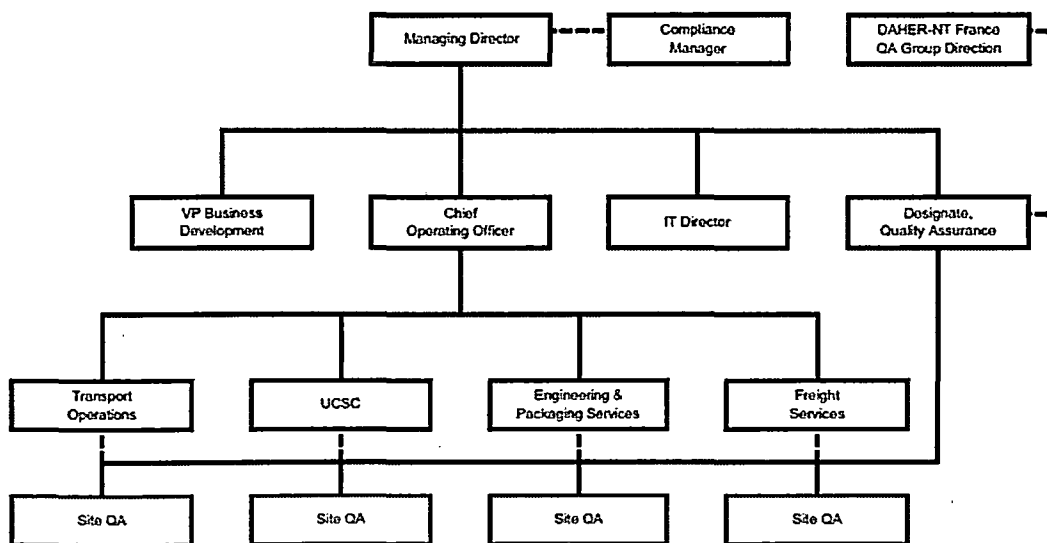
1.2.6 Information Technology: Responsible for the administration of the computer-based information systems; computer hardware and software requirements, functions, installation and use; and software selection, maintenance, upgrade and replacement.


1.3 DELEGATION OF DUTIES

1.3.1 Any individual designated responsibility by the program may delegate the performance of that responsibility to a qualified individual; but, the individual retains the overall responsibility for ensuring compliance with the requirements of the Program.

1.3.2 The Site Director may perform any of the activities assigned to individuals within their Site provided the Director is qualified to perform the activities.

1.4 ORGANIZATIONAL CHART




	Section:	Title:	Revision:	Date:
	QAPD 2.0	Quality Assurance Program	1	05-12-2016

2.1 PURPOSE AND RESPONSIBILITY

2.1.1 SCOPE

The Quality Assurance Program Description (QAPD) defines and documents those measures to plan, implement, and maintain the Quality Assurance Program (QA Program, Program, or program); to assure all functions and requirements pertaining to safety-related or important-to-safety quality activities conducted by TLI. This includes as required: design, procurement, fabrication, assembly, inspection, testing, handling, shipping, storing, cleaning, operation, maintenance, repair and modification of package systems and/or components; under control of this QA Program; and when required, a license, certificate, or application for Certificate of Compliance (CoC) operated by DAHER-TLI.


1. Suppliers used for performance of activities subject to the requirements of the QA Program are qualified to ensure compliance; however, TLI retains the overall responsibility for the quality of those activities.
2. The QA Program comprises all planned and systematic actions to provide adequate confidence that all activities are in accordance with the rules and requirements identified in 10 CFR Part 71 Subpart H, 10 CFR Part 50 Appendix B, and ASME NQA-1.
3. The QA Program provides for the accomplishment of activities affecting quality under controlled conditions utilizing as applicable: appropriate equipment, special controls, processes, suitable environmental conditions, test equipment, tools, skills, and personnel to (a) attain the required quality, (b) satisfy established prerequisites for given activities, and (c) verify quality by examination, inspection, or test.
4. The QA Program is supported by implementing procedures (Quality Procedures; QP) and written instructions defining methods of operation for processes, controls, and examinations, personnel qualifications and certifications. Additional procedures are issued as needed to satisfy requirements of specific customer requirements. In the case of conflict between an existing procedure or instruction and the program, the QAPD prevails and the documents shall be revised.
5. Annual internal audits and the management report shall be completed to assure effective program implementation in accordance with Section QAPD 18.0, *Audits*.

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	QAPD 2.0	Quality Assurance Program	1	05-12-2016

6. Revisions to the QAPD are subject to review and approval by the U.S. Nuclear Regulatory Commission (USNRC; NRC) prior to implementation when the changes reduce the commitments made in the previously-approved QA Program. The date of implementation for the QA Program revision shall be as follows:
- When changes do not reduce the commitments made to the NRC, the date of implementation shall be the approval date of the QA Program by TLI Management; and upon completion of all programmatic requirements (i.e., training, etc.
 - When changes are made that reduce the commitments made to the NRC, the date of implementation is to be on or after the date of NRC approval; and upon completion of all programmatic requirements (i.e., training, etc.).
7. Changes made to the QA Program that do not reduce the commitments previously approved by the NRC shall be submitted to the NRC every 24 months (start date coincides with date of last approval), in accordance with regulatory requirements [i.e., §71.1(a)].

The following are changes made to the QA Program that do not require NRC approval prior to implementation:

- Administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items,
- The use of a quality assurance standard approved by the NRC that is more recent than the quality assurance standard designated in the QA Program at the time of the change;
- The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there are no substantive change to functional relationships, authorities, or responsibilities;
- The elimination of QA program information that duplicates language in the QA regulatory guides and QA standards to which the QA Program is committed on record;
- Organizational revisions that ensure persons and organizations performing quality assurance functions continue to have the requisite

	Section:	Title:	Revision:	Date:
	QAPD 2.0	Quality Assurance Program	1	05-12-2016

authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations;

- f. Records of the QA Program changes are to be maintained and incorporated into the QA Program; and shall identify the following: Regulatory reference(s); QA Program reference(s); Changes (Before / After); and Justification (reason for change; basis for considering the change continues to satisfy the regulatory requirements).

2.1.2 RESPONSIBILITY

1. The DQA is responsible for all aspects of the QA Program, and flows-down responsibility to the Site QA at their level.
2. The responsibility for conformance to the contractual and program requirements as related to other services belongs to the designated TLI Site Director.

2.2 INDOCTRINATION AND TRAINING OF PERSONNEL


2.2.1 Employees shall be indoctrinated in the program, instructions and procedures relating to their specific job functions, and trained in their respective activities by their immediate supervisor/manager using training requirements provided by the DQA.

1. Personnel indoctrination and training shall be adequate to the scope, complexity, and importance of the activities, and based on education, experience, and proficiency.
2. Additional training shall be performed as required when necessitated by changes in the program, company policies or procedures.
3. Records of personnel indoctrination, training and/or qualification shall be established, certified and maintained by Quality Assurance.

2.3 PERSONNEL QUALIFICATION AND CERTIFICATION

2.3.1 Personnel (including subcontractors) designated for the performance of specialized activities affecting quality shall be qualified and certified in accordance with the appropriate implementing procedures.


1. Specialized activities may include, but not be limited to: Audit, Engineering, Inspection and Test (I&T), and Nondestructive Examination (NDE) personnel.

 DAHER-TLI	Section:	Title:	Revision:	Date:
	QAPD 2.0	Quality Assurance Program	1	05-12-2016

2. Personnel training shall be adequate to the scope, complexity, and importance of the activities; and based on education, experience, and proficiency.
3. Personnel qualification records shall be established and maintained by Quality Assurance.
4. Recertification of personnel shall be completed within the designated intervals and accomplished by continued satisfactory performance, written examination, or capability demonstration of proficiency as determined by stated requirements.

2.4 ETHICS OF COMPANY PERSONNEL

All DAHER-TLI employees shall be trained in accordance with the Foreign Corrupt Practices Act of 1977 (FCPA; 15 U.S.C. § 78dd) Anti-Bribery & Anti-Corruption Rules; and must sign for and abide with the DAHER Group Code of Conduct.

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3.1 DESIGN CONTROL

3.1.1 Measures are established to assure that applicable regulatory and design requirements for safety-related or important-to-safety activities specified by reference documents or the license are adhered to and are described in detail by the implementing procedures. Design control measures are applied to ensure that the following items are correctly identified, as applicable: criticality or reactor physics, radiation shielding, stress, thermal, hydraulic, and accident analyses, and cooling; compatibility of materials, accessibility for in-service inspection, maintenance and repair; features that facilitate decontamination, handling, storage, and cleaning requirements; and delineation of inspection and test acceptance criteria.

1. Design controls ensure applicable codes, standards, regulatory requirements, inspection and test criteria, operational and maintenance requirements, handling and storage are correctly translated into specifications, drawings, procedures, and instructions.
2. Codes and standards used in the design are specified by the design documents; and when these are not available, alternate approaches shall be identified.
3. Providing for the inclusion of specified and appropriate quality standards in the design documents.
4. Measures establish the control of material, parts, equipment and processes for the selection and review of suitability; and essential to the safety function of the component.
5. Design analyses are sufficiently detailed and documented in order that a technically qualified person who is experienced in the subject can review and understand the analyses, to verify the adequacy of the results without recourse to its originator.
6. Computer programs used for design analysis or verification are controlled in accordance with the implementing procedures; which provide for verification of the accuracy of the computer results, and to assess and resolve reported computer program errors.


3.1.2 Interface between participating design organizations are controlled by implementing procedures.

3.1.3 All design documents are reviewed to verify adequacy of the design; and approved by designated, independent individuals or groups other than those responsible for the

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original design using specified methods. Verification methods used to assure design adequacy may be one or more of the following: design reviews, alternate calculations, or qualification testing.

- 3.1.4 Conditions and requirements for testing programs used to verify design adequacy are specified.
- 3.1.5 Design changes are subject to the same controls utilized for the original design; and any approved design conditions established by the regulatory authority are submitted for approval, prior to implementation.

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	QAPD 4.0	Procurement Document Control	1	05-12-2016


4.1 PROCUREMENT DOCUMENT REQUIREMENTS

- 4.1.1 Implementing procedures have been established to describe the control of procurement documents to ensure that technical, safety-related or important-to-safety, and quality assurance requirements are identified in the appropriate procurement documents.
- 4.1.2 Procurement documents shall contain reference to the applicable provisions of 10 CFR Part 71 Subpart H, 10 CFR 50 Appendix B, ASME NQA-1, and other regulations, codes or standards as appropriate to the scope of the procurement. Documents shall identify the following, as required: scope of work, technical requirements, applicable regulatory requirements, material identification requirements, drawings, specifications, codes and standards, special process instructions, inspection and test requirements, supplier quality assurance program requirements, right of access, documentation, nonconformance requirements (includes 10 CFR Part 21, when applicable), and provision for spare parts and replacement parts.
- 4.1.3 Documentation required from the supplier to perform activities affecting quality (e.g., drawings, specifications, procedures, fabrication and inspection plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) are to be prepared, maintained and submitted for TLI approval.
- 4.1.4 When the suppliers identify the use of subtier suppliers, requirements to pass down appropriate QA program requirements are identified.
- 4.1.5 Procurement documents are reviewed and approved by appropriate organizations prior to issuance, as required; by personnel with access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.
- 4.1.6 Procurement of replacement parts required for components that are important to safety are subject to the same control as the original parts, including designation of supplier status, technical and QA requirements, and approval of the procurement documents prior to issuance.
- 4.1.7 Changes made to procurement documents are subject to the same control as the original document. The originating organization prepares the change, with a change order or revision indicator and date; and presents to the responsible person for review and approval.

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	QAPD 5.0	Instructions, Procedures, and Drawings	1	05-12-2016

5.1 DOCUMENT REQUIREMENTS

- 5.1.1 Implementing procedures describe in detail the measures to ensure that all safety-related or important-to-safety activities that affect quality are performed in accordance with the QA Program are done using documents (instructions, procedures and drawings) that include pertinent information for activities affecting quality.
- 5.1.2 It is mandatory that all personnel performing safety-related or important-to-safety activities adhere to strict compliance with the approved documents.
- 5.1.3 Pertinent information is disseminated in the form of instructions, procedures, and drawings to describe the activity required with a level of detail commensurate with the complexity of the activity, and to assure consistent and acceptable results.
- 5.1.4 The implementing procedures provide the structure used in the development, review, approval and control of the instructions or procedures. These documents include or reference the appropriate quantitative and/or qualitative acceptance criteria to determine that prescribed results have been attained.
- 5.1.5 The documents are to describe the required activity to a level of detail that is appropriate for the following considerations: complexity of the task, significance of the item or activity, work environment, and worker proficiency and capability.
- 5.1.6 Documents provided to suppliers for the completion of the procurement of material, items, or services are identified in the procurement documents or associated specifications.

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	QAPD 6.0	Document Control	1	05-12-2016

6.1 DOCUMENT CONTROL REQUIREMENTS

6.1.1 Implementing procedures describe in detail the requirements provided for the preparation, issuance, and change of documents that prescribe safety-related or important-to-safety activities that affect quality. These documents are controlled to assure that the correct documents are being employed.


6.1.2 Documents prescribing safety-related or important-to-safety activities that affect quality are reviewed and approved for technical adequacy, completeness, and incorporation of appropriate quality requirements prior to acceptance and issuance.

Controlled documents may include, but are not limited to:

- a. Design and fabrication specifications
- b. Design and fabrication drawings
- c. Special process specifications and procedures
- d. Inspection and test procedures
- e. QA program description and implementing procedures, and
- f. Operational, maintenance, and test procedures and data


6.1.3 Document Control reports to the DQA, through the Site QA, as applicable, and is responsible for the execution of the company document control procedures, measures to assure only current documents are in use, and document storage, as a function of the QA Program. Document Control is responsible for electronic document storage, control, and access to current records and changes; and includes implementation and access requirements.

6.1.4 Changes made to documents are subject to the same control as the original document in accordance with the applicable implementing procedures. The originating organization prepares the change, with a revision indicator and date; and presents to the responsible person or organization for review and approval.


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	QAPD 7.0	Control of Purchased Material, Equipment and Services	1	05-12-2016

7.1 MATERIAL CONTROL REQUIREMENTS

- 7.1.1 Implementing procedures describe in detail the provisions for documentation and control of material, equipment and services for safety-related or important-to-safety activities affecting quality; and to assure conformance to the established procurement documents.
- 7.1.2 In the design process, Engineering designates safety classifications to items and services.
- 7.1.3 Supplier selection shall be determined prior to the issuance of an order utilizing the Approved Suppliers List; considering the supplier's capability, source evaluation, and objective evidence.
- 7.1.4 Audits/surveys of suppliers are completed to determine supplier approval. These are performed by qualified personnel and documented and is based on one or more of the following criteria:
 - a. Compliance with the established codes, standards, or specifications (i.e., 10 CFR Part 71 Subpart H; 10 CFR Part 50 Appendix B; ASME NQA-1; ASME Section III).
 - b. Review of previous records to establish the supplier's past performance.
 - c. Survey of the supplier's facilities and QA Program to assess and verify adequacy and implementation of quality controls consistent with invoked requirements.
 - d. QA assessment of control and effectiveness of supplier at intervals consistent with the importance, complexity and quantity of the product described.
- 7.1.5 When required by procurement documents, suppliers are to submit documentary and objective evidence for activities affecting quality (e.g., drawings, specifications, procedures, fabrication and inspection plans and records, personnel and procedure qualifications, material chemical and physical test results for approval. For conditions not met by the supplier, documentation is to be submitted to ensure technical and quality requirements have not been compromised.
- 7.1.6 Implementing procedures provide control of source and receiving inspection verification.
- 7.1.7 Implementing procedures provide control of commercial grade item or service dedication.
- 7.1.8 Customer-furnished material is controlled; including— material certification, receipt inspection, and control; and shall only be used for its intended customer and designated purpose.


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	QAPD 7.0	Control of Purchased Material, Equipment and Services	1	05-12-2016

- 7.1.9 When post-installation testing is required, test requirements and acceptance documentation shall be established by TLI, with technical input furnished by the supplier, as required.
- 7.1.10 Subcontracted services (e.g., engineering, auditing, calibration, etc.) require verification of the technical data and objective evidence received for purchase document conformance. Surveillance and/or audit of the activity are considered when warranted.
- 7.1.11 Consulting personnel used in organizational responsibilities are evaluated for compliance; and authorized to work under the QA Program. Verification is accomplished by review of pertinent documentation, or by internal audit.
- 7.1.12 Nonconformances and corrective actions are controlled in accordance with the QA Program.

	Section:	Title:	Revision:	Date:
	QAPD 8.0	Identification and Control of Materials, Parts and Components	1	05-12-2016


8.1 IDENTIFICATION AND CONTROL REQUIREMENTS

- 8.1.1 Implementing procedures describe in detail the methods and controls established to ensure that all material, parts, and components to be used in manufacturing and assembly or installed during maintenance and repair (by TLI and/or approved suppliers) for safety-related or important-to-safety activities have been correctly identified and controlled. Controls ensure the prevention of the use of incorrect or defective material, parts, or components in the items; and for those that have not received the required examinations, tests, or inspections.
- 8.1.2 Identification marks used for traceability purposes are applied using methods and materials that are legible and not detrimental to the item involved. Identification shall be located in areas that will not interfere with function or quality aspects. When individual marking of items is not practical, then containers (e.g., totes, bags, or boxes) properly identified, and accompanied by its proper documentary evidence, are suitable alternatives, providing that the identity is maintained at all times. Identification marks used during storage of items shall be controlled, with provisions for maintenance or replacement due to damage from handling, aging, or environmental exposure.
- 8.1.3 Personnel responsible for activities performed in accordance with process documentation shall be required to exercise extreme caution when performing work so as not to remove those markings required for traceability purposes.
- 8.1.4 Process documentation shall establish the method of identification and traceability for specified activities, including transfer, when required.
- 8.1.5 Personnel are to be responsible to verify the required identification and to record the traceability on the appropriate documentation, as required.
- 8.1.6 If the required identification or traceability should become lost or illegible, the item is considered nonconforming and shall be controlled in accordance with Section QAPD 15.0, *Nonconforming Materials, Parts, and Components*.
- 8.1.7 Implementing procedures provide the controls and requirements for material determined to have a shelf-life or limited-life.
- 8.1.8 Records of identification and control of materials, parts, or components are to be maintained in accordance with QA Program requirements.

 DAHER-TLI	Section:	Title:	Revision:	Date:
	QAPD 9.0	Control of Special Processes	1	05-12-2016


9.1 SPECIAL PROCESS REQUIREMENTS

- 9.1.1 Implementing procedures describe in detail the controls that have been established to ensure that special processes designated to be safety-related or important-to-safety are performed by TLI and/or its approved suppliers, contractors, or subcontractors, and accomplished in accordance with specified requirements.
- 9.1.2 Special processes include, but are not limited to: welding, heat treating, nondestructive examination, and destructive testing. The special processes are to be controlled and accomplished by qualified personnel using qualified procedures, including appropriate acceptance criteria, as required.
- 9.1.3 Special processes are completed in accordance with the applicable codes, standards, specifications, criteria, or other special requirements defined by project requirements and the QA Program.
- 9.1.4 The use of standardized procedures and qualifying records are acceptable to the referencing codes or standards (i.e. ASME Boiler and Pressure Vessel Code [ASME], or American Welding Society [AWS]; American Society of Nondestructive Testing [ASNT], etc.) when specified in applicable design documents. When special processes are not covered or where specified quality requirements exceed those of the existing codes and standards, the necessary requirements for personnel qualifications, procedures, or equipment are specified or referenced in procedures or instructions.
- 9.1.5 Adherence to the approved procedures and processes in executing special processes is the responsibility of the organization performing the same.
- 9.1.6 Records of all special process activities, procedures and personnel qualifications are to be maintained in accordance with QA Program requirements.

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	QAPD 10.0	Inspection	1	05-12-2016


10.1 INSPECTION REQUIREMENTS

- 10.1.1 Implementing procedures describe in detail the program for the inspection of safety-related or important-to-safety activities that affect quality (performed by TLI; and/or its approved suppliers, contractors, or subcontractors), for the verification of conformance to documented drawings, instructions and procedures used for accomplishing the activity, and for providing for the timely identification, disposition, and recommended corrective action of nonconforming conditions.
- 10.1.2 Inspections are performed by qualified personnel other than those who perform or directly supervise the work being inspected. Inspection personnel shall meet the requirements specified in QA Program requirements.
- 10.1.3 Inspection or surveillance shall be completed, as required, with both inspection and process monitoring being completed when control of the inspection is inadequate without both.
- 10.1.4 Inspections are to be performed in accordance with written procedures and the results are to be documented. This includes modifications, repairs, or replacements to applicable systems or components in accordance with the original design and inspection requirements or acceptable alternatives. Procedures shall provide, as required for identification of acceptance criteria, performance characteristics, attribute recording, reference documents, and other requirements determined to be applicable.
- 10.1.5 Mandatory hold points of inspection activities shall be designated in applicable procedures or shop documentation and documented accordingly. Work beyond a Hold Point shall not proceed without the approval of the organization assigning the Hold Point; or consent to waive the specified hold point shall be recorded.
- 10.1.6 Measuring and test equipment (M&TE) shall be selected to assure calibration status and of proper type, range, and accuracy to accomplish the specified activities.
- 10.1.7 Records of inspections shall be completed, maintained and stored in accordance with QA Program requirements.

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	QAPD 11.0	Test Control	1	05-12-2016


11.1 TEST CONTROL REQUIREMENTS

- 11.1.1 Implementing procedures describe in detail the program for the performance of safety-related or important-to-safety tests (performed by TLI; and/or its approved suppliers, contractors, or subcontractors) required to demonstrate that structures, systems and components will perform satisfactorily in service.
- 11.1.2 Tests are to be performed by qualified personnel other than those who perform or directly supervise the work being tested. Test personnel shall meet the requirements specified in QA Program requirements.
- 11.1.3 Direct or indirect (process monitoring) testing or surveillance methods shall be completed as required; with both test and process monitoring being done when control of the test is inadequate without both.
- 11.1.4 Testing is performed in accordance with written procedures controlled in accordance with QA Program requirements and the results are to be documented. This includes modifications, repairs, or replacements to applicable systems or components in accordance with the original design and inspection requirements or acceptable alternatives. Procedures shall provide, as required for identification of acceptance criteria, performance characteristics, attribute recording, reference documents, and other requirements determined to be applicable. Test procedures shall ensure that all prerequisites for the test have been met, adequate test instrumentation is available and used, and the testing is performed under suitable environmental conditions.
- 11.1.5 Mandatory hold points of test activities shall be designated and documented accordingly. Work beyond a Hold Point shall not proceed without the approval of the organization assigning the Hold Point; or consent to waive the specified hold point shall be recorded.
- 11.1.6 M&TE used for testing purposes shall be selected to assure calibration status and of proper type, range, and accuracy to accomplish the specified activities.
- 11.1.7 Test control for computer programs are in accordance with the established implementing procedures.
- 11.1.8 Records of tests shall be completed, maintained and stored in accordance with QA Program requirements.

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	QAPD 12.0	Control of Measuring and Test Equipment	1	05-12-2016


12.1 CALIBRATION CONTROL REQUIREMENTS

- 12.1.1 Implementing procedures describe in detail the methods that have been established for the identification, control, calibration and selection of Measuring and Test Equipment (M&TE) used in safety-related or important-to-safety activities affecting quality (performed by TLI; and/or its approved suppliers, contractors, or subcontractors).
- 12.1.2 M&TE used for safety-related and important-to-safety applications shall be calibrated periodically and at scheduled intervals, or whenever the accuracy of the M&TE is suspect to assure acceptable accuracy to the stated requirements. Calibration methods and intervals shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions that affect performance.
- 12.1.2.1 Calibration is to be completed using certified master standards having known relationship to nationally recognized standards, where such standards exist. Where none exist, the manufacturer's recommended standard shall be documented and used.
- 12.1.2.2 Calibration of M&TE is to be performed by properly trained personnel, or by qualified suppliers.
- 12.1.2.3 Calibration of M&TE shall be completed in accordance with written instructions or procedures which include the requirements for methods, tolerances and calibration intervals.
- 12.1.2.4 Control of M&TE shall be done using unique equipment serial numbers, records, and calibration status indicators.
- 12.1.3 When M&TE is determined to be out-of-calibration, an evaluation is performed and documented to determine the validity of inspections or tests performed and the acceptability of items inspected or tested since the last acceptable calibration. This is to be controlled in accordance with QA Program requirements.
- 12.1.4 Commercial equipment such as rulers, tape measures, levels, etc. do not require calibration and control measures when normal commercial practices provide the required accuracy; unless other requirements are determined by the Division QA.
- 12.1.5 Records of calibration are to be completed, maintained and stored in accordance with QA Program requirements.

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	QAPD 13.0	Handling, Storage and Shipping Control	1	05-12-2016


13.1 CONTROL REQUIREMENTS

- 13.1.1 Implementing procedures describe in detail the methods established for the control of items in order to prevent damage, deterioration, or loss during all phases of safety-related or important-to-safety activities affecting quality (performed by TLI; and/or its approved suppliers, contractors, or subcontractors). These include provisions for handling, storing, packaging and shipping materials, parts, assemblies, spare parts, special tools, and equipment to prevent damage, loss of identity, or deterioration.
- 13.1.2 Special handling, storage and shipping requirements for a project are to be performed in accordance with written procedures addressing the need for special coverings, special equipment and tools, marking and labeling that is used to adequately maintain and preserve items, or indication of the presence of special environments or the need for special controls, as required.
- 13.1.3 Personnel performing special handling and lifting operations with equipment are to be experienced and trained in the use of said equipment, as required.

	Section:	Title:	Revision:	Date:
	QAPD 14.0	Inspection, Test, and Operating Status	1	05-12-2016

14.1 STATUS REQUIREMENTS

- 14.1.1 Implementing procedures describe in detail the methods providing to determine the inspection, test or operating status of safety-related or important-to-safety inspection and test activities of materials, items, components, structures, and systems during ongoing phases of fabrication, installation, operating and maintenance (performed by TLI; and/or its approved suppliers, contractors, or subcontractors).
- 14.1.2 Procedures identify and provide as applicable: criteria, procedure, equipment, personnel qualifications, acceptance criteria, and control documentation.
- 14.1.3 Procedures provide for means of identification through by the use of suitable means (i.e., cards, labels, tags, checklists, shop documentation, etc.).
- 14.1.4 The status of nonconformances is to be controlled in accordance with QA Program requirements.


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	QAPD 15.0	Nonconforming Materials, Parts, or Components	1	05-12-2016

15.1 NONCONFORMANCE REQUIREMENTS

- 15.1.1 Implementing procedures describe in detail the controls for preventing items and activities that do not conform to specified requirements from inadvertent installation or use. Controls provide for the identification, documentation, evaluation, segregation (when practical), disposition, and proper notification to affected organizations.
- 15.1.2 Nonconformances including those issues identified through: fabrication, inspection, and testing (performed by TLI; and/or its approved suppliers, contractors, or subcontractors); in accordance with approved written procedures, use of qualified processes, or qualified personnel) are to be documented in writing on a Nonconformance Report (NCR). It is presented to appropriate organizations for review, acceptance and disposition.
- 15.1.3 Nonconformances are to be identified and segregated by legible and easily recognizable tagging, marking, or by some other method not adversely affecting the end use of the item.
- 15.1.4 Nonconformances are dispositioned as: Accept (Use) As-Is, Repair, Rework, or Reject/Scrap/ Return to Supplier.
1. Technical justification and independent verification shall be documented to assure compliance with the design, regulatory and contractual requirements for the acceptance of "repair" or "use-as-is" disposition.
 2. Items dispositioned "repair" or "rework" are to be completed, controlled, and verified by re-inspection or re-testing to the original acceptance criteria, as required by documented and approved methods unless an alternate acceptance criteria is established.
- 15.1.5 Dispositions shall not negate regulatory, code, specification, design, or technical requirements.
- 15.1.6 Nonconformances and associated work is to be completed and accepted prior to closure.
- 15.1.7 Nonconformance records are to be maintained in accordance with QA Program requirements.

15.2 10CFR PART 21 – *Reporting of Defects and Noncompliances*


- 15.2.1 The applicable provisions of Federal Regulation 10 CFR Part 21, "*Reporting of Defects and Noncompliances*" shall be controlled in accordance with implementing procedures.

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	QAPD 15.0	Nonconforming Materials, Parts, or Components	1	05-12-2016

15.2.2 When 10CFR21 is designated a part of any contract or order, the requirements shall also be incorporated in procurement documents issued to suppliers, sub-tiers, and subcontractors.


15.2.3 NCRs and Corrective Action Reports (CAR) shall be evaluated for 10CFR21 compliance, as required.

15.2.4 Postings shall include, as a minimum: Federal Regulation 10CFR Part 21, and the Law (from the Energy Reorganization Act of 1974) – Noncompliance Section 206, as described by the implementing procedure.

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	QAPD 16.0	Corrective Action	1	05-12-2016

16.1 CORRECTIVE ACTION REQUIREMENTS

- 16.1.1 Implementing procedures describe in detail the methods established for the prompt identification and correction of conditions adverse to quality and corrected as soon as practical.
- 16.1.2 Significant conditions adverse to quality are to be reported to the appropriate levels of management. The cause of the condition and the corrective actions taken shall be documented.
- 16.1.3 Corrective Actions are to be documented in writing on a Corrective Action Report (CAR). The CAR is presented to the responsible organization for determination of action and response. Corrective actions shall in no way negate regulatory, code, specification, design, or technical requirements.
- 16.1.4 Corrective actions, associated work and objective evidence is to be completed and accepted prior to closure.
- 16.1.5 Periodic evaluations of corrective actions are to be conducted to determine quality trends, and appropriate corrective action measures taken and documented.
- 16.1.6 Corrective action records are to be maintained in accordance with QA Program requirements.

	Section:	Title:	Revision:	Date:
	QAPD 17.0	Quality Assurance Records	1	05-12-2016

17.1 QA RECORD REQUIREMENTS

17.1.1 Implementing procedures describe in detail the requirements for documentary evidence provided for safety-related or important-to-safety items and activities completed that affect quality, and meet the specified quality requirements. QA records shall be identified, generated, authenticated, and maintained and their final disposition specified.

17.1.2 Records are to be specified in the appropriate documents, as required (e.g., design specifications, procurement documents, test and operational procedures are to be legible, accurate and traceable to the associated items and activities and shall be authenticated.

17.1.3 Implementing procedures describe in detail specific requirements for the control of documents and records which are maintained by electronic media, including: generated format, hardware and software requirements, security measures, network back-up, and storage and retention requirements.


17.1.4 QA records are identified and retained as lifetime or non-permanent records by TLI or its customers, as appropriate. Records are identified, indexed, stored, and maintained in accessible locations. Storage of such records shall be done in locations and facilities designed to prevent, damage, deterioration, or loss.

17.1.5 In addition to the requirements in the implementing procedures, any other applicable regulatory requirements must be adhered to.

17.1.6 QA records are maintained for periods specified by the implementing procedures, and furnish evidence for safety-related and important-to-safety structures, systems or components (including design, procurement, manufacturing, and assembly records).


17.1.6.1 QA records for 10CFR Part 71 activities are retained for a period beyond the date of last engagement in the activities under the scope of the QAPD for the following:

1. Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].
2. Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(d)].
3. Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program approval is terminated [10 CFR 71.135].

 DAHER-TLI	Section:	Title:	Revision:	Date:
	QAPD 18.0	Audits	1	05-12-2016

18.1 AUDIT REQUIREMENTS

- 18.1.1 Implementing procedures describe in detail the system established for conducting audits of TLI and supplier safety-related or important-to-safety activities that affect quality. Audits are to verify compliance with all applicable regulations, codes and standards and to determine effectiveness and compliance with the appropriate QA Program.
- 18.1.2 Planned and periodic audits of all aspects of the TLI QA Program and supplier's quality programs shall be conducted in accordance with pre-determined schedules. These are supplemented with additional audits, surveillances, or annual evaluations, when necessary. All applicable elements of the TLI QA Program are audited at least once each year.
- 18.1.3 Personnel conducting audits shall be appropriately trained, shall meet the requirements specified in the QA Program requirements, and shall not have direct responsibility in the area being audited.
- 18.1.4 An audit plan is developed for the establishment of an audit; to identify the personnel, scope, requirements, and applicable documentation.
- 18.1.5 Audits are conducted using written checklists. The audit personnel are to obtain sufficient objective evidence to determine effective implementation and effectiveness. The audit is to include an evaluation of the results of previous QA program audits and results of audits from other sources; and significant changes in personnel, the organization, or the QA program.
- 18.1.6 An audit report is completed and includes identification of the objective evidence established and recorded, and the effectiveness of program implementation. The results of the audits are reported to the appropriate level(s) of management for the area(s) audited.
- 18.1.7 Corrective actions resulting from audits are undertaken by responsible management. Schedules are established, and results are verified for implementation and closure. When necessary, determine the need for performance of appropriate follow-up, including re-audit of deficient areas.

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	QAPD 19.0	QA Program References	1	05-12-2016

19.1 QA PROGRAM REFERENCES


The following referenced documents are integral, in whole or in part, as a basis for the QA Program. The QA Program meets the latest edition/revision of the referenced documents, unless otherwise identified in any of the corresponding documents or as identified below.

- 19.1.1 10CFR Part 21, Code of Federal Regulations, Title 10 – *Reporting of Defects and Noncompliance*
- 19.1.2 10CFR Part 50 Appendix B, Code of Federal Regulations – *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*
- 19.1.3 10CFR Part 71 Subpart H, Code of Federal Regulations – *Packaging and Transportation of Radioactive Material, Quality Assurance*
- 19.1.4 USNRC Regulatory Guide 1.28 – *Quality Assurance Program Requirements (Design and Construction)*

NOTE: As stated in RG 1.28 Rev. 4 Section C Regulatory Position, “The requirements specified in Part I and Part II requirements included in NQA-1-2008 and the NQA-1a-2009 Addenda [20.1.3] for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants are acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to the modifications of NQA-1-2008 and the NQA-1a-2009 Addenda identified below.”

Therefore, references made to ASME NQA-1 requirements in QA Program documents shall collectively include the requirements of 10 CFR Part 50 Appendix B.


- 19.1.5 USNRC Regulatory Guide 7.10 – *Establishing Quality Assurance Programs for Packaging Used In The Transport of Radioactive Material*
- 19.1.6 NUREG/CR-6407, *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*
- 19.1.7 ASME NQA-1– *Quality Assurance Requirements for Nuclear Facilities*
- 19.1.8 ANSI N45.2 – *Quality Assurance Program Requirements for Nuclear Facilities* (and associated daughter standards as applied to this QA Program)
- 19.1.9 IAEA Safety Requirements No. TS-R-1, *Regulations for the Safe Transport of Radioactive Material*
- 19.1.10 IAEA Safety Guide No. TS-G-1.1 (ST-2), Appendix IV - *Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Materials, Quality Assurance in the Safe Transport of Radioactive Material*

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	QAPD 20.0	QA Implementing Procedure References	1	05-12-2016

20.0 QA IMPLEMENTING PROCEDURE REFERENCES

Reference to the Implementing Procedures in this section of the QA Program is for information purposes only to demonstrate implementation of the documented QAPD. Control of the implementing procedures is identified in DAHER-TLI Procedure No. QP-0.0.01, *Quality Assurance Program and Quality Procedures*. This procedure provides for the control, implementation, and revision of the referenced documents without change to the QAPD and requiring USNRC involvement.

PROCEDURE	DESCRIPTION	SECTION
QP-0.0.01	<i>Quality Assurance Program and Quality Procedures</i>	--
QP-0.0.02	<i>Terms and Definitions</i>	--
QP-1.0.01	<i>Organization and Responsibility</i>	1.0
QP-2.0.01	<i>Control of the Quality Assurance Program</i>	2.0
QP-2.0.02	<i>Quality Related Indoctrination and Training of Personnel</i>	2.0
QP-2.0.03	<i>Qualification of Audit Personnel</i>	2.0
QP-2.0.04	<i>Qualification of Inspection & Test (I&T) Personnel</i>	2.0
QP-2.0.05	<i>Qualification of Nondestructive Examination (NDE) Personnel</i>	2.0
QP-2.0.06	<i>Qualification of Engineering Personnel</i>	2.0
QP-3.0.01	<i>Design Control</i>	3.0
QP-3.0.03	<i>Computer Software Control</i>	3.0
QP-3.0.06	<i>Project Planning</i>	3.0
QP-3.0.07	<i>Identification of Quality Categories</i>	3.0
QP-4.0.01	<i>Procurement Document Control</i>	4.0
QP-6.0.01	<i>Document Control</i>	6.0
QP-7.0.01	<i>Control of Purchased Materials, Equipment, and Services</i>	7.0
QP-7.0.03	<i>Surveillance of Activities Affecting Quality</i>	7.0
QP-7.0.04	<i>Receiving Inspection</i>	7.0
QP-7.5.05	<i>Dedication of Commercial Grade Items and Services</i>	7.0
QP-8.0.01	<i>Identification and Control of Materials, Parts and Components</i>	8.0
QP-9.0.01	<i>Control of Special Processes</i>	9.0
QP-10.0.01	<i>Inspection</i>	10.0
QP-11.0.01	<i>Test Control</i>	11.0
QP-12.0.01	<i>Control of Measuring and Test Equipment</i>	12.0
QP-13.0.01	<i>Handling, Storage and Shipping Control</i>	13.0
QP-14.0.01	<i>Inspection, Test, and Operating Status</i>	14.0
QP-15.0.01	<i>Nonconforming Material, Parts, and Components</i>	15.0

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PROCEDURE	DESCRIPTION	SECTION
QP-15.0.02	<i>Reporting of Defects and Noncompliances in Accordance With 10CFR21</i>	15.0
QP-16.0.01	<i>Corrective Action</i>	16.0
QP-17.0.01	<i>Quality Assurance Records</i>	17.0
QP-18.0.01	<i>Audits</i>	18.0
QP-19.0.01	<i>Order Entry</i>	--