

800-219-9095

Fax: 800-219-9096 Website: www.labtesting.com E-mail: sales@labtesting.com

2331 Topaz Drive, Hatfield, PA 19440

# **QUALITY SYSTEM PROGRAM MANUAL**

Original Rev. Issued May 13, 1985

Revision 21, Issued May 1, 2019

This manual is the property of Laboratory Testing, Inc. and incorporates policies and procedures developed by the company.



# Section i

# POLICY AND AUTHORITY STATEMENT

It is the policy of Laboratory Testing, Incorporated (LTI)\*, as a Material Organization, to furnish and perform testing services in nondestructive, mechanical, chemical, metallographic and metrology fields, including the production of test specimens and machining services, in accordance with all applicable requirements and regulations and to serve our customers' needs and expectations with professionalism, competence and the highest degree of ethical standards. LTI's Quality Policy is also defined in the latest revision of LTI Procedure \*LTI-QPOLICY.

\*Also doing business as LTI Metrology.

To accomplish this objective, Laboratory Testing, Incorporated has developed and implemented this Quality System Program Manual that contains the quality management system organizational structures and practices required by the documents as indicated in Section 3.

This Quality System Program Manual shall include instructions for preparation and review of written procedures, training and monitoring of all activities concerned with the control of operations and materials, conducting of examinations and tests, calibration services, calibration of measurement and test equipment, periodic audit of the overall Quality System Program, corrective action, retention of essential records, the protection of customer confidential information and proprietary rights, preparation of test and examination reports and the purchasing of materials and services to be able to perform all the above activities.

This manual shall apply to all work performed in the laboratory's permanent facilities, at sites away from its permanent facilities or in associated temporary or mobile facilities.

Laboratory Testing Incorporated is a corporation registered in the State of Georgia and is located at 2331 Topaz Drive – Hatfield, Pennsylvania 19440. LTI Metrology is located in an adjacent building. A satellite facility is located in the same industrial park, ~1/3-mile distant, at 2246 North Penn Road – Hatfield, Pennsylvania 19440.

The authority and organizational freedom are hereby granted to the Director of Quality & Improvement to implement and maintain the quality management systems, including the resources needed to implement and maintain the Quality System Program and the responsibilities described in Section 4.6 of this manual. The signatures below acknowledge the granting of this authority and the acceptance of this responsibility.

*Jonathan Faia* Director of Quality & Improvement Laboratory Testing, Inc.

Michael J Mc Vaugh

Michael J. McVaugh President Laboratory Testing, Inc.



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QUALITY SYSTEM PROGRAM MANUAL Revision 21 Dated 5/1/19

# **SECTION 1**

### **REVISION 21 AMENDMENT RECORD**

| SECTION    | DATE       | DESCRIPTION   | APPROVAL              |
|------------|------------|---|-----------------------|
| Manual     | 12-03-2018 | Changed Manual Revision to "21"   | E. Deeny              |
| Section 1  | 12-03-2018 | Replaced table with "Amendment Record"  | E. Deeny              |
| Section 2  | 12-03-2018 | Updated Organization Chart  | J. Faia               |
| Section 3  | 12-03-2018 | Updated Specifications List and insertion of A2LA scopes hyperlink  | E. Deeny              |
| Section 4  | 12-03-2018 | Revised section to incorporate new ISO 17025-17 requirements  | E. Deeny /<br>J. Faia |
| Section 5  | 12-03-2018 | Revised section to incorporate new ISO 17025-17 requirements  | E. Deeny              |
| Section 6  | 12-03-2018 | Revised section to incorporate new ISO 17025-17<br>requirements and align with updated ERP and other<br>applications / processes  | J. Faia               |
| Section 7  | 12-03-2018 | Deleted paragraph 7.1.3   | E. Deeny              |
| Section 8  | 05-01-19   | Added customer PO identification and marking requirements to paragraph 8.2.1.1  | J. Faia               |
| Section 10 | 12-27-2018 | Added "rental equipment" reference  | E. Deeny              |
| Section 11 | 12-03-2018 | Added item "k" to 85-CP-1 requirements list   | E. Deeny              |
| Section 12 | 12-03-2018 | Added new test verification paragraph 12.10.2   | E. Deeny              |
| Section 15 | 12-03-2018 | Revised section to incorporate new ISO 17025-17<br>requirements, align with updated ERP and other<br>applications / processes, and added clarification on<br>interpretations paragraph 15.2.7 | J. Faia               |
| Section 17 | 12-27-2018 | Added ILAC-MRA acceptance alternative for calibration and testing services paragraph 17.3.3   | E. Deeny              |
| Section 18 | 01-03-2019 | Section title revised to: "Control of Purchased Items<br>and Services" and revised section to incorporate new<br>ISO 17025-17 requirements  | E. Deeny /<br>J. Faia |
| Section 19 | 01-30-2019 | Added "Significant Conditions" and "Risk and<br>Opportunities" and revised section to incorporate new<br>ISO 17025-17 requirements  | J. Faia               |

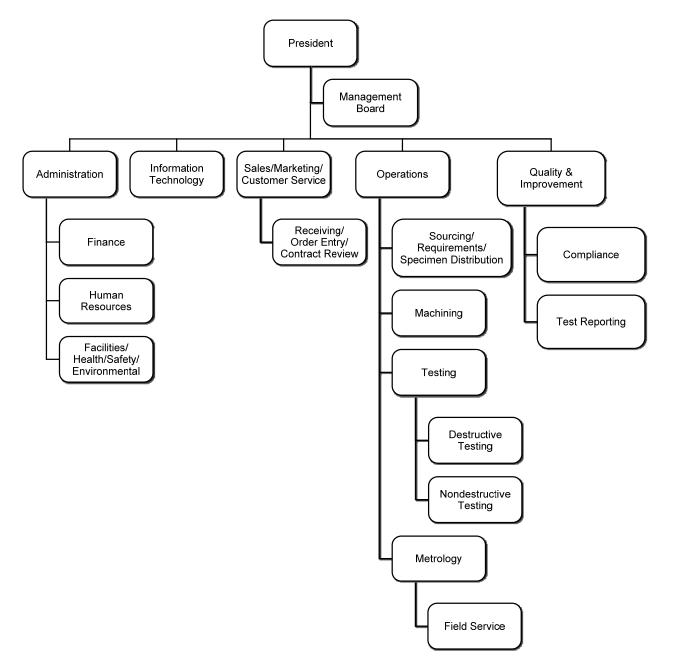
NOTES:

- All significant changes from the previous revision are notated in bold and italics.
- Director of Quality job title changed to Director of Quality & Improvement.



# **SECTION 2**

# LTI ORGANIZATIONAL STRUCTURE



Modifications may be made to the organizational structure *without resulting in a revision of the above chart or this QSPM*. However, the Director of Quality & Improvement and the Quality Department shall always report to the President so that the required authority, impartiality and organizational freedom are maintained. *Additionally, name-specific departmental organizational charts are actively maintained by Human Resource Management in LTI's administrative application and database and may be viewed upon request.* 



# **SECTION 3**

# QUALITY SYSTEMS PROGRAM

# 3.1 <u>SCOPE:</u>

- 3.1.1 This section provides for the description of the documentation systems used at Laboratory Testing, Inc. (LTI), including instructions on how this quality manual will be controlled.
- 3.1.2 This Quality System Program Manual contains a description of the system and is further supplemented by procedures that detail the operational controls of specific processes and examinations.
- 3.1.3 This manual and any associated procedures shall apply to all testing, dimensional inspections, examinations, calibration, specimen preparation and machining services performed by LTI and the purchasing of materials and equipment to be able to perform the above to the requirements of the Codes, Standards, Specifications or Regulations referenced in Paragraph 3.1.4 In addition, applicable sections of this manual shall apply to testing, examinations, calibration, specimen preparation and machining services performed to the requirements of the Codes, Standards, Specifications or Regulations referenced in Paragraph 3.1.4 which are subcontracted by LTI. As a service organization, design and development are excluded from the scope of this program.
- 3.1.4 This manual and associated documents are written to meet or exceed the applicable requirements of our customers and the standards / specifications listed below. The latest-endorsed / approved edition, addenda or revision shall be maintained.
  - ASME Boiler and Pressure Vessel Code, Section III, Division I, Subsection NCA, (NCA-3800 / 4200)
  - ASME NQA-1
  - 10CFR50, Appendix B
  - 10CFR21
  - ISO/IEC 17025
  - ANSI/NCSL Z540-1
  - MIL-STD-45662A
  - MIL-I-45208A
  - ISO 10012-1
  - AS 9100
  - ISO 9001

\* See Section 20 for Procedure Number and Title



- AC7101/1/2/3/4/5/6/7/9 & AC7110/13
- AC7004
- AC7114 /1/2/3
- IATF 16949
- ISO 13485
- 3.1.5 This Quality System Program Manual and revisions will be issued to the American Association for Laboratory Accreditation (A2LA) and Performance Review Institute (PRI) and other accredited bodies and maintained on LTI's website. The Quality System Program Manual may also be issued to other authorized stakeholders upon request.
- 3.1.6 This manual and associated procedures shall be controlled in accordance with LTI Procedure \*LTI-MAN-CTRL.
- 3.1.7 This manual and associated procedures shall be reviewed and revised by the Director of Quality & *Improvement* for conformance to the latest **endorsed / approved editions** of the Codes, Standards, Specifications and Regulations referenced above.
- 3.1.8 The Director of Quality & Improvement is responsible for obtaining the approval of the President of LTI for this Quality System Program Manual.
- 3.1.9 The range of laboratory activities which conform with ISO/IEC 17025 (current revision) are listed and defined on LTI's current A2LA Scopes of Accreditation certificates, maintained on file by the Quality Assurance Department. The accreditations can be found at A2LA's website:

| For Calibration | Calibration Scope      |
|-----------------|------------------------|
| For Chemistry   | <u>Chemistry Scope</u> |

For Mechanical Testing Mechanical Scope

# 3.2 DOCUMENTATION TIERS:

- 3.2.1 Quality System Program Manual
- 3.2.2 Quality Procedures
- 3.2.3 Department Procedures, Technique Sheets and Work Instructions



# **SECTION 4**

# PERSONNEL: RESPONSIBILITIES, QUALIFICATION, CERTIFICATION

- **4.1** It shall be the responsibility of the Director of Quality & Improvement to assure that all personnel performing functions within the scope of this manual are qualified and / or certified as required. This shall include nondestructive testing, mechanical testing, chemical analysis, dimensional inspection, calibration and specimen preparation personnel.
- **4.2** <u>**RESPONSIBILITIES ALL PERSONNEL**</u>: Shall have the responsibility and authority as stated in their Job Descriptions. In addition, all LTI personnel shall be responsible for:
  - i. Achieving and maintaining quality for the work performed.
  - ii. Maintenance of material traceability.
  - iii. Notifying Quality Assurance of the following:
    - a) Suspected loss of traceability
    - b) Equipment Malfunction
    - c) Procedural Discrepancies
    - d) Contaminated Materials
    - e) Suspected Fraud, Falsification or Malpractice.
  - 4.2.1 Maintaining proper qualifications for the work assigned.
  - 4.2.2 Having proper procedures on hand for the activity being performed.
  - 4.2.3 Documentation of completion of work in hardcopy and / or electronic format.
  - 4.2.4 Compliance with applicable requirements of this Quality Systems Program Manual and related procedures.
  - 4.2.5 All personnel shall be *impartial* and be free from any commercial, financial or other pressures which might adversely affect the quality of their work or technical judgment. Testing, calibration and QA personnel shall have the authority, independence and organizational freedom to identify quality problems *or risks*, recommend solutions and control further processing of nonconformances until proper disposition has occurred.
  - 4.2.6 All personnel shall comply with the \*LTI Employee Handbook and agreements including avoiding involvement in any activities that would diminish confidence in its competence, impartiality, independence in judgment or operational integrity.
  - 4.2.7 All personnel are responsible for verifying that measuring and test equipment have a current calibration date before using that instrument.

- 4.2.8 Proper handling of materials in-plant to preclude damage or contact with detrimental materials.
- 4.2.9 All personnel shall comply with non-disclosure and confidentiality policies, procedures (\*LTI-C&P RIGHTS) and agreements regarding company, customer or vendor confidential information.

# 4.3 RESPONSIBILITIES - EXECUTIVE LEADERSHIP TEAM ("ELT"):

- 4.3.1 The ELT shall consist of the President and Directors. The President may select Managers and other key personnel to serve on the ELT.
- 4.3.2 The ELT shall be responsible for providing guidance to the President on establishing quality and other policies, setting goals and objectives, reviewing performance indicators, *reviewing risks and resource needs* and taking appropriate action and undertake projects in order to achieve compliance and continuing improvement in the management system.
- *4.3.3* Meetings are scheduled on a regular basis. An agenda and minutes may be prepared for meetings as applicable.
- 4.3.4 The ELT shall be responsible for communicating the quality and company objectives and the importance of meeting customer, statutory and regulatory requirements by means of department meetings, employee meetings, newsletters and the posting or distribution of key performance indicators.

# 4.4 **RESPONSIBILITIES - OUTSIDE BOARD OF ADVISORS:**

4.4.1 The Board of Advisors shall consist of business leaders who have been selected by the President and ownership of the corporation. The Board of Advisors shall provide guidance to the President and ownership on the operation of the business. The function of the board is strictly advisory without any responsibility or authority for the operation of Laboratory Testing, Inc.

# 4.5 **RESPONSIBILITIES - PRESIDENT:**

- 4.5.1 Assuring that the Director of Quality & Improvement has the authority and organizational freedom to meet the responsibilities listed in Section i and 4.6 of this manual.
- 4.5.2 Review the status and adequacy / effectiveness of the Quality Program through the Management Review process included in this manual.
- 4.5.3 Performance of a management review of the Quality System Program once each year.
- 4.5.4 Assuring that facilities, equipment and personnel are adequate to perform the required work.



- 4.5.5 May perform final review and sign certifications in the absence of the Director of Quality & Improvement and other authorized signers in accordance with Section 15 of this manual.
- 4.5.6 Reporting of defects and non-compliances in accordance with the requirements of 10CFR21.

# 4.6 <u>RESPONSIBILITIES – QUALITY ASSURANCE; REPORTS TO THE PRESIDENT:</u>

- 4.6.1 The Director of Quality & Improvement shall be responsible for the following:
  - 4.6.1.1 Is appointed the Management Representative.
  - 4.6.1.2 Revision and control of this Quality System Program Manual.
  - 4.6.1.3 Performance of Internal Audits.
  - 4.6.1.4 Reporting regularly to management on the status and adequacy of the program.
  - 4.6.1.5 Oversees preparation of all certifications including review of request for changes to certifications.
  - 4.6.1.6 Delegates others to perform these responsibilities, provided they are independent of the activity or process but retains the overall responsibility for ensuring compliance with the requirements of the QA Program.
  - 4.6.1.6 Reports to the President on all 10CFR21 defects and non-compliances.

#### 4.6.1.7 Ultimately responsible for the storage of Quality Assurance records.

- 4.6.2 The Director of Quality & Improvement and the Quality Assurance Manager shall be responsible for the following:
  - 4.6.2.1 Reviewing of customer purchase orders and contracts for defined requirements, capability to meet requirements and the availability of appropriate methods. This responsibility may be performed by Order Entry personnel, Managers / Supervisors, Customer Service Representatives, Technical Specialists, Coordinators, QA Personnel and the President.
  - 4.6.2.2 Review / approval and control of all quality, calibration and test procedures.
  - 4.6.2.3 Control of non-conforming materials, equipment and services.
  - 4.6.2.4 Performance of vendor audits and preparation and control of the Approved Vendors List.
  - 4.6.2.5 Control and documentation of calibration system.



- 4.6.2.6 Preparation and control of corrective action requests.
- 4.6.2.7 Assuring that the policies in this manual are strictly followed for all work performed under the scope of this manual. Promote the awareness of customer and regulatory requirements throughout the organization.
- 4.6.2.8 Identify quality system problems.
- 4.6.2.9 Initiate actions which result in solutions.
- 4.6.2.10 Verify implementation and adequacy of corrective actions.
- 4.6.2.11 Control further processing and shipment of non-conforming items, deficiencies or unsatisfactory conditions, until a proper disposition has been obtained.
- 4.6.2.12 Monitoring the overall effectiveness of the program by the performance of surveillance / audits, etc.
- 4.6.2.13 May perform final review and sign certifications in accordance with Section 15 of this manual.
- 4.6.2.14 Control of personnel indoctrination, training and certification records.
- 4.6.2.15 Review and initial or sign all purchase orders for items and services that directly affect examination, testing and calibrations.
- 4.6.2.16 Be sufficiently independent from the pressures of production.
- 4.6.2.17 Have direct access to responsible management at a level where appropriate action can be initiated.

#### 4.6.2.18 Any identified need or area for improvement.

- 4.6.3 Quality Assurance department personnel shall assist the Director of Quality & Improvement and Quality Assurance Manager in the performance of these functions.
- 4.6.4 When procedures and other LTI documents refer to the Quality Manager, the requirement, responsibility and authority shall apply to the Director of Quality & Improvement as well as the Quality Manager.

#### 4.7 **RESPONSIBILITIES – DIRECTORS, MANAGERS AND SUPERVISORS:**

- 4.7.1 Shall provide adequate supervision of testing and calibration staff, including trainees and be familiar with methods a procedure, purpose of each test and / or calibration, and with the assessment of the test or calibration results.
- 4.7.2 Shall have the overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.



# 4.8 **RESPONSIBILITIES – COORDINATORS:**

4.8.1 Shall obtain and schedule work, communicate requirements and process work.

# 4.9 <u>RESPONSIBILITIES – QUALITY REPRESENTATIVE – SATELLITE FACILITY: REPORTS</u> TO DIRECTOR OF QUALITY & IMPROVEMENT:

4.9.1 The Responsible Level III shall have the responsibility and authority for nondestructive testing at both the satellite and the main facility and reports to the Director of Quality & Improvement.

#### 4.10 PERSONNEL TRAINING AND COMPETENCE:

- 4.10.1 All employees working at Laboratory Testing Inc., whose jobs affect the validity of laboratory activities shall be competent. This means that the education, experience and training requirements for the job are defined, and the employee meets those requirements.
- 4.10.2 Procedures are established and maintained for identifying *qualifications, technical knowledge and competency requirements* and provide for the training of all personnel performing activities affecting quality. \*PQ-NDT-1, PQ-MAS-1, PQ-AUD-1, PQ-2132-AQP, PQ-2132-1, LTI-VT-TO, LTI-UT-TO, LTI-RT-TO, LTI-QUAL-NQA-1, LTI-MP-TO and LTI-LP-TO.
- **4.10.3** The Director of Quality & Improvement shall ensure employees whose function affects quality receive the training / indoctrination they need for their position.
- **4.10.4** Personnel performing and managing specific assigned tasks are qualified based on appropriate education, training and / or experience.
- **4.10.5** When contracted, and if additional technical and key support personnel are used, LTI shall ensure that such personnel are competent and that they work in accordance with LTI's Quality System.

#### 4.11 KEY PERSONNEL:

4.11.1 Nadcap and / or A2LA shall be notified of any changes to key personnel. Key personnel are defined as the only person employed by LTI that possess the knowledge or techniques that are essential to the performance of the specific test or calibration.

#### 4.12 CHANGES TO RESPONSIBILITIES AND AUTHORITY:

4.12.1 The President, upon written notification to the Directory of Quality & Improvement, may revise or append responsibilities and authority stated in this manual.



# **SECTION 5**

# **INTERNAL AUDIT**

# 5.1 <u>SCOPE:</u>

5.1.1 This section provides instructions for the periodic evaluation and audit of the LTI Quality Management system to assure its adequacy and implementation. *The internal audit process also supports corrective action, risk management and continual improvement.* 

# 5.2 PROCEDURE:

- 5.2.1 Personnel (internal or external) conducting internal audits shall be appointed by the President and have no direct line of responsibility for the area or activity being audited.
- 5.2.2 Internal auditors shall be qualified in accordance with LTI procedure **\*PQ-AUD-1**.
- 5.2.3 Audits of testing departments, calibration and specimen preparation, including the quality system, shall be performed at least once each year to a defined documented schedule in accordance with LTI Procedure \*LTI-INT-1.

#### 5.3 MANAGEMENT REVIEW:

5.3.1 The President is responsible for performance of an annual review of the Quality Management System to determine its adequacy, effectiveness and implementation. This review shall take into consideration the *risks and opportunities associated with the lab activities in order to:* 

- a. give assurance that the management system achieves its intended results;
- b. enhance opportunities to achieve the purpose and objectives of the lab;
- c. prevent or reduce undesired impacts and potential failures in lab activities;
- d. achieve improvement.
- 5.3.2 At a minimum, the following *are inputs to Management Review*:
  - a. changes, including internal and external issues relevant to LTI;
  - b. fulfillment of or performance to objectives (process performance and conformance);
  - c. suitability of policies and procedures;
  - d. follow-up actions from previous management reviews;
  - e. the results of recent internal audits;
  - f. corrective actions;
  - g. assessments by external bodies;
  - h. changes in the volume and type of work or in the range of laboratory activities;
  - i. customer and personnel feedback;
  - j. complaints;
  - k. effectiveness of implemented improvements;
  - l. adequacy of resources;
  - m. results of risk identification (preventive actions);
  - n. **outcomes of the assurance of validity of results (**results of inter-laboratory comparisons or proficiency tests);
  - o. other relevant factors, such as monitoring activities and training.



- **5.3.2** The results and outputs from the management review and any decisions and actions that arise from it shall be recorded and should include goals, objectives and plans for the coming year. Management shall ensure that those actions are carried out within an appropriate and agreed timetable. The actions shall be related to *the effectiveness and improvements* of the quality management system and its processes, improvement of testing, machining and calibrations related to customer requirements, resources needed, *and any need for change*.
- 5.3.3 The Management Review Report shall be distributed to the ELT.



# **SECTION 6**

# **ORDER ENTRY / CONTRACT REVIEW**

#### 6.1 <u>SCOPE:</u>

**6.1.1** This section shall detail the requirements for order entry and contract review of orders for materials and services within the scope of this manual.

# 6.2 PROCEDURE:

# 6.2.1 The customer's purchase order shall be received and processed in accordance with LTI Procedure \*RI-1 and \*CR-OE-1.

- 6.2.2 Order Entry personnel and other authorized personnel (see paragraph 6.2.2.1) review orders to ensure that:
  - a. orders include appropriate technical requirements and / or methods and are documented and understood;
  - b. requirements are within the scope of LTI's technical capabilities, accreditations, approvals and resources, and
  - c. the appropriate test and / or calibration methods are selected and are capable of meeting customer's requirements.

The review shall also cover any work that is to be subcontracted by LTI.

- 6.2.2.1 QA personnel, Testing and Calibration Managers and Supervisors, Customer Service personnel, Calibration Coordinator, Technical Specialists and NDT Level III's may also perform this review as needed to ensure compliance.
- 6.2.3 When Order Entry personnel are unable to determine the appropriate test / process or if the customer's test method is inappropriate, the order will be forwarded to the responsible *Customer Service Representative* for disposition. The *Customer Service Representative* will select the appropriate method, procedure or process. The appropriate Laboratory Manager, Supervisor or *Customer Service Representative* shall also assure that LTI has the capability and resources to comply with the requirements of the order. When required, the Customer Service Department or responsible department manager / supervisor shall notify the customer to obtain a documented resolution of any questionable items.
- 6.2.4 Order entry personnel will enter applicable information into *the appropriate customer / work / job order fields in the LTI ERP system*.



# 6.3 CHANGES TO ORDERS:

- 6.3.1 Changes to orders shall be reviewed by the same personnel authorized to perform contract reviews. The appropriate Lab Manager or Supervisor shall be notified of any changes to orders affecting processing. The *Customer Service Representative and/or Order Entry Representative* is responsible for *updating the appropriate Customer / Work / Job Order fields in the LTI ERP system to reflect the change.*
- 6.3.2 This review shall be documented. Changes for pricing or delivery do not require documentation of the review.

#### 6.4 STATEMENT OF CONFORMITY:

- 6.4.1 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined.
- 6.4.2 Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with the customer. Agreement may be conveyed when a customer does not disagree with or provide documented alternatives to LTI's provided Standard Terms & Conditions, quotations, order acknowledgements, and/or other order-related documents referencing LTI's Statements of Conformity.



# **SECTION 7**

# DOCUMENT CONTROL

# 7.1 <u>SCOPE:</u>

- 7.1.1 This section provides instructions for the review, issuance and maintenance of customer, commercial, military and internal procedures, specifications, standards and drawings covering systems, traceability, testing, calibration, machining and examination.
- 7.1.2 Procedures, standards, specifications and drawings are defined as documents per this manual.

# 7.2 **DISTRIBUTION:**

- 7.2.1 All standard internal procedures are available in t**he Document Management System** to personnel using the procedure. Original hardcopies are maintained in the Quality Assurance Department.
- 7.2.2 Effected personnel will be notified of new and revised procedures by the Quality Assurance Department.
- 7.2.3 It is the responsibility of the Quality Assurance Department to assure that invalid or obsolete procedures are removed from the main *Document Management System* file and put into the superseded file.

#### 7.3 <u>REVIEW, APPROVAL AND REVISION:</u>

7.3.1 All internal procedures and revisions thereto shall be prepared, reviewed and approved as described in **\*LTI-PROCEDURE** as applicable. Additionally, these procedures are subject to periodic review and / or revision as described in **\*LTI-DOC**.

# 7.4 PUBLISHED INDUSTRY AND CUSTOMER DOCUMENTS:

- 7.4.1 Published documents (either hardcopy or in electronic format) such as ASME, ASTM and SAE shall be purchased as required. LTI shall keep up to date with new endorsed/approved releases, revisions or addenda of required standards / specifications.
- 7.4.2 LTI may maintain relationship(s) with update service(s) to ensure notification and access to the latest documents needed.
- 7.4.3 All published, and customer documents shall be maintained in various libraries (hardcopies or electronic) throughout LTI on an as needed basis.
- 7.4.4 LTI shall also maintain customer specifications where applicable.



# **SECTION 8**

# **IDENTIFICATION AND TRACEABILITY**

# 8.1 <u>SCOPE:</u>

8.1.1 This section shall outline the requirements for marking or identification of material and to maintain traceability from the time LTI receives the material, through completion of processes or examinations and ships the material back to the customer or scraps the material at LTI.

#### 8.2 **PROCEDURE**:

- 8.2.1 Equipment or material markings or identification are verified against customer purchase orders / packing lists upon receipt by the receiving department in accordance with LTI Procedure \***RI-1**. Discrepancies or unidentified equipment or material shall be reported to the Customer Service or Quality Assurance Department.
  - 8.2.1.1 Equipment and material shall be tagged, marked or otherwise identified with LTI Lab Report Number. *Required identification or markings listed on Customers' Purchase Orders* are included on the LTI work order *and/or LTI certifications*.
  - 8.2.1.2 Markings on material shall not be removed unless required by the test or examination procedure. If markings are removed, the material shall be placed in an envelope or container bearing the identification or be accompanied by a document which includes the identification. Marking shall be reapplied when required using either the customer's number or LTI Lab Report / Order Number as appropriate.
- 8.2.2 Additional procedures exist for orders having unique requirements.
- 8.2.3 Equipment provided for calibration as well as materials submitted for examination and test that are suspected of having lost traceability in the LTI facility, shall be reported immediately to Quality Assurance and segregated in a holding area designated by Quality Assurance.



# **SECTION 9**

# ACCOMMODATION AND ENVIRONMENT

#### 9.1 <u>SCOPE:</u>

9.1.1 This section details the general requirements for accommodation and environment for the Laboratory.

#### 9.2 **GENERAL REQUIREMENTS**:

- 9.2.1 Each area of test shall have appropriate energy sources, lighting, heating, ventilation and environmental conditions to facilitate correct performance of tests and calibrations.
  - 9.2.1.1 Areas that require documentation of specific lighting, heating and ventilation shall have the specific requirements described in working procedures for applicable area.
- 9.2.2 The environment in which all testing is performed shall be undertaken so as not to invalidate the results or adversely affect the required accuracy of measurement or test.
  - 9.2.2.1 Areas that require specific environmental controls shall have those specific controls addressed in working procedures for specific applicable areas. (\*85-CP-1)
- 9.2.3 Areas that require specific environmental controls shall maintain records for those controls.
- 9.2.4 Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and / or calibrations. (\*85-CP-1)
- 9.2.5 All areas that are incompatible shall have effective separation so as not to adversely affect the required accuracy of measurement or test.
- 9.2.6 It is the responsibility of all employees to maintain acceptable housekeeping within their respective areas.
  - 9.2.6.1 Acceptable housekeeping shall be defined as floors and equipment clean of litter, trash, grease, oil, dust and anything else that will prohibit personnel from performing their respective jobs.
- 9.2.7 Access to and use of areas affecting the quality of the tests and / or calibrations is limited to authorized personnel.
- 9.2.8 Particular care shall be taken when tests and / or calibrations are undertaken at sites other than the permanent laboratory facility to ensure that environmental conditions do not adversely affect the required accuracy of the measurement and / or test or invalidate the results. (\*CP-17025-FIELD)



# **SECTION 10**

# EQUIPMENT AND REFERENCE MATERIALS / STANDARDS

#### 10.1 <u>SCOPE:</u>

10.1.1 This section describes the control of equipment and reference standards required for the correct performance of tests and calibrations including preparation of test and calibration items.

# 10.2 CONTROL OF EQUIPMENT:

- 10.2.1 Equipment and its software used for testing and calibration will be capable of achieving the accuracy required and shall comply with specifications relevant to the tests in accordance with LTI Procedure \*CP-MU-1. Software shall be controlled in accordance with LTI procedure \*LTI-SWQA-1. Measuring and test equipment shall be entered into the instrument database and assigned a unique instrument number. Prior to being placed in service and/or used, equipment shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications.
- 10.2.2 Equipment shall be operated by authorized personnel. Personnel are authorized to operate equipment listed in the procedures for which they have been indoctrinated / trained. Up-to-date instructions or procedures on the use and maintenance of equipment shall be available to appropriate personnel or shall be obtained from the OEM when required. Generally preventative maintenance shall be performed at the time of calibration as indicated in LTI procedure \*85-CP-1, ADDENDA A. Maintenance is also performed on an as required basis.
- 10.2.3 Records are maintained for each item of measuring and test equipment.
- 10.2.4 The following are entered into the instrument database:
  - a. Instrument number
  - b. Description
  - c. Manufacturer, model no. and / or serial no. (where assigned)
  - d. Department where used and work center (if applicable)
  - e. Date in service (indicates initial compliance with specifications)
  - f. Maintenance, modifications & repairs are listed in the "Notes" section of the Instrument database
  - g. Calibration date and due date



10.2.5 All equipment shall be handled, stored and transported in such a manner as to prevent damage and to ensure proper function. Equipment shall be kept clean and free from dirt, oil, rust and other containments that may adversely affect the item or its function. Personnel shall report to their supervisor or manager any damage or malfunction and/or requirements for maintenance of equipment. Equipment that has been subjected to overloading or mishandling, gives suspect results, is defective or outside specified limits shall be removed from service, isolated and labeled or marked to indicate that it should not be used.

An evaluation shall be made to determine the effect on previous tests and calibrations and where determined necessary a nonconformance report shall be generated in accordance with LTI Procedure \*LTI-NONCONFORMANCE. Where appropriate the customer will be notified.

- 10.2.6 Equipment used outside the laboratory's facility shall be controlled in accordance with LTI Procedure **\*CP-17025-FIELD**.
- 10.2.7 Whenever equipment is sent outside the laboratory (ex: calibration, repair, etc.) or when equipment is rented, it shall be examined for function and calibration status and determined to be satisfactory\* prior to being returned to or used for service.
- \*Note: Satisfactory being defined as meeting the equipment requirements of ISO/IEC 17025.

# 10.3 **REFERENCE STANDARDS**:

10.3.1 LTI has procedures for the calibration of its reference standards. Reference standards are calibrated by an organization that can provide traceability to national or international standards in the International System of Units (SI). These reference standards are held by LTI and are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

# 10.4 INTERMEDIATE CHECKS:

10.4.1 Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards shall be carried out in accordance with LTI Procedure **\*LTI-AQMR.** 



# **SECTION 11**

# EQUIPMENT, TOOL AND INSTRUMENT CONTROL

#### 11.1 <u>SCOPE:</u>

11.1.1 This section covers the calibration of all equipment, tools and instruments used for testing, inspection, examination and calibration, as well as measurement standards used for calibration.

# 11.2 **REQUIREMENTS**:

- 11.2.1 A procedure (**\*85-CP-1**) is maintained in accordance with ISO / IEC 17025, MIL-STD-45662, ANSI 45.2, NQA-1, ISO-10012-1 and ANSI / NCSL Z540-1, latest revisions, that include the following requirements:
  - a) Unique serialization of all equipment, tools and instruments;
  - b) Controls to assure positive identification and disposition of out-of-service equipment, tools and instruments;
  - c) Adequacy of instruments and standards for calibration;
  - d) Estimates of the uncertainty of measurement where appropriate;
  - e) Consideration of environmental controls;
  - f) Calibration of environmental controls;
  - g) Maintenance of calibration records that are traceable to measuring and test equipment via the serial number or unique identification number and the data included on the calibration record;
  - h) Traceability to national or international standards or fundamental physical constants, where such standards exist;
  - i) Control of material tested with equipment, tools or instruments discovered to be out of calibration;
  - j) The labeling of equipment, tools or instruments to show calibration date, unique number, calibration technician and recalibration date.
  - *k)* When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements, if not inherently addressed in the calibration.

11.2.2 LTI will maintain an internal calibration recall system.

# 11.3 <u>COMPUTERIZED EQUIPMENT:</u>

- 11.3.1 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, LTI shall assure that:
  - a) all applicable requirements are complied with;
  - b) computer software is documented and adequate for use;
  - c) procedures are established and implemented for protecting the integrity of data; such procedures shall include but are not limited to integrity of data entry or capture, data storage, data transmission and data processing;



- d) computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of the test data;
- e) the IT Department establishes and implements appropriate *policies or* procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of computer records.



# **SECTION 12**

# EXAMINATION, TEST, CALIBRATION SERVICES AND SPECIMEN PREPARATION

# 12.1 <u>SCOPE:</u>

12.1.1 This section provides the general requirements on how examinations, testing, specimen preparation and calibration services are carried out at LTI.

# 12.2 NONDESTRUCTIVE EXAMINATION:

- 12.2.1 All nondestructive examinations shall be performed by personnel qualified by the latest revision of LTI Procedures **\*PQ-NDT-1**, **\*PQ-410-1** or **\*PQ-2132-1**, whichever is applicable.
- 12.2.2 All contractually required nondestructive examinations shall be performed in accordance with written, qualified procedures prepared and approved by Level III Examiners and reviewed by the Director of Quality & Improvement or Quality Assurance Manager. Evaluation of nondestructive examination shall be in accordance with contractually required acceptance criteria.
- 12.2.3 All nondestructive examination activities are performed in accordance with the procedure or specification referenced in the work order, including the customer's acceptance criteria as applicable. (\*LTI-DOC)
- 12.2.4 When nondestructive examinations are complete, the results are recorded in hard copy or electronic format and submitted for preparation of formal report.
- 12.2.5 When the nondestructive examination is performed by an outside source, the procedure and technique used to perform the examination shall be approved by the Director of Quality & Improvement, Quality Assurance Manager or a Level III, as required. Upon completion of the examination, Quality Assurance or NDE Level III shall review results and sign or initial the subcontractors report *when deemed acceptable*.

# 12.3 CHEMICAL, DIMENSIONAL, MECHANICAL AND METALLURGICAL:

- 12.3.1 All chemical, dimensional, mechanical and metallurgical testing shall be performed by personnel qualified to the latest revision of LTI Procedure **\*PQ-MAS-1**.
- 12.3.2 Chemical, dimensional, mechanical and metallurgical testing shall be performed by LTI or an approved outside source in accordance with written procedures, industry specification or equipment manufacturer's instructions. All written procedures, industry specifications, or equipment manufacturer's instructions applicable to tests being performed shall be referenced in the work order. (\*LTI-PROCEDURE, LTI-DOC)
- 12.3.3 When a chemical, dimensional, mechanical or metallurgical test has been completed, the results are recorded on work sheets or templates in hard copy or electronic format and submitted for preparation of formal report.



12.3.4 When a chemical, dimensional, mechanical or metallurgical test is performed by an outside source, Quality Assurance, the Manager or Supervisor of the respective area involved, shall review the results and sign or initial the subcontractors' report when deemed acceptable.

# 12.4 CALIBRATION SERVICES:

- 12.4.1 All *in-house* calibration services shall be performed by personnel qualified to the latest revision of LTI Procedure \***PQ-MAS-1**.
- 12.4.2 All calibration performed by LTI or an approved outside source, shall be done in accordance with written procedures developed from ANSI, Federal Standards, National / International Standards or equipment manufacturer's instructions. All written procedures, ANSI Specifications, Federal Standards, National Standards or equipment manufacturer's instructions as applicable to the calibration being performed shall be included on the certificate. (\*LTI-PROCEDURE, LTI-DOC)
- 12.4.3 Upon completion of calibration, the results are recorded in hard copy or electronic format.
- 12.4.4 When calibrations are performed by an outside source, Quality Assurance, Metrology Manager, Supervisor, Metrologist or Coordinator shall review the results and sign or initial the subcontractors' calibration certificate when deemed acceptable.

# 12.5 MACHINING SERVICES:

- 12.5.1 Machining services (without testing) shall be performed by personnel qualified by the latest revision of LTI Procedure **\*PQ-MAS-1**.
- 12.5.2 When the Machine Shop Supervisor receives a work order for Machining services, a Machine Shop Process Control Plan is prepared and implemented. (\*LTI-MACH-1)

# 12.6 <u>REPORTS:</u>

12.6.1 Work orders for all completed examinations, tests and calibration services shall be submitted to the appropriate personnel for preparation of the test reports or calibration certificates. (\*LTI-CERT/REPORT)

#### 12.7 **PROCEDURE SUBMITTAL:**

12.7.1 Specific examination, testing and calibration procedures are available and shall be submitted for customer review when contractually required.

#### 12.8 CUSTOMER "HOLD" POINTS:

12.8.1 Customer witnessing of tests or calibrations shall be noted *in the LTI ERP customer order system.* 



- 12.8.2 When work is ready for testing, Customer Service or the appropriate Manager shall be responsible for notifying the customer or their designated representative to coordinate a suitable time for witnessing of the test.
- 12.8.3 Work shall not proceed until appropriate instructions are received from the appropriate customer or their designated representative.
- 12.8.4 LTI shall ensure the confidentiality of work being performed for other customers during such monitoring.
- 12.8.5 Customer representatives shall be provided with the necessary facilities, equipment and the assistance of personnel to perform their functions.

# 12.9 SAMPLING:

12.9.1 Unless otherwise stipulated by contract, all material will undergo testing or examination for 100% of the lot received.

# 12.10 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS:

- 12.10.1 Monitoring the validity of test, inspection and calibration results shall be performed in accordance with LTI Procedures \*LTI-AQMR or LTI-AQTR.
- 12.10.2 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary. The following records shall be obtained:
  - a. the validation procedure used;
  - b. specification of the requirements;
  - c. determination of the performance characteristics of the method;
  - d. results obtained;
  - e. a statement on the validity of the method, detailing its fitness for the intended use.

#### 12.11 **REPLACEMENT OR RETESTING:**

12.11.1 Prior to completing Technique and Inspection Record on failed items, replacement or retesting per LTI Procedure **\*MAS-RETEST** shall be done wherever possible.

#### 12.12 <u>RETURNING TESTED MATERIAL:</u>

12.12.1 All material that is to be returned to customers upon completion of testing shall be tagged or have container tagged with an acceptance or rejection tag, if applicable.



# 12.13 GENERAL REQUIREMENTS FOR PROCEDURES AND NON-STANDARD METHODS:

- 12.13.1 Validation of non-standard methods and methods used outside their intended scope.
  - 12.13.1.1 LTI shall validate non-standard methods and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as necessary to meet the needs of the given test and / or calibration.
  - 12.13.1.2 LTI shall record the results obtained, the procedure used for the validation and a statement as to whether the method is fit for the intended use.
- 12.13.2 When necessary to employ methods that have not been established as a standard, the customer shall give written approval to do so.
- 12.13.3 Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized and accepted by the customer.



# **SECTION 13**

#### NON-CONFORMING TESTING AND / OR CALIBRATION

#### 13.1 <u>SCOPE:</u>

- 13.1.1 This section describes the process of reporting and controlling any aspect of testing, machining and / or calibration work that does not conform to internal procedures or customer requirements.
- 13.1.2 Items found not conforming to acceptance standards during testing or out of tolerance during calibration are addressed in Paragraph 13.2.

# 13.2 ITEMS NOT MEETING ACCEPTANCE STANDARDS OR TOLERANCE:

- 13.2.1 Customer materials and equipment which are rejected as a result of testing shall be identified as such.
  - 13.2.1.1 Where feasible, parts shall be tagged as to reason for rejection.
  - 13.2.1.2 All rejected material shall be separated from acceptable material where applicable.
  - 13.2.1.3 The Certified Test Report shall identify the noncomplying characteristic(s).
- 13.2.2 Any item that has been submitted for calibration and found out of tolerance shall be identified on the certificate as the "As Found" condition.
  - 13.2.2.1 If the item can be adjusted, it shall be calibrated and identified on the Calibration Certificate "As Left".
  - 13.2.2.2 If the item can be repaired and the customer gives consent, the item shall be repaired and recalibrated. Upon successful repair and acceptable recalibration, certification will be issued.
  - 13.2.2.3 Items that cannot be calibrated in tolerance or repaired shall be identified as such.

#### 13.3 DISCREPANT MATERIALS, EQUIPMENT OR PROCESSING:

- 13.3.1 Any LTI employee can initiate a Nonconformance Report. Any deficiency detected during testing, calibration or machining shall be documented on a *Root Cause / Corrective Action (RCCA)* Nonconformance Report (NCR) in accordance with LTI Procedure \*LTI-NONCONFORMANCE. Work in process shall be stopped, including the withholding of test reports and calibration certificates.
- 13.3.2 The NCR shall be forwarded to Quality Assurance for initial evaluation and determination of significance as well as 10CFR21 reportability.



- 13.3.3 Nonconformances may be dispositioned by the department manager, Director of Quality & Improvement, Quality Assurance Manager and customer as required/necessary. Once the disposition has been completed, a copy of the Nonconformance Report will be forwarded to the appropriate personnel to implement the disposition. All repaired or reworked items will be re-inspected to assure conformance to LTI and customer requirements.
- 13.3.4 LTI shall notify customers promptly, in writing, of any identification of defective measuring and test equipment that cast a doubt on the validity of results given in any Test Report or Calibration Certificate.

# 13.4 10CFR21 COMPLIANCE:

- 13.4.1 For discrepant conditions reportable under the provisions of 10CFR21, the President shall be notified by the Director of Quality & Improvement or Quality Assurance Manager in writing. The President is responsible for all notification outside the company in accordance with established procedures.
- 13.4.2 The procedure **\*10CFR21 COMPLIANCE** along with required documents shall be posted by in areas accessible and conspicuous to all employees.



# **SECTION 14**

#### HANDLING, STORAGE, PRESERVATION AND SHIPMENT

#### 14.1 <u>SCOPE:</u>

14.1.1 This section describes the way that LTI shall handle, store, preserve and ship material or items that come to LTI for testing, machining and calibration.

#### 14.2 METHOD OF HANDLING, STORAGE, PRESERVATION AND SHIPMENT:

- 14.2.1 All materials or items shall be stored and moved in containers which are not detrimental to the product. In general, materials will be stored and moved in the container in which they were received.
  - 14.2.1.1 When specified in the contract or purchase order, material shall not come in contact with sulfur, mercury, halogens or other detrimental materials while in LTI's possession.
  - 14.2.1.2 Slings and other handling equipment shall not be detrimental to the product.
- 14.2.2 All items and material to be shipped back to the customer shall be placed in the returned material holding area after processing.
  - 14.2.2.1 Items for calibration shall remain in the calibration lab or in a specified holding area until calibration certificates have been completed.
  - 14.2.2.2 Upon receiving the certifications and a packing list, shipping shall pack all materials and items in a manner as to preclude any damage. Shipping shall return the package to the customer in accordance with best commercial practice and Interstate Commerce Rules or as required by Purchase Order / Contract.
  - 14.2.2.3 Nuclear orders shall be packed in accordance with LTI Procedure **\*LTI-2.2**, which is in accordance with NQA-1, Subpart 2.2, when referenced.
- 14.2.3 Specific instructions about handling / storage of certain materials shall be put into working procedures, or the work order when specified by contract.

#### 14.3 DIRECT SHIPMENTS:

14.3.1 Shipments to other parties shall be done in accordance with the instructions given by our customer.



# **SECTION 15**

# **TEST REPORTS AND CERTIFICATIONS**

#### 15.1 <u>SCOPE:</u>

15.1.1 This section describes the requirements for Test Reports and Calibration Certificates completed at LTI.

# 15.2 CERTIFICATES AND TEST REPORTS:

- 15.2.1 Test reports and certificates shall be prepared by *authorized personnel* upon completion and review of all testing, dimensional inspection and calibration results.
- 15.2.2 Certifications and Test Reports shall be signed or equivalent identification of the person(s) as designated by the President.
- 15.2.3 Certifications and Test Reports retained by LTI and / or supplied to customers shall comply with the following:
  - 15.2.3.1 Certification and Test Reports shall be legible, reproducible and in good condition.
  - 15.2.3.2 The legibility and contrast of records shall be such that every line, number, letter and character of data shall be clearly legible and readable.
  - 15.2.3.3 The certifications and test reports shall have such clarity as to be capable of providing a second generation copy which shall meet the legibility requirements as stated in 15.2.3.2 above.
  - 15.2.3.4 The certification and test report shall accurately describe the item to which they are certifying.
- 15.2.4 Each certification or report shall meet the requirements as stated in LTI Procedure **\*LTI-CERT/REPORT** and include customer's required information.
- 15.2.5 Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified.
- 15.2.6 Changes to a Test Report or Calibration Certificate after issue shall be made only in the form of a revised document, or data transfer including a *"Revised Certification"* statement.
  - 15.2.6.1 An "Amended" Test Report or Calibration Certificate *signifies* the change was at the request of the customer.
  - 15.2.6.2 A "Corrected" Test Report or Calibration Certificate *signifies* the change was due to an error by LTI.



- 15.2.7 When opinions and interpretations are included, LTI shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be *made by technical personnel, supervisors and managers as appropriate. Opinions and interpretations shall* be clearly marked as such in a test report.
- 15.2.8 In case of transmission of test or calibration results by telephone, email, facsimile or other electronic or electromagnetic means, the requirements of ISO / IEC 17025 shall be met.
- 15.2.9 The format shall be designated to accommodate each type of test or calibration carried out to minimize the possibility of misunderstanding or misuse. Each type of test or calibration shall be separated with heading standardized as much as possible.
- 15.2.10 The use of assessment body logos, such as A2LA and PRI / Nadcap, shall be in accordance with the policies and guidelines for their use.



## **SECTION 16**

# CONTROL OF RECORDS

#### 16.1 <u>SCOPE:</u>

16.1.1 This section describes the requirements for the control of Quality Records which may be in any media, such as hardcopy or electronic media.

# 16.2 QUALITY RECORDS:

- 16.2.1 **Definition** Quality Records are those completed records which furnish documentary evidence of the quality of items and of activities affecting quality.
  - 16.2.1.1 Quality Records include, but are not limited to Work Orders, Calibration Records, Personnel Qualifications and Certifications, Examination Procedures, Internal Audits, Corrective Action, Nonconformance Reports, Management Reviews and Reports, Vendor Audits, Customer Complaints, completed certifications and any records or original observations derived from data and sufficient information to establish an audit trail.
- 16.2.2 Quality records and specimen remnants shall be controlled in accordance with LTI Procedure \*LTI-QR-1.
- 16.2.3 All quality records shall be legible and stored to preclude deterioration, promote retrievability, prevent loss and maintain traceability to the items to which they apply.
- 16.2.4 All quality records shall be stored for a minimum of ten (10) years. The customer shall specify any records requiring retention for longer than this retention time or if notification is required prior to disposal of specified records. In such cases, the specified records shall be provided to the customer upon completion of the order and will become the responsibility of the customer for retention.
- 16.2.5 Sample materials / remnants, in the absence of regulatory and / or contractual requirements, shall be kept for a minimum of thirty (30) days.
- 16.2.6 For paper records, all errors shall be crossed out with a single line, not erased or whited out, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed and dated by the person making the correction. The use of correction fluid on any of the Quality Records is strictly prohibited. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.



# **SECTION 17**

# VENDOR EVALUATION

#### 17.1 <u>SCOPE:</u>

17.1.1 This section details the requirements for the selection and approval of vendors for supplying materials and services, including calibration and testing.

#### 17.2 APPROVED VENDORS:

17.2.1 Vendors supplying material or subcontracted services that effect quality shall be approved prior to procurement.

#### 17.3 SELECTION:

- 17.3.1 Vendors shall be selected and placed on the Approved Vendors List (AVL), based on at least one of the following criteria:
  - a. Accredited to ANSI/ISO/IEC 17025 or by a recognized accreditation body.
  - b. On-site audit and approval as being competent and compliance with the quality system standard applicable to the items and services that are being supplied. (\*LTI-EXT-AUD)
  - c. Vendor is qualified at LTI for services performed at LTI based on acceptance of the following:
    - Vendor's Quality Manual or program description.
    - Procedure for the specific work being performed.
    - Personnel Qualification records.
    - Calibration certificates for the equipment or standards used.
  - d. Vendor is a National Metrology Institute (Ex: NIST).
  - e. Review and approval of vendors' QA Program and/or satisfactory performance. Such vendors are designated on the AVL as "Commercial Use Only" and shall not be used when compliance to ANSI/ISO/IEC 17025 or nuclear standards such as 10CFR50 Appendix B, 10CFR21, ASME Section III NCA-3800 / 4200 and/or ASME NQA-1 as required.
- 17.3.2 As a material organization for nuclear customers requiring compliance to 10CFR50, Appendix B and/or ASME Section III, NCA-3800 / 4200, LTI shall perform an audit of the vendors' quality program. The audit shall be performed by a qualified representative of LTI, using a checklist for detailing applicable requirements. Objective evidence shall be reviewed during the audit and documented. Any non-conformances shall be noted on a Corrective Action Request form.



- 17.3.2.1 Personnel conducting audits of vendors shall be qualified in accordance with LTI Procedure \***PQ-AUD-1**.
  - 17.3.2.1.1 All audit reports, including any corrective action request responses and follow-ups, shall be reviewed and approved by the Director of Quality & Improvement, Quality Assurance Manager, Lead Auditor or the President of LTI.
- 17.3.3 As an alternate to an audit or commercial-grade survey of suppliers of subcontracted calibration and testing services, LTI may accept accreditation by Accreditation Bodies (ABs) recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). Purchase documents impose additional technical, quality and administrative requirements, as necessary, to satisfy LTI Quality Assurance requirements. Program and technical requirements will also include the following:
  - a) The service must be provided in accordance within the scope of their accredited ISO / IEC 17025 program.
  - b) As-Found and As-Left calibration data must be reported in the certificate of calibration. (For calibration services only)
  - c) The calibration certificate/report shall include identification of the laboratory equipment/standards used. (For calibration services only)
  - d) The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
  - e) That the selected laboratory shall not subcontract the service;

# At receipt, LTI QA will review objective evidence of conformance and that the subcontracted calibration or testing was performed in accordance with the supplier's ISO/IEC 17025 program and scope of accreditation.

This alternative shall be performed in accordance with LTI Procedure \*LTI-SCS-RAL.

- 17.3.4 Upon approval, the vendor shall be placed on LTI's Approved Vendors List for three years or until the accreditation expiration date. Once a year, Approved Vendors, other than those accredited, are contacted to confirm organizational structure and quality program status as well as to verify address, responsible party, etc. or to note any significant company change.
  - 17.3.4.1 If the vendors' performance becomes unsatisfactory, or if their services are no longer needed, vendors may be removed from the Approved Vendors List by Quality Assurance or designated representative.
  - 17.3.4.2 The list shall be updated as required and be available to personnel of the respective areas who would be responsible for purchase materials or services for their departments.



# **SECTION 18**

# **CONTROL OF PURCHASED ITEMS AND SERVICES**

#### 18.1 <u>SCOPE:</u>

# 18.1.1 This section describes the established measures for assuring purchased material, items and services conform to procurement documents.

#### 18.2 **REQUIREMENTS**:

- 18.2.1 All purchase orders for materials, items or services shall be documented and controlled in accordance with the latest revision of LTI Procedure **\*PI-1**.
  - 18.2.1.1 Purchase Orders issued to vendors for materials, *items or services* shall include applicable quality, technical acceptance and personnel qualification requirements as needed in accordance with \*PI-1.
  - 18.2.1.2 Prior to release, the purchase order will be reviewed and approved by Quality Assurance.
  - 18.2.1.3 Changes to purchase orders (other than for quantity, price or delivery) will require the same approval as the original.
- 18.2.2 Upon receipt of materials and services, the Director of Quality & Improvement or his designated representative shall review and approve certifications verifying that what was purchased complies with the requirements of the purchase order.
- 18.2.3 LTI shall be responsible for the subcontracting of work, except where the customer specifies a subcontractor to use.
- 18.2.4 When LTI subcontracts any testing or calibration requiring compliance to ANSI / ISO / IEC 17025, the customer shall be notified in writing and, when appropriate, gain the approval of the customer.

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# **SECTION 19**

#### CORRECTIVE ACTION PREVENTATIVE ACTION CONTINUOUS IMPROVEMENT

#### 19.1 <u>SCOPE:</u>

19.1.1 This section describes the requirements for corrective action for conditions **or** *significant conditions* that have an adverse effect on quality, preventative action and continuous improvement.

#### 19.2 **GENERAL REQUIREMENTS:**

- 19.2.1 Corrective action and prevention of recurrence shall be accomplished in accordance with LTI Procedure **\*LTI-CAR**.
- 19.2.2 The corrective action and / or prevention of recurrence shall be recorded on the *Root Cause* / Corrective Action *(RCCA)* form.
- 19.2.3 The need for corrective action and prevention of recurrence shall be determined by nonconformances, formal or informal audit results, customer complaints, management reviews or other conditions **or significant conditions** adverse to quality.
  - 19.2.3.1 Formal audit results could be generated through customer audits of our facility, internal audit of Quality System or Management Review by the President.
  - 19.2.3.2 Informal audit results could be generated through spot checks of any area at any time.
  - 19.2.3.3 Initiation of a corrective action is the responsibility of any LTI employee.

# 19.3 CORRECTIVE ACTION:

- 19.3.1 The procedure for Corrective Action, **\*LTI-CAR** shall include:
  - a) investigation of the root cause of non-conformities relating to product, process and the quality system and recording the results of the investigation;
  - b) determination of the corrective action needed to eliminate the cause of nonconformities;
  - c) application of controls to ensure that the corrective action is taken and that it is effective.





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#### 19.4 PREVENTATIVE ACTION / CONTINUOUS IMPROVEMENT / RISK AND OPPORTUNITIES:

19.4.1 Preventative Action, Continuous Improvement, and Risk and Opportunities Assessment shall be in accordance with LTI Procedure \*LTI-PACI. Preventative action and risk and opportunities assessment are pro-active processes to prevent and reduce undesired impacts in the laboratory activities, and to achieve continuous improvement rather than being reactive to problems and complaints. Risks to impartiality and other risks are addressed in accordance with LTI Procedure \*LTI-PACI.

#### 19.5 CUSTOMER COMPLAINTS AND FEEDBACK:

- 19.5.1 Customer complaints shall be processed and resolved in accordance with LTI Procedure \*LTI-COMP and are documented on a *Root Cause / Corrective Action* (*RCCA*) Customer Complaint Form. Customer complaints are generated based on the Customer's verbal or written notification.
- 19.5.2 Feedback, both positive and negative is sought from customers in the following manner:
  - a. Customer Satisfaction Questionnaires
  - b. Marketing Department contacting customers and prospective customers.
  - c. Customer Service Department daily contact with customers.
  - d. Participation in trade shows.

Such information is analyzed and used to improve our systems, testing and calibration activities and customer service.

#### 19.6 VENDOR CORRECTIVE ACTION AND PREVENTION OF RECURRENCE:

19.6.1 LTI shall require Corrective Action and / or Prevention of Recurrence from its vendors whenever material or services are received which are non-conforming, or upon deficiencies noted during audit of vendors quality system. (\*PI-1)

#### 19.7 <u>RECORDS:</u>

19.7.1 All Corrective Action Requests shall be kept on file by the Quality Assurance Department.



# 19.8 MONITORING OF CORRECTIVE ACTIONS:

- 19.8.1 LTI will monitor the results of corrective actions and prevention of recurrence actions to ensure that the corrective actions taken have been effective.
- 19.8.2 When identification of nonconformances cast doubt as to *LTI's ability to intermediately comply or conform* with procedures and policies, ISO / IEC 17025 or this Quality Manual *during the time permanent corrective/preventive actions are in development*, LTI shall audit the areas of nonconformances *in the time-frame* specified on the *Root Cause / Corrective Action (RCCA) Form or as directed by the Director of Quality & Improvement or Quality Assurance Manager.*
- 19.8.3 The results of these processes shall be considered during the annual Management Review.



QUALITY SYSTEM PROGRAM MANUAL Revision 21 Dated 5/1/19

#### **SECTION 20**

#### **REFERENCED PROCEDURES AND DOCUMENTS**

| PROCEDURE<br>NUMBER    | MANUAL<br>SECTION                    | PROCEDURE TITLE  | WHERE<br>REFERENCED                 |
|------------------------|--------------------------------------|--|-------------------------------------|
| LTI-QPOLICY            | POLICY<br>STATEMENT                  | Quality Policy   | Section i                           |
| LTI-C&P RIGHTS         | SECTION 4                            | Protection of Confidentiality & Proprietary<br>Rights of LTI Customers   | 4.2.9                               |
| LTI-MAN-CTRL           | SECTION 3                            | Control of Quality System Program Manual   | 3.1.6                               |
| PQ-NDT-1               | SECTION 4<br>SECTION 12              | Personnel Qualification and Certifications – NDT   | 4.10.2<br>12.2.1                    |
| PQ-2132-1              | SECTION 4<br>SECTION 12              | Personnel Qualification to MIL-STD-2132<br>and<br>NSTR-99  | 4.10.2<br>12.2.1                    |
| PQ-410-1               | SECTION 4<br>SECTION 12              | NDT Personnel Qualification & Certification in accordance with NAS 410   | 4.10.2<br>12.2.1                    |
| PQ-MAS-1               | SECTION 4<br>SECTION 12              | Procedure for Personnel Qualification of<br>Material Analysis Services   | 4.10.2<br>12.3.1, 12.4.1,<br>12.5.1 |
| PQ-AUD-1               | SECTION 4<br>SECTION 5<br>SECTION 17 | Qualification and Certification of Auditors<br>and Lead Auditors in accordance with<br>ASME / ANSI N45.2.23 and ASME / ANSI<br>NQA-1 | 4.10.2<br>5.2.2<br>17.3.2.1         |
| LTI-INT-1              | SECTION 5                            | Procedure for Performance of Internal<br>Audits  | 5.2.3                               |
| CR-0E-1                | SECTION 6                            | Order Entry / Contract Review<br>Procedure   | 6.2.1                               |
| RI-1                   | SECTION 6<br>SECTION 8               | Procedure for Receiving  | 6.2.1<br>8.2.1                      |
| LTI-DOC                | SECTION 7<br>SECTION 12              | Document Control of Internal Procedures,<br>Customer, Government and International<br>Standards & Specifications                     | 7.3.1<br>12.2.3, 12.3.2,<br>12.4.2  |
| LTI-PROCEDURE          | SECTION 7<br>SECTION 12              | Preparation of Documents   | 7.3.1<br>12.3.2, 12.4.2             |
| 85-CP-1                | SECTION 9<br>SECTION 11              | Calibration Procedure in accordance with MIL-STD-45662A, ANSI/NCSL Z540-1, ISO-10012-1 & ISO-17025                                   | 9.2.2.1, 9.2.4<br>11.2.1            |
| 85-CP-1, Addenda A     | SECTION 10                           | Calibration Frequency List   | 10.2.2                              |
| LTI-<br>NONCONFORMANCE | SECTION 10<br>SECTION 13             | Reporting and Control of Nonconforming<br>Testing and/or Calibration Items   | 10.2.5<br>13.3.1                    |
| CP-MU-1                | SECTION 10                           | Procedure for Calculating Measurement<br>Uncertainty   | 10.2.1                              |
| 10CFR21<br>COMPLIANCE  | SECTION 13                           | Reporting of Defects and<br>Nonconformances in accordance with<br>10CFR21  | 13.4.2                              |
| LTI-2.2                | SECTION 14                           | Packing, Shipping and Marking in<br>accordance with ASME NQA-1   | 14.2.2.3                            |
| LTI-CERT / REPORT      | SECTION 12<br>SECTION 15             | Procedure for Compiling Certificate or Test<br>Report  | 12.6.1<br>15.2.4                    |



# REFERENCED PROCEDURES AND DOCUMENTS (cont'd)

| PROCEDURE<br>NUMBER      | MANUAL<br>SECTION        | PROCEDURE TITLE   | WHERE<br>REFERENCED        |
|--------------------------|--------------------------|---|----------------------------|
| LTI-QR-1                 | SECTION 16               | Procedure for the Control of Quality Records  | 16.2.2, 16.2.4             |
| PI-1                     | SECTION 18<br>SECTION 19 | Purchasing Instructions for Materials and<br>Services   | 18.2.1, 18.2.1.1<br>19.6.1 |
| LTI-CAR                  | SECTION 19               | Procedure for Corrective Action   | 19.2.1, 19.3.1             |
| LTI-COMP                 | SECTION 19               | Resolution of Customer Complaints   | 19.5.1                     |
| LTI EMPLOYEE<br>HANDBOOK | SECTION 4                | LTI Employee Handbook   | 4.2.6                      |
| LTI-SWQA-1               | SECTION 10               | Validation of Computer Software   | 10.2.1                     |
| CP-17025-FIELD           | SECTION 9<br>SECTION 10  | Calibration Procedure of ISO / IEC 17025<br>Field Calibrations  | 9.2.8<br>10.2.6            |
| LTI-AQMR                 | SECTION 10<br>SECTION 12 | Assuring Quality of Metrology Results   | 10.4.1<br>12.10.1          |
| LTI-SCS-RAL              | SECTION 17               | Subcontracted Calibration Services from<br>Recognized Accredited Laboratories   | 17.3.3                     |
| MAS-RETEST               | SECTION 12               | Material Analysis Services Procedure for<br>Retests and Replacement Tests   | 12.11.1                    |
| LTI-PACI                 | SECTION 19               | Risk and Opportunities Assessment and<br>Continual Improvement  | 19.4.1                     |
| PQ-2132-AQP              | SECTION 4                | NDT Personnel Qualification to the<br>Requirements of MIL-STD-2132 and NSTR-<br>99, Rev. 4 Utilizing the Alternate<br>Qualification Program | 4.10.2                     |
| LTI-VT-TO                | SECTION 4                | Training Outline for Visual Inspection  | 4.10.2                     |
| LTI-UT-TO                | SECTION 4                | Training Outline for Ultrasonic Inspection  | 4.10.2                     |
| LTI-RT-TO                | SECTION 4                | Training Outline for Radiographic Testing   | 4.10.2                     |
| LTI-QUAL-NQA-1           | SECTION 4                | Qualification and Certification of Inspection<br>and Testing Personnel  | 4.10.2                     |
| LTI-MP-TO                | SECTION 4                | Training Outline for Magnetic Particle<br>Testing   | 4.10.2                     |
| LTI-LP-TO                | SECTION 4                | Training Outline for Liquid Penetrant Testing   | 4.10.2                     |
| LTI-MACH-1               | SECTION 12               | Machining Services  | 12.5.2                     |
| LTI-AQTR                 | SECTION 12               | Assuring Quality of Test Results  | 12.10.1                    |
| LTI-EXT-AUD              | SECTION 17               | Procedure for Performance of External<br>Audits and Surveys   | 17.3.1b                    |