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QUALITY SYSTEM PROGRAM MANUAL

Original Rev. Issued May 13, 1985

Revision 22, Issued September 13, 2024

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SECTION 1

POLICY AND AUTHORITY STATEMENT

It is the policy of Laboratory Testing Incorporated (LTI), ***also doing business as LTI Metrology, to be committed to a culture of quality and continual improvement, acting in accordance with The LTI Way fundamentals, in order to consistently meet and exceed our customers' needs and expectations. Our team operates with professionalism, competence, accuracy, and unwavering ethical standards as we perform calibration, examinations, machining, testing and other services in strict compliance with all applicable requirements and regulations. LTI's Quality Policy is also defined in the latest revision of LTI Procedure LTI-QPOLICY.***

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 (QSPM) 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 Pennsylvania*** and is located at 2331 Topaz Drive – Hatfield, Pennsylvania 19440. ***This location encompasses a campus of three adjacent buildings.***

The authority and organizational freedom are hereby granted to the ***Director of Quality*** 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
Digitally signed by Jonathan Faia
Date: 2024.09.05 17:15:18 -04'00'

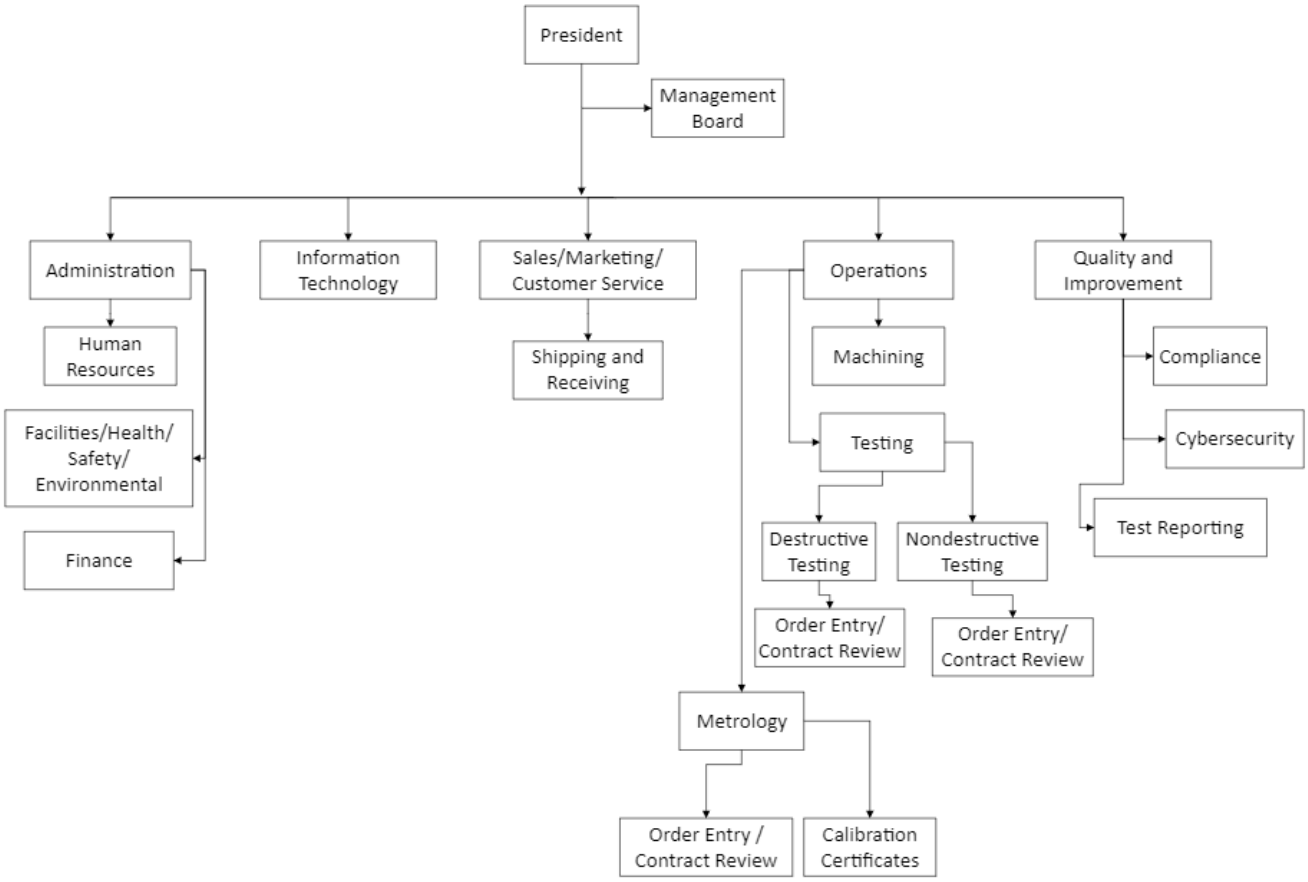
Jonathan Faia
Director of Quality & Cybersecurity
Laboratory Testing Inc.

Brandon McVaugh
Digitally signed by Brandon McVaugh
Date: 2024.09.05 18:15:59 -04'00'

Brandon McVaugh
President
Laboratory Testing Inc.

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*** 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 SCOPE:

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 ***as well as manufacturing related requirements from referenced documents*** are excluded from the scope of this program.

3.1.4 This manual and associated documents are written ***incorporating the applicable requirements of our customers and the standards / specifications listed below***, ***to include customer Nuclear Power Generation quality system requirements and approved vendor lists which identify LTI as a "Material Organization."*** The latest endorsed / approved edition, addenda or revision shall be maintained.

LTI maintains accreditation/certification to:

- ***ISO/IEC 17025:2017 – International Standard for Testing and Calibration Laboratories***
- ***PRI/Nadcap Checklists:***
  - ***AC7101/1/2/3/4/5/6/7/9***
  - ***AC7110/13***
  - ***AC7004***
  - ***AC7114 /1/2/3***
- ***ANSI/NCSL Z540.1 – Calibration Laboratories and Measuring and Test Equipment General Requirements***

LTI is audited by the Nuclear Industry Assessment Corporation (NIAC) for compliance to:

- ***ASME Boiler and Pressure Vessel Code, Section III Rules for Construction of Nuclear Facility Components, Subsection NCA General Requirements for Division 1 and Division 2***
- ***ASME NQA-1 – Quality Assurance Requirements for Nuclear Facility Applications***
- ***10 CFR Part 50, Appendix B – Quality Assurance Requirements for Nuclear Power Plants and Fuel Reprocessing Plants***
- ***10 CFR Part 21 – Reporting of Defects and Noncompliance***

LTI's quality system incorporates applicable requirements from:

- ***MIL-STD-45662A – Calibration System Requirements***
- ***MIL-I-45208A – Inspection System Requirements***
- ***ISO 10012-1 – Quality Assurance Requirements for Measuring Equipment – Part 1: Metrological Confirmation System for Measuring Equipment***
- ***SAE AS9100 – Quality Managements Systems – Requirements for Aviation, Space, and Defense Organizations***
- ***ISO 9001 – Quality Management Systems – Requirements***
- ***ISO 13485 – Medical Devices – Quality management Systems – Requirements for Regulatory Purposes***
- ***IATF 16949 – Quality Management System Requirements for Automotive Production and Relevant Service Parts Organizations***
- ***CSA N299.3 - Quality Assurance Program Requirements for the Supply of Items and Services for Nuclear Power Plants, Category 3***

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-Documentation.***

3.1.7 This manual and associated procedures shall be reviewed and revised by the ***Director of Quality*** for conformance to the latest endorsed / approved editions of the Codes, Standards, Specifications and Regulations referenced above.

3.1.8 The ***Director of Quality*** 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 ***through the directory of accredited organizations***:

Calibration	***Certificate Number 0117.04***
Chemical Testing	***Certificate Number 0117.05***
Mechanical Testing	***Certificate Number 0117.02***

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, QUALIFICATIONS, CERTIFICATIONS

4.1 It shall be the responsibility of the ***Director of Quality*** 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 **RESPONSIBILITIES – ALL PERSONNEL**: 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.
f. Nonconformances
g. Security issues related to customer confidentiality or protected information
h. Violations of scopes of approval

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-Security***) and agreements regarding company, customer or vendor confidential information.

4.2.10 Adherence to security requirements including ITAR/EAR, NOFORN, and CUI. (LTI-Security)

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 ***continual*** 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*** 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 ***Approval of*** 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.

4.6 RESPONSIBILITIES – QUALITY ASSURANCE; REPORTS TO THE PRESIDENT:

4.6.1 The ***Director of Quality*** 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 ***Overview of*** performance of Internal Audits ***and qualification of lead auditors***.

4.6.1.4 Reporting regularly to management on the status and adequacy of the program.

4.6.1.5 Oversees preparation of all ***test reports and calibration certificates*** including review of request for changes to same.

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 all 10 CFR Part 21 defects and non-compliances to the President and issues relevant notifications.***

4.6.1.7 Ultimately responsible for the storage of Quality Assurance records.

4.6.1.8 ***Conducts and issues or delegates annual management review of the quality system.***

4.6.2 The ***Director of Quality*** and the Quality Assurance Manager shall be responsible for the following:

4.6.2.1 ***Responsibility for assurance of the accurate and complete review*** 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 test reports and calibration certificates 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.

4.6.2.19 Responsibility for the management of vendors, procurement activities, and receipt of services that impact the quality of testing and calibration services.

4.6.3 Quality Assurance department personnel shall assist the ***Director of Quality*** 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*** as well as the Quality Manager.

4.7 RESPONSIBILITIES – DIRECTORS, MANAGERS, *TEAM LEADERS* 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 PERSONNEL TRAINING AND COMPETENCE*:*

4.9.1 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.

4.9.2 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. (***LTI-Training)***

4.9.3 The ***Director of Quality*** shall ensure employees whose function affects quality receive the training / indoctrination they need for their position.

4.9.4 Personnel performing and managing specific assigned tasks are qualified based on appropriate education, training and / or experience.

4.9.5 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.

4.10 KEY PERSONNEL:

4.10.1 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.

4.11 CHANGES TO RESPONSIBILITIES AND AUTHORITY:

4.11.1 The President, upon written notification to the ***Director of Quality***, may revise or append responsibilities and authority stated in this manual.

SECTION 5

INTERNAL AUDIT

5.1 SCOPE:

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 ***Director of Quality*** 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 ***LTI-Training.***

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-Audit***.

5.3 MANAGEMENT REVIEW:

5.3.1 The ***Director of Quality*** 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 ***inputs addressing the performance and effectiveness of the quality management system are included in the*** Management Review:

a. changes, including internal and external issues relevant to LTI;
b. ***suitability, adequacy and*** fulfillment of or performance to objectives (process performance and conformance);
c. suitability ***and adequacy*** of policies and procedures ***to include the quality policies.***
d. follow-up actions from previous management reviews;
e. the results of recent internal audits;
f. corrective actions ***and opportunities for improvement;***
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.

5.3.3 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.

5.3.3.1 Outputs of the management review includes decisions and actions related to:

a Opportunities for Improvement
b Any need for changes to the quality management system
c Other actions as necessary

5.3.4 The Management Review Report shall be approved by the President and distributed to the ELT.

SECTION 6

ORDER ENTRY / CONTRACT REVIEW

6.1 SCOPE:

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 Procedures **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 ***personnel are unable to determine the appropriate test / process or if the customer's test method is inappropriate, LTI shall notify the customer to obtain a documented resolution of any questionable items in accordance with LTI procedure CR-OE-1.***

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 ***in accordance with CR-OE-1.***

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

PROCEDURES, SPECIFICATIONS, AND DRAWINGS

7.1 SCOPE:

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 internal procedures are available in the Document Management System to personnel using the procedure.***

7.2.2 ***Affected*** 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 REVIEW, APPROVAL AND REVISION:

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

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 ***as prescribed in LTI-Documentation.***

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 or specifications shall be maintained on an as needed basis in accordance with LTI-Documentation.

SECTION 8

IDENTIFICATION AND TRACEABILITY *OF CUSTOMER ORDERS*

8.1 **SCOPE:**

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. ***Discrepancies shall be resolved with the customer prior to completing the receiving and order entry steps as described in RI-1 and CR-OE-1.***

8.2.1.1 Equipment and material shall be tagged, marked or otherwise identified with ***the LTI customer order number***. Required identification or markings listed on Customers' Purchase Orders are included on the LTI work order and/or LTI ***test reports and calibration certificates***.

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 ***may*** exist for orders having unique requirements ***and shall be invoked on the order where applicable***.

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. ***These shall be dispositioned as a nonconformance in accordance with LTI-Correction-Improvement.***

SECTION 9

ACCOMMODATION AND ENVIRONMENT

9.1 SCOPE:

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

CONTROL OF EQUIPMENT AND REFERENCE MATERIALS / STANDARDS

10.1 SCOPE:

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 (*where measurement uncertainty applies*) and 85-CP-1**. Software shall be controlled in accordance with LTI procedure **LTI-SOFTWARE**. 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, preventive 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-Correction-Improvement**. 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 applicable procurement requirements of LTI-Procurement

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 ***The quality of calibration and test results are assured in accordance with 12.10 of this quality manual. Additional intermediate checks may be performed on an as needed basis as directed by the department manager.***

10.5 REAGENTS AND CERTIFIED MATERIALS:

10.5.1 Reagents and certified materials used to perform testing or inspection shall be controlled to extent necessary to meet regulatory or specification requirements (i.e., batch control, certification, expiration, etc.). This shall be as defined by the relevant test procedure to assure compliance with invoked specifications. Containers shall be clearly marked with material type, batch, and expiration where these apply. Expired material shall be removed from storage to prevent unintended use.

SECTION 11

EQUIPMENT, TOOL AND INSTRUMENT *CALIBRATION* CONTROL

11.1 SCOPE:

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, which includes 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 COMPUTERIZED EQUIPMENT:

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 ***the software meets the requirements of LTI-SOFTWARE to assure:***

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 SCOPE:

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 applicable invoked specification (SNT-TC-1A, NAS410, MIL-STD-2132, etc.) as necessary. Qualification shall be in accordance with the relevant written practice or procedure as referred to in LTI-Training.***

12.2.2 All contractually required nondestructive examinations shall be performed in accordance with written, qualified procedures prepared and approved by ***Level III Examiners, NAS 410 Level 3 personnel, MIL-STD-2132 examiners, or other relevant qualification systems deemed acceptable to prepare procedures as required by the governing specification*** and reviewed by the ***Director of Quality*** or Quality Assurance Manager. Evaluation of nondestructive examination shall be in accordance with contractually required acceptance criteria. This procedure preparation shall be performed in accordance with ***LTI-Documentation.***

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-Documentation)***

12.2.4 ***When nondestructive examinations are complete, the results are submitted for preparation of formal report.***

12.2.5 When the nondestructive examination is performed by an outside source ***this activity shall be performed as specified in LTI-Procurement.***

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 ***LTI-Training.***

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-Documentation)***

12.3.3 ***When a chemical, dimensional, mechanical or metallurgical test has been completed, the results are recorded and submitted for preparation of formal report.***

12.3.4 When a chemical, dimensional, mechanical or metallurgical test is performed by an outside source ***it shall be performed in accordance with LTI-Procurement.***

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 ***LTI-Training.***

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-Documentation)***

12.4.3 Upon completion of calibration, ***the results are recorded and submitted for preparation of formal report.***

12.4.4 When calibrations are performed by an outside source, ***the activity shall be performed in accordance with LTI-Procurement.***

12.5 MACHINING SERVICES:

12.5.1 Machining services (without testing) shall be performed by personnel qualified by the latest revision of LTI Procedure ***LTI-Training.***

12.5.2 ***These services shall be performed in accordance with LTI Procedure LTI-MACH-1.***

12.6 REPORTS:

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-Documentation***)

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 ***accomplished through implementation of proficiency testing, round robin, observations of test, overchecks and internal auditing programs as applicable. (LTI-PT, LTI-IRR, LTI-Audit, LTI-Training).***

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.

12.10.3 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed. Changes to methods shall involve notification to customers or accrediting bodies as required.

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 RETURNING TESTED MATERIAL:

12.12.1 All material that is to be returned to customers upon completion of testing ***for the purpose of being placed into service*** 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. ***Deviations shall be logged in accordance with CR-OE-1.***

SECTION 13

NON-CONFORMING TESTING AND / OR CALIBRATION

13.1 SCOPE:

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. ***Such results are considered a normal output of the services provided by LTI and, while considered a non-conforming test result, are not considered nonconformances by LTI for the purposes of investigation, trending, and corrective action.***

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. ***Rejected material shall be clearly marked to prevent any confusion between rejected and accepted material for production components. Traceability shall be maintained.***

13.2.1.3 The ***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 and dispositioned in accordance with LTI-Correction-Improvement.***

13.3.2 ***Nonconformances shall be evaluated in accordance with LTI-Correction-Improvement and customers will be notified as applicable. Determination of significance as well as 10 CFR Part 21 reportability shall be determined.***

13.3.3 ***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 10 CFR PART 21 COMPLIANCE:

13.4.1 For discrepant conditions reportable under the provisions of ***10 CFR Part 21***, the President shall be notified by the ***Director of Quality*** or Quality Assurance Manager in writing. ***LTI Procedure 10CFR21 Compliance shall be followed for reporting and notification requirements.***

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 SCOPE:

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 test reports or calibration certificates 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-Shipping***, 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 *CALIBRATION CERTIFICATES*

15.1 SCOPE:

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

15.2 CALIBRATION CERTIFICATES AND TEST REPORTS:

15.2.1 Test reports and calibration certificates shall be prepared by authorized personnel upon completion and review of all testing, dimensional inspection and calibration results.

15.2.2 Calibration Certificates and Test Reports shall be signed ***in accordance with LTI-Documentation.***

15.2.3 Calibration Certificates and Test Reports retained by LTI and / or supplied to customers shall comply with the following:

15.2.3.1 Calibration Certificates 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 calibration certificates 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 calibration certificate 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-Documentation*** 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 ***revision 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 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.

15.2.9 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 SCOPE:

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 ***test reports and calibration certificates*** 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-Documentation.***

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 SCOPE:

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 ***impact*** 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 a documented review in accordance with LTI-Procurement. This may include acceptance of ISO/IEC 17025 accreditation status or an audit of the vendor.***

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 SCOPE:

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 ***LTI-Procurement.***

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 ***LTI-Procurement***.

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, Quality Manager or their*** designated representative shall review and approve ***reports or*** 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 to satisfy a customer order, the customer shall be notified in writing and gain the approval of the customer.***

18.2.5 **The procurement documents (purchase order and associated attachments) shall be in accordance with LTI-Procurement including:**

18.2.5.1 Traceability of documents with the test articles, a description of the item including the manufacturer's or supplier's designation, where applicable; For services - scope of work, i.e., calibration service or testing

18.2.5.2 For calibration - instrumentation to be calibrated, including manufacturer, model, serial number and parameters to justify acceptance such as accuracy, range, percentage, etc. as applicable

18.2.5.3 Technical requirements, acceptance criteria, personnel competence and qualification requirements, including customer requirements, specifications, or standards relevant to the material, calibration or testing to be performed, or other procedures or instructions, including revisions thereto

18.2.5.4 Quality Assurance program requirements, applicable only to the material, calibration or testing; This shall include the prohibition of subcontracting to any other organization, unless authorization to do so is given by LTI. Reference to the vendor's quality manual shall be included for vendors approved by audit.

18.2.5.5 Rights of access to the vendor's plant facilities and records and the vendor's subcontractors (if used) for inspection or audit by LTI or other duly authorized parties

18.2.5.6 Certificate / test report requirements

18.2.5.7 A statement imposing the requirements of 10 CFR Part 21, when applicable

18.2.5.8 Customer / Prime Contractor / Regulatory Agency requirements applicable to the item or service being purchased.

18.2.5.9 Requirement for the vendor to notify LTI of any changes in product or services from that previously supplied

18.2.5.10 LTI's PO Quality Clauses document with quality related requirements attached to the purchase order

18.2.6 Receipt inspection shall be performed in accordance with LTI-Procurement and shall verify that the purchase order requirements have been met.

SECTION 19

CORRECTIVE ACTION
PREVENTIVE ACTION
CONTINUAL IMPROVEMENT

19.1 SCOPE:

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

19.2 GENERAL REQUIREMENTS:

19.2.1 Corrective action and prevention of recurrence shall be accomplished in accordance with LTI Procedure ***LTI-Correction-Improvement***

19.2.2 The corrective action and / or prevention of recurrence shall be recorded on the ***log and final reports shall be issued in accordance with LTI-Correction-Improvement.***

19.2.3 The need for corrective action and prevention of recurrence ***shall be determined as specified in LTI-Correction-Improvement. This may include nonconformances, formal or informal audit results, customer complaints, management reviews or other conditions or significant conditions adverse to quality.***

19.3 CORRECTIVE ACTION:

19.3.1 The procedure for Corrective Action, ***LTI-Correction-Improvement*** 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.

19.4 *PREVENTIVE* ACTION / *CONTINUAL* IMPROVEMENT */ RISK AND OPPORTUNITIES*:

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

19.5 CUSTOMER COMPLAINTS AND FEEDBACK:

19.5.1 Customer complaints shall be processed and resolved in accordance with LTI Procedure ***LTI-Correction-Improvement*** and are documented on ***the log with a final report issued***. 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 ***in accordance with LTI-Correction-Improvement.***

19.7 RECORDS:

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 in ***LTI-Correction-Improvement*** or as directed by the ***Director of Quality*** or Quality Assurance Manager. ***Containment activities may be enforced in accordance with LTI-Correction-Improvement as necessary to prevent the release of nonconforming work.***

19.8.3 The results of these processes shall be considered during the annual Management Review.

SECTION 20

CYBERSECURITY AND INFORMATION SECURITY

20.1 SCOPE:

20.1.1 This section describes the general policy, requirements, and system for Cybersecurity and Information Security for LTI to comply with regulations, customer requirements, and industry best practices.

20.2 POLICY AND PURPOSE:

20.2.1 LTI's system of Cybersecurity and Information Security compliance and implementation of industry best practices is crucial to assure access to business information, protect sensitive data, prevent or respond to security incidents, comply with legal and regulatory requirements, manage risk, build trust and reputation, and to assure operational continuity and efficiency. Maintaining a system for Cybersecurity and Information Security compliance creates a secure environment that supports LTI's strategic objectives and protects our assets, reputation, and stakeholders.

20.3 GENERAL REQUIREMENTS:

20.3.1 LTI's system for information security compliance and best practices is primarily based on:

20.3.1.1 The National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 controls.

20.3.1.2 International Traffic in Arms Regulations (ITAR), and U.S. Department of Defense (DoD) NOFORN (No Foreign Dissemination) requirements.

20.3.2 Expectations to comply with NIST SP 800-171, ITAR, and NOFORN requirements to protect Controlled Unclassified Information (CUI) and other sensitive data are typically flowed down to DoD contractors and the supply chain through a variety of Defense Federal Acquisition Regulations (DFARS) and contract clauses.

20.3.3 A compliant and effectively implemented Cybersecurity and Information Security system prioritizes confidentiality, integrity, and availability of sensitive information. NIST SP 800-171 outlines the controls for protecting CUI in non-federal systems and organizations. The ITAR are State Department rules governing the manufacture and transfer of defense products, services, and related technical data.

20.4 SYSTEM AND PROCESSES

20.4.1 ***NIST SP 800-171 controls and ITAR and NOFORN requirements are implemented through a comprehensive suite of LTI Information Security-related policies and procedures, which framework is detailed in LTI Policy, "LTI NIST-CUI System Security Plan," and overseen by the Information Security Governance Committee (ISGC).***

20.4.2 ***LTI's Information Security and Cybersecurity system and program complies with all 110 basic and derived NIST SP 800-171 security controls and all applicable requirements for control and protection of ITAR technical data control, which means of implementation includes, but is not limited to:***

- ***a*** ***a formal system security plan (SSP),***
- ***b*** ***a comprehensive suite of cybersecurity policies and procedures, with annual reviews and updates,***
- ***c*** ***an Information Security Calendar of Events for all required security activities, including recurring cybersecurity assurance and vulnerability testing,***
- ***d*** ***an active Information Security Governance Committee (ISGC),***
- ***e*** ***Incident Response training and playbook, and***
- ***f*** ***recurring companywide Phishing email and cybersecurity training and testing.***

20.4.3 ***Specific guidelines and instructions for handling and protecting various types of CUI, such as information classified as ITAR, NOFORN and other similar data classifications, are documented in LTI procedure LTI-Security.***

SECTION 21

COUNTERFEIT, FRAUD, FALSIFICATION, AND MALPRACTICE

21.1 Prevention of Counterfeit, Fraud, Falsification and Malpractice

21.1.1 All employees are responsible for the prevention and reporting of potential, suspected, or known counterfeit, fraud, falsification, and malpractice in accordance with LTI-Security and LTI ethics policies.

21.1.2 Employees shall receive training on prevention and detection of counterfeit, fraud, falsification, and malpractice activities.

21.1.3 Examples of these activities may include (but is not limited to):

a Issuing a procedure or instruction known to contain unauthorized deviations from contractual requirements.

b Knowingly waiving a requirement without authority to do so.

c Deliberately accepting unsatisfactory work.

d Verifying performance based on hearsay, not personal observation.

e Tampering with calibrated instruments.

f Falsifying dates or data.

g Concealing fraudulent activities of others.

21.1.4 Any suspected counterfeit, fraud, falsification, or malpractice activity should be reported to and investigated by the Director of Quality, Quality Assurance Manager, or Quality Engineer in accordance with LTI-Correction-Improvement as a nonconformance investigation. Customers, Accrediting Bodies, or Regulatory Agencies shall be notified as necessary or required should such investigations determine actual fraud, falsification, or malpractice.

21.1.5 The requirements of EB2678 and 10 CFR Part 21 shall be posted for reference in conspicuous locations.

SECTION 22

SAFETY

22.1 Statement of Policy

22.1.1 It is the policy of Laboratory Testing Inc. (LTI) that all employees play an active role in ensuring the safety, health, and wellbeing of all visitors and LTI staff. In doing so, employees shall continuously work together to promote safe work practices, observe all rules and regulations, and shall consistently maintain property and equipment in safe working condition.

The requirements for safety during employment are an established policy. The safety practices set forth in the Safety Manual, HR Policy #216: General Safety Rules/Safety Committee, and the LTI Safety Committee Environmental, Health and Safety Policy Statement are intended to provide for the maximum safety of our employees and our customers. No job shall be deemed so important that it cannot be done safely. Safety is to be a part of every operation and cannot be separated. Those who benefit most are the employees themselves through elimination of physical suffering, personal hardships, and worry. Therefore, our safety program comprises the following fundamental principles:

1. Employing qualified safe personnel
2. Training individuals to be safety-oriented employees
3. Provide safe working conditions and equipment
4. Investigation of incidents to determine basic causes
5. Maintain and enforce established rules and procedures
6. Promote safety through supervisors

The complete cooperation of each employee is solicited in carrying out all the safety procedures necessary to assure safe job completion.

All persons shall follow the safety rules, render every possible aid to safe operations and report all unsafe conditions or practices to their supervisor immediately. All supervisors shall insist on employees observing and obeying every rule, regulation, and order for the safe conduct of the work and shall take such action as is necessary to ensure observance.

REVISION 22 AMENDMENT RECORD

SECTION	DATE	DESCRIPTION	APPROVAL
Section I	9/5/2024	Updated job title for Jonathan Faia and added new LTI President Name. Updated first paragraph to move “material organization” designation to section 3. Added reference to LTI metrology. Also updated state of incorporation and removed old satellite facility. Added clarification for additional buildings.	B. Shumway
Table of Contents	9/5/2024	Corrected Section Titles and updated new sections	B. Shumway
Section 2 Organizational Structure	9/5/2024	Updated organizational chart and updated Director of Quality job title	B. Shumway
3.1.3	9/5/2024	Clarified exclusion of manufacturing related requirements.	B. Shumway
3.1.4	9/5/2024	Updated quality system program references	B. Shumway
3.1.6	9/5/2024	Revised Procedure Reference	B. Shumway
3.1.7 / 3.1.8 / 4.1	9/5/2024	Updated title	B. Shumway
3.1.9	9/5/2024	Included certificate number instead of link	B. Shumway
4.2 iii f, g, h	9/5/2024	Added reporting of nonconformances, customer confidentiality, and approval scopes	B. Shumway
4.2.9	9/5/2024	Updated procedure reference	B. Shumway
4.2.10	9/5/2024	Added document security	B. Shumway
4.3.2	9/5/2024	Changed continuous to continual	B. Shumway
4.5.1	9/5/2024	Revised title	B. Shumway
4.5.3	9/5/2024	Revised to indicate approval of management review.	B. Shumway
4.5.5 / 4.5.6	9/5/2024	Removed responsibilities from President	B. Shumway
4.6.1.3	9/5/2024	Clarified internal auditing oversight	B. Shumway
4.6.1.6	9/5/2024	Clarified 10 CFR Part 21 reporting	B. Shumway

4.6.1.8	9/5/2024	Added section addressing management review to QA director responsibilities	B. Shumway
4.6.2.19	9/5/2024	Added vendor/procurement responsibilities	B. Shumway
4.6.2	9/5/2024	Updated title	B. Shumway
4.6.2.1	9/5/2024	Clarified contract review responsibility	B. Shumway
4.6.3	9/5/2024	Updated title	B. Shumway
4.6.4	9/5/2024	Updated title	B. Shumway
4.7	9/5/2024	Added team leader job title	B. Shumway
4.9	9/5/2024	Removed satellite facility section. All section 4 numbers after 4.9 reduced to accommodate removed section	B. Shumway
4.9.2	9/5/2024	Updated procedure reference	B. Shumway
4.9.3	9/5/2024	Updated title	B. Shumway
4.11.1	9/5/2024	Updated title	B. Shumway
5.2.1	9/5/2024	Changed role responsible for appointment of auditors	B. Shumway
5.2.2	9/5/2024	Updated procedure reference	B. Shumway
5.2.3	9/5/2024	Updated procedure reference	B. Shumway
5.3.1	9/5/2024	Changed role responsible for issuance of management review	B. Shumway
5.3.2	9/5/2024	Included additional management review inputs	B. Shumway
5.3.3	9/5/2024	Added portion on management review outputs	B. Shumway
6.2.3	9/5/2024	Revised wording and made reference to quality procedure	B. Shumway
6.3.2	9/5/2024	Added procedure reference	B. Shumway
Section 7	9/5/2024	Revised Section Title	B. Shumway
7.2.1	9/5/2024	Removed hardcopy requirement.	B. Shumway
7.2.2	9/5/2024	Corrected spelling error	B. Shumway

7.3.1	9/5/2024	Updated procedure reference	B. Shumway
7.4.1	9/5/2024	Added procedure reference	B. Shumway
7.4.3	9/5/2024	Simplified wording	B. Shumway
Section 8	9/5/2024	Revised title	B. Shumway
8.2.1	9/5/2024	Added procedure reference	B. Shumway
8.2.1.1	9/5/2024	Changed lab number to customer order number	B. Shumway
8.2.3	9/5/2024	Added procedure reference	B. Shumway
Section 10	9/5/2024	Updated Section title	B. Shumway
10.2.1	9/5/2024	Added clarification of applicability of CP-MU-1 along with reference to 85-CP-1	B. Shumway
10.2.5	9/5/2024	Revised procedure reference	B. Shumway
10.2.7	9/5/2024	Revised wording to make reference to procedure	B. Shumway
10.4.1	9/5/2024	Updated verbiage and removed reference to obsolete procedure	B. Shumway
10.5.1	9/5/2024	Added section regarding reagents and materials	B. Shumway
Section 11	9/5/2024	Updated section title	B. Shumway
11.3.1	9/5/2024	Added procedure reference	B. Shumway
12.2.1	9/5/2024	Updated wording and procedure references	B. Shumway
12.2.2	9/5/2024	Clarified qualification types	B. Shumway
12.2.3	9/5/2024	Updated procedure reference	B. Shumway
12.2.4	9/5/2024	Simplified wording of the section	B. Shumway
12.2.5	9/5/2024	Added procedure reference	B. Shumway
12.3.1	9/5/2024	Updated procedure reference	B. Shumway
12.3.2	9/5/2024	Updated procedure reference	B. Shumway

12.3.3	9/5/2024	Simplified wording	B. Shumway
12.3.4	9/5/2024	Updated procedure reference	B. Shumway
12.4.1	9/5/2024	Updated procedure reference	B. Shumway
12.4.2	9/5/2024	Updated procedure reference	B. Shumway
12.4.3	9/5/2024	Simplified wording of the section	B. Shumway
12.4.4	9/5/2024	Added procedure reference	B. Shumway
12.5.1	9/5/2024	Updated procedure reference	B. Shumway
12.5.2	9/5/2024	Restated section to make reference to the procedure	B. Shumway
12.6.1	9/5/2024	Updated procedure reference	B. Shumway
12.10.1	9/5/2024	Revised procedures and clarified methods of assuring quality results	B. Shumway
12.10.3	9/5/2024	Added details for changes to validated methods	B. Shumway
12.12.1	9/5/2024	Clarified intent of section	B. Shumway
12.13.3	9/5/2024	Added procedure reference	B. Shumway
13.1.2	9/5/2024	Clarified differences between nonconforming test results and nonconformances	B. Shumway
13.2.1.2	9/5/2024	Added requirements for maintaining traceability and clear marking	B. Shumway
13.2.1.3	9/5/2024	Revised wording to align with current test report verbiage (removed “certified”)	B. Shumway
13.3.1	9/5/2024	Revised wording and updated procedure reference	B. Shumway
13.3.2	9/5/2024	Revised wording and updated procedure reference	B. Shumway
13.3.2	9/5/2024	Revised wording and updated procedure reference	B. Shumway
13.4.1	9/5/2024	Revised and clarified wording and updated procedure reference	B. Shumway
14.2.2.3	9/5/2024	Updated procedure reference	B. Shumway
Section 15	9/5/2024	Updated section title	B. Shumway

15.2.2	9/5/2024	Revised procedure reference	B. Shumway
15.2.4	9/5/2024	Added procedure reference	B. Shumway
15.2.6	9/5/2024	Revised wording to include revision statement	B. Shumway
15.2.8	9/5/2024	Removed section and updated numbers of sections after this	B. Shumway
17.2.1	9/5/2024	Updated word to “impact”	B. Shumway
17.3.1	9/5/2024	Extensive rewrite of section to remove most requirements and make reference to the procedure instead.	B. Shumway
18.2.1	9/5/2024	Updated procedure reference	B. Shumway
18.2.1.1	9/5/2024	Updated procedure reference	B. Shumway
18.2.2	9/5/2024	Updated job titles	B. Shumway
18.2.4	9/5/2024	Updated wording of section to clarify intent	B. Shumway
18.2.5	9/5/2024	Added section for requirement of PO meeting procedure	B. Shumway
18.2.6	9/5/2024	Added section for requirement to perform receipt inspection in accordance with procedure	B. Shumway
Section 19	9/5/2024	Updated section title	B. Shumway
19.1.1	9/5/2024	Added significant conditions, changed continuous to continual, changed preventative to preventive	B. Shumway
19.2.1	9/5/2024	Updated procedure reference	B. Shumway
19.2.2	9/5/2024	Updated wording to reference the log and added procedure reference	B. Shumway
19.2.3.1	9/5/2024	Updated wording of section	B. Shumway
19.3.1	9/5/2024	Updated procedure reference	B. Shumway
19.4	9/5/2024	Changed continuous to continual and preventative to preventive	B. Shumway
19.4.1	9/5/2024	Updated procedure reference and changed continuous to continual along with preventative to preventive	B. Shumway
19.5.1	9/5/2024	Updated wording to make reference to the log and added procedure reference	B. Shumway
19.6.1	9/5/2024	Updated procedure reference	B. Shumway

19.8.2	9/5/2024	Added procedure reference, added containment activity reference, and updated job title.	B. Shumway
Section 20	9/5/2024	Removed section detailing the location of every referenced procedure	B. Shumway
Section 20 (New)	9/5/2024	Added section for Cybersecurity and Information Security	J. Faia
Section 21 (New)	9/5/2024	Added new section for Counterfeit, Fraud, Falsification, and Malpractice	B. Shumway
Section 22 (New)	9/5/2024	Added new section for safety.	B. Shumway

NOTES:
All significant changes from the previous revision are notated in bold and italics.