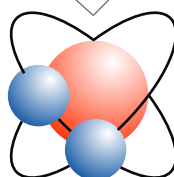
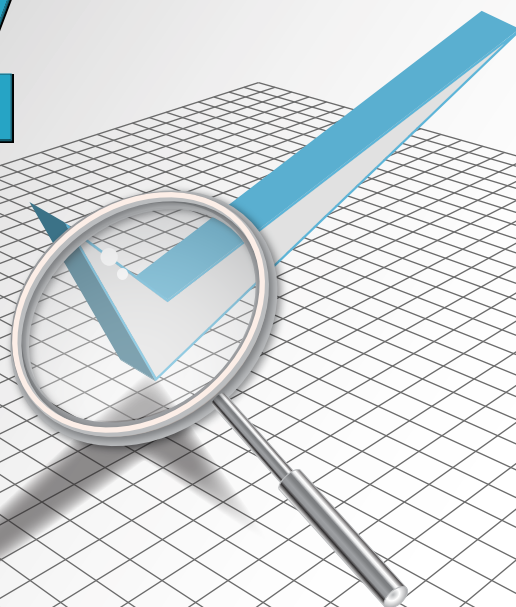


Thunder Scientific Calibration Laboratory Quality Manual



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APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 1 of 31

THUNDER SCIENTIFIC CALIBRATION LABORATORY QUALITY MANUAL

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Thunder Scientific Corporation
623 Wyoming Blvd., SE
Albuquerque, NM 87123
(505) 265-8701
(505) 266-7728 Fax

THUNDER SCIENTIFIC CALIBRATION LABORATORY

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APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
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Page 2 of 31

Contents

	Page
Introduction	4
1 Scope	5
2 References	5
2.1 External References	5
2.2 Internal References	5
3 Terms and definitions	6
4 General requirements	7
4.1 Impartiality	7
4.2 Confidentiality	8
5 Structural requirements	8
6 Resource requirements	10
6.1 General	10
6.2 Personnel	10
6.3 Facilities and environmental conditions	11
6.4 Equipment	12
6.5 Metrological traceability	13
6.6 Externally provided products and services	14
7 Process requirements	15
7.1 Review of requests, tenders and contracts	15
7.2 Selection, verification and validation of methods	16
7.2.1 Selection and verification of methods	16
7.2.2 Validation of methods	17
7.3 Sampling	17
7.4 Handling of test or calibration items	18
7.5 Technical records	19
7.6 Evaluation of measurement uncertainty	19
7.7 Ensuring the validity of results	19
7.8 Reporting of results	20
7.8.1 General	20
7.8.2 Common requirements for reports (test, calibration or sampling)	21
7.8.3 Specific requirements for test reports	22
7.8.4 Specific requirements for calibration certificates	22
7.8.5 Reporting sampling – specific requirements	23
7.8.6 Reporting statements of conformity	23

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 3 of 31

7.8.7	Reporting opinions and interpretations	24
7.8.8	Amendments to reports	24
7.9	Complaints	24
7.10	Nonconforming work	25
7.11	Control of data and information management	25

8	Management system requirements	26
8.1	Options	26
8.1.1	General	26
8.1.2	Option A	26
8.1.3	Option B	27
8.2	Management system documentation (Option A)	27
8.3	Control of management system documents (Option A)	27
8.4	Control of records (Option A)	28
8.5	Actions to address risks and opportunities (Option A)	28
8.6	Improvement (Option A)	29
8.7	Corrective actions (Option A)	29
8.8	Internal audits (Option A)	30
8.9	Management reviews (Option A)	31

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 4 of 31

Introduction

This Quality Manual describes the quality management system in place at Thunder Scientific's Calibration Laboratory (TSCL). It references quality policies, procedures and other related documents, which together make up the management system.

The manual is primarily, but not exclusively, based upon requirements set forth in ISO/IEC 17025:2017, with its layout largely coinciding with that of ISO/IEC 17025:2017. This offers users the convenience of easily correlating the requirements with the specific TSCL documents supporting those requirements.

Concurrent with the publication of this revision of *Thunder Scientific Calibration Laboratory Quality Manual (CL-1000)*, TSCL is completing the transition from the Calibration Manager (CalMgr) database to QT9™ QMS software's MAINTENANCE module for tracking laboratory standards and equipment. Periodic updates will be made to the quality manual and other supporting documents as necessary to keep pace with any further system/process changes that may come to light as a result of fully incorporating the new module.

Throughout this manual, documents that support or supplement a given requirement are listed within a given paragraph or grouped at the end of the corresponding quality policy section as "Supporting Documents."

Quality Manager
Thunder Scientific Calibration Laboratory

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 5 of 31

1 Scope

This Quality Manual applies to all Thunder Scientific Corporation (TSC) systems, processes and personnel involved with and/or responsible for the execution and/or quality of calibration activities performed by Thunder Scientific Calibration Laboratory (TSCL).

2 References

ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories"

ISO/IEC 17034 "General requirements for the competence of reference material producers"

NIST Handbook 150 "Procedures and General Requirements"

NIST Handbook 150-2 "NVLAP Calibration Laboratories"

ISO/IEC Guide 98-3 "Uncertainty of measurement—Part 3: Guide to the Expression of Uncertainty in Measurement (GUM)"

NIST Technical Note 1297 "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results"

2.1 Internal References

Calibration Certificate Preparation and Approval Procedure (CL-3008)

Calibration History – Instrument (CL-5000)

Calibration Laboratory Quality Policy (CL-2000)

Calibration Measurement Assurance Procedures

Calibration Recall Procedure (CL-3009)

Calibration Status and Safeguarding of Calibration Equipment (CL-3012)

Calibration Work Instructions (CL-4xxx)

Confidentiality Policy (HR-2000)

Control of Documents Procedure (QS-4006)

Control of Nonconforming Product and Services (QS-4002)

Control of Purchased Product or Services (QS-4008)

Control of Records Matrix (QS-5004)

Control of Records Procedure (QS-4007)

Corrective Action Procedure (QS-3001)

Customer Complaint Processing (QS-4010)

Customer Order Process (SAL-4001)

Customer Quote Process (SAL-4000)

Data Protection and Backup Procedure (IT-3000)

Electronic Transmission Procedure (CL-3018)

Feedback Process (CL-3015)

Gifts and Gratuities Policy (HR-2001)

Good Housekeeping Policy (SAF-2000)

Handling of Reference Standards and Calibrated Items (CL-3011)

Internal Audit Process (QS-4003)

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 6 of 31

Laboratory Access Policy (CL-2001)
Laboratory Environment Control Procedure (CL-3007)
Management Review Process (QS-4005)
NVLAP Term/Logo and ILAC MRA Mark Control Policy (CL-2002)
NVLAP Term/Logo and ILAC MRA Mark Control Procedure (CL-3017)
Proficiency Testing: Monitoring the Validity of Results (CL-3010)
Purchase, Receipt and Storage of Consumables Procedure (QS-4004)
Quality Document Numbering System (QS-5001)
Reporting Statements of Conformity (CL-3019)
Reporting Statements of Conformity-Sales Quote ADDENDUM (CL-5015)
Software Development Policy (SW-2001)
Thunder Scientific Corporation Organization Chart (HR-5000)
Thunder Scientific Software Development Overview (SW-2000)
Traceability Flow Charts for each model TSC Generator (CL-4xxx)
Traceability of Calibration Equipment Procedure (CL-3005)
Training Procedure (CL-3014)
TSCL Table of Authorizations (QS-5003)
Workplace Activity Evaluation Procedure (HR-3001)

3 Terms and definitions

3.1 Abbreviations

CalMgr	Calibration Manager Database
CL	Calibration Laboratory
HR	Human Resources
ILAC MRA	International Laboratory Accreditation Cooperative Mutual Recognition Arrangement
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission
IT	Information Technology
NVLAP	National Voluntary Laboratory Accreditation Program
NIST	National Institute of Standards and Technology
PUR	Purchasing
QMS	Quality Management System
QS	Quality Systems
SAF	Safety
SW	Software
TSC	Thunder Scientific Corporation
TSCL	Thunder Scientific Calibration Laboratory

- 3.2 **Calibration Manager (CALMGR)**—Data management system for tracking calibration/servicing of TSCL reference standards and calibration equipment. Final phase-out to be completed first quarter 2020.
- 3.3 **Complaint**--expression of dissatisfaction from any person or organization to TSCL, relating to the activities or results of TSCL, where a response is expected

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 7 of 31

- 3.4 **Decision rule**--formula that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement
- 3.5 **Impartiality**--neutrality; objectivity; lack of prejudice
- 3.6 **Interlaboratory comparison**--organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions
- 3.7 **Intralaboratory comparison**--organization, performance and evaluation of measurements or tests on the same or similar items within TSCL in accordance with predetermined conditions
- 3.8 **Process Map**--An enhanced flow chart used as a planning and management tool that visually describes the flow of a process or part of a process.
- 3.9 **Proficiency testing**--evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons*
- 3.10 **QT9™ QMS**--Quality management software program used for administrating TSCL's document control, training and ISO functions, including but not limited to audits, corrective actions, and management reviews. Also used for tracking calibration/servicing of TSCL calibration standards and calibration equipment.
- 3.11 **TSC** (Thunder Scientific Corporation)—Legal entity of which the Thunder Scientific Calibration Laboratory is a part.
- 3.12 **TSCL** (Thunder Scientific Calibration Laboratory)--body that performs calibrations
- 3.13 **Validation**--verification, where the specified requirements meet the operational needs of the users.
- 3.14 **Verification**--provision of objective evidence that the specifications are correctly implemented

4 General requirements

4.1 Impartiality

- 4.1.1 TSCL's management and workforce are committed to, and take full responsibility for, designing, performing and managing laboratory activities in a manner that preserves impartiality. That impartiality shall not be compromised by commercial, financial or other pressure (e.g. no preferential treatment given to higher volume customers, employees are never asked to meet productivity goals that will jeopardize their impartial approach to the job or the quality of their work, etc.).
- 4.1.2 TSCL makes it an on-going practice to review systems/activities for the risk of impartiality through planned system reviews (e.g. periodic management communiqués, annual Management Review meetings). If such a risk is identified, TSCL takes steps to eliminate or mitigate it using the quality tools at its disposal (e.g. Pareto Analysis, FMEA, 5 Whys, etc.).

Supporting Documents: *Workplace Activity Evaluation Procedure (HR-3001), Gifts and Gratuities Policy (HR-2001), Management Review Process (QS-4005)*

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 8 of 31

4.2 Confidentiality (Quoted here verbatim from ISO/IEC 17025:2017, Paragraph 4.2)

- 4.2.1 [TSCL] shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of its activities. [TSCL] shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between [TSCL] and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.
- 4.2.2 When [TSCL] is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.
- 4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and [TSCL]. The provider (source) of this information shall be confidential to [TSCL] and shall not be shared with the customer, unless agreed by the source.
- 4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on [TSCL]'s behalf, shall keep confidential all information obtained or created during the performance of its activities, except as required by law.

Supporting Documents: *Confidentiality Policy (HR-2000), Data Protection and Backup (IT-3000), Electronic Transmission Procedure (CL-3018)*

5 Structural requirements

- 5.1 TSCL is a defined part of a legal entity--Thunder Scientific Corporation--that is legally responsible for its activities. Thunder Scientific Corporation is incorporated in the state of New Mexico, United States of America. Physical address is 623 Wyoming Blvd. SE, Albuquerque, NM 87123.
- 5.2 TSCL's Calibration Laboratory Manager has overall responsibility for the laboratory activities.
- 5.3 TSCL laboratory activities which are defined in its Scope of Accreditation conform to the requirements of ISO/IEC 17025. No other claims of compliance with ISO/IEC 17025 are made beyond its Scope of Accreditation.
- 5.4 TSCL conducts its activities to comply with the requirements of ISO/IEC 17025, any other accrediting body requirements, the TSCL customers, regulatory authorities and organizations providing recognition. These activities include TSCL activities performed on site at Thunder Scientific and at customer sites during the performance of field calibrations.

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 9 of 31

5.5 TSCL:

- a) organization, management structure, and interrelationships of all personnel who manage, perform or verify work affecting the results of TSCL activities are defined in the *Thunder Scientific Corporation Organization Chart (HR-5000)*;
- b) responsibilities for all personnel who manage, perform or verify work affecting the results of TSCL activities are defined in the *QT9™ QMS Training Module*. The authorities afforded those same personnel are identified in *TSCL Table of Authorizations (QS-5003)*, including assignment of deputies for several key job positions.
- c) maintains necessary documentation (e.g. procedures, policies, work instructions, forms, records) to ensure the consistent application of its activities and to support the validity of its results.

Supporting Documents: *Thunder Scientific Corporation Organization Chart (HR-5000)*, *TSCL Table of Authorizations (QS-5003)*

5.6 TSCL ensures that it has necessary personnel who, without regard for their other responsibilities, have the authority and resources needed to carry out their duties, including:

- a) set-up, upkeep and continuous improvement of the management system;
- b) identification of deviations from the quality management system or from the procedures/work instructions for performing its activities;
- c) initiation of preventive or corrective actions to eliminate or reduce such deviations;
- d) providing TSCL management with information on the performance of the management system/needed improvements;
- e) ensuring the efficacy of TSCL activities.

Supporting Documents: *Thunder Scientific Corporation Organization Chart (HR-5000)*, *TSCL Table of Authorizations (QS-5003)*

5.7 TSCL management ensures that:

- a) all TSCL personnel are involved in regular written and verbal communications regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
- b) when changes to the management system are implemented, the reliability of the management system is maintained.

Supporting Documents: *Management Review Process (QS-4005)*

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 10 of 31

6 Resource requirements

6.1 General

TSCL ensures that it has access to the resources needed to manage and perform its activities per the requirements of ISO/IEC 17025.

6.2 Personnel

6.2.1 All *TSCL* personnel capable of influencing the laboratory's activities shall act without bias, be competent and work in accordance with the management system.

TSCL only uses personnel who are employed by, or under contract to, *TSC*. Where contracted and/or additional technical key support personnel are used, *TSCL* ensures such personnel are competent, supervised to the degree necessary and that they work in accordance with *TSCL*'s management system.

6.2.2 *TSCL* documents the capability requirements for each function influencing the results of its activities in the QT9™ QMS Training Module under Job Title descriptions.

6.2.3 *TSCL* ensures that the personnel are capable of performing the activities for which they are responsible and evaluating the significance of deviations. Refer to the QT9™ QMS Training Module for Skill Set descriptions.

6.2.4 *TSCL* management communicates to personnel their duties, responsibilities and authorities.

6.2.5 *TSCL* has procedure(s) for and retains records for:

- a) determining the competence requirements;
- b) personnel selection;
- c) personnel training;
- d) personnel supervision;
- e) personnel authorizations;
- f) monitoring the competence of personnel.

6.2.6 *TSCL* authorizes personnel to perform specific laboratory activities, including but not limited to, the following:

- a) development, modification, verification and validation of methods;
- b) analysis of results, including statements of conformity or opinions and interpretations;
- c) reporting, review and authorization of results.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 11 of 31

Supporting Documents: *TSCL Table of Authorizations (QS-5003), Training Procedure (CL-3014), Management Review Process (QS-4005), Feedback Process (CL-3015)*

6.3 Facilities and environmental conditions

6.3.1 *TSCL* maintains facilities that are suitable for its activities. *TSCL*'s facilities for calibration, including but not limited to energy sources, lighting and environmental conditions, are designed to facilitate correct performance of the tests and/or calibrations.

TSCL ensures that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Calibration activities are stopped if/when the environmental condition limits are exceeded and do not resume until conditions have been returned to acceptable levels.

6.3.2 *TSCL*'s requirements for facilities and environmental conditions necessary for the performance of its activities are documented in all calibration work instructions by way of reference to *Laboratory Environment Control Procedure (CL-3007)*. The overall laboratory environment is maintained at:

Temperature: 24 °C ± 4 °C Relative Humidity: 40% ± 20%

6.3.3 *TSCL* monitors, controls and records environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results. If a calibration activity requires special conditions, those conditions will be noted in the work instruction for that item.

6.3.4 Measures to control facilities are implemented, monitored and periodically reviewed and include, but may not be limited to:

- a) access to and use of areas affecting *TSCL* activities;
- b) prevention of contamination, interference or adverse influences on *TSCL* activities;
- c) effective separation between areas with incompatible *TSCL* activities.

6.3.5 *TSCL* monitors and records the environmental conditions during all field calibrations to ensure the requirements related to facilities and environmental conditions of *Laboratory Environment Control Procedure (CL-3007)* are met.

Supporting Documents: *Laboratory Environment Control Procedure (CL-3007), Laboratory Access Policy (CL-2001), Workplace Activity Evaluation Procedure (HR-3001), Good Housekeeping Policy (SAF-2000)*

6.4 Equipment

6.4.1 *TSCL* has access to all equipment needed to correctly perform its activities and which have the potential for influencing the results of those activities. 'Equipment' includes, but is not limited to,

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 12 of 31

measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus.

6.4.2 When *TSCL* uses equipment outside its permanent control, it ensures that the requirements for equipment required by ISO/IEC 17025 are met.

6.4.3 *TSCL* has a procedure for handling, transport, storage, use and planned maintenance of equipment that ensures proper functioning and prevents contamination or deterioration.

6.4.4 *TSCL* verifies that equipment conforms to specified requirements—e.g. function and calibration status are checked and shown to be satisfactory--before the equipment is put into/returned to service.

6.4.5 *TSCL* ensures, through the *Calibration Measurement Assurance Procedures* in QT9™QMS Document Control Module, that the equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 *TSCL* ensures that measuring equipment is calibrated when:

- the measurement accuracy or measurement uncertainty affects the soundness of the reported results, and/or
- that calibration is required to establish the metrological traceability of the reported results.

6.4.7 *TSCL's* calibration program is reviewed and adjusted as needed to maintain confidence in the status of calibration.

6.4.8 The status of all calibrated equipment, including next due date where applicable, is made clearly visible by the use of labels as described in *Calibration Status and Safeguarding of Calibration Equipment (CL-3012)*.

Supporting Documents: *Handling of Reference Standards and Calibrated Items (CL-3011)*, *Calibration Status and Safeguarding of Calibration Equipment (CL-3012)*, *Traceability of Calibration Equipment Procedure (CL-3005)*, *Calibration Recall Procedure (CL-3009)*

6.4.9 Equipment that has been over-ranged or mishandled, gives questionable results, or is known to be malfunctioning or outside specifications, is removed from service as soon as possible. It is isolated to prevent its use or clearly labeled or marked as being out of service until it has been verified to perform correctly. *TSCL* analyzes the effect of the defect or deviation from specified requirements and initiates the management of nonconforming work procedure (see 7.10).

Supporting Documents: *Calibration Status and Safeguarding of Calibration Equipment (CL-3012)*, *Control of Nonconforming Product and Services (QS-4002)*.

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to the applicable calibration work instruction.

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 13 of 31

6.4.11 When calibration and reference material data include reference values or correction factors, *TSCL* ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements. Refer to *Calibration History – Instrument (CL-5000)*.

6.4.12 *TSCL* takes practicable measures to prevent unintended adjustments of equipment from invalidating results. Refer to *Calibration Status and Safeguarding of Calibration Equipment (CL-3012)*.

6.4.13 Records are retained for equipment which can influence *TSCL* activities. Refer to *Calibration Certificate Preparation and Approval (CL-3008)*. The records shall include the following, where applicable:

- a) the identity of equipment, including software and firmware version;
- b) the manufacturer's name, type identification, and serial number or other unique identification;
- c) evidence of verification that equipment conforms with specified requirements;
- d) the current location;
- e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
- f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
- g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
- h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological traceability

6.5.1 *TSCL* has established a program in place to maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5.2 *TSCL* ensures that measurement results are traceable to the International System of Units (SI) through:

- a) calibration provided by a competent ISO/IEC 17025 accredited laboratory; or
- b) certified values of certified reference materials provided by a competent producer (ISO/IEC 17034 accredited) with stated metrological traceability to the SI where applicable; or
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with intrinsic, national or international standards.

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 14 of 31

6.5.3 When metrological traceability to the SI units is not technically possible, *TSCL* demonstrates metrological traceability to an appropriate reference, e.g.:

- a) certified values of certified reference materials provided by a competent producer;
- b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

Supporting Document: *Traceability of Calibration Equipment Procedure (CL-3005)*, *Traceability Flow Charts* for each model TSC Generator (CL-4xxx)

6.6 Externally provided products and services

6.6.1 *TSCL* ensures that only suitable externally provided products and services that affect *TSCL* activities are used, when such products and services:

- a) are intended for incorporation into *TSCL*'s own activities;
- b) are provided, in part or in full, directly to the customer by *TSCL*, as received from the external provider;
- c) are used to support the operation of *TSCL*.

6.6.2 *TSCL* has a procedure and retains records for:

- a) defining, reviewing and approving *TSCL*'s requirements for externally provided products and services;
- b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
- c) ensuring that externally provided products and services conform to *TSCL*'s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
- d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 *TSCL* communicates its requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that *TSCL*, or its customer, intends to perform at the external provider's premises

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 15 of 31

Supporting Document: *Control of Purchased Product or Services (QS-4008), Purchase, Receipt and Storage of Consumables Procedure (QS-4004)*

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 *TSCL* has a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

- a) the requirements are adequately defined, documented and understood;
- b) *TSCL* has the capability and resources to meet the requirements;
- c) where external providers are used, the requirements of 6.6 are applied and *TSCL* advises the customer of the specific *TSCL* activities to be performed by the external provider and gains the customer's approval;
- d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

7.1.2 *TSCL* informs the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3 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 are clearly defined, as in *Reporting Statements of Conformity-Sales Quote ADDENDUM (CL-5015)*.

7.1.4 Any differences between the request or tender and the contract are resolved before *TSCL* activities commence. *TSCL* ensures that each contract is acceptable to both *TSCL* and the customer. Deviations requested by the customer are reviewed to ensure that it does not impact the integrity of *TSCL* or the validity of the results.

7.1.5 *TSCL* ensures that the customer is informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review process is repeated and any amendments are communicated to all affected parties.

7.1.7 *TSCL* cooperates with customers or their representatives in clarifying the customer's request and in monitoring its performance in relation to the work performed.

7.1.8 Records of reviews, including any significant changes, are retained by *TSCL*. Records are retained of pertinent discussions with a customer relating to the customer's requirements or the results of the *TSCL* activities.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 16 of 31

Supporting Documents: *Customer Quote Process (SAL-4000), Customer Order Process (SAL-4001), Reporting Statements of Conformity-Sales Quote ADDENDUM (CL-5015)*

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

- 7.2.1.1 *TSCL* utilizes appropriate methods and procedures for all its activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.
- 7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to *TSCL* activities, are kept up to date and are readily available to personnel (see 8.3).
- 7.2.1.3 *TSCL* ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.
- 7.2.1.4 When the customer does not specify the method to be used, *TSCL* selects an appropriate method and informs the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. *TSCL*-developed or modified methods are also allowed for use.
- 7.2.1.5 *TSCL* verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.
- 7.2.1.6 When method development is required, *TSCL* conducts it as a planned activity and assigns competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan are approved and authorized.
- 7.2.1.7 Deviations from methods for all *TSCL* activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

Supporting Documents: *Calibration Work Instructions, Calibration Measurement Assurance Procedures, Control of Documents Procedure (QS-4006)*

7.2.2 Validation of methods

- 7.2.2.1 *TSCL* validates non-standard methods, *TSCL*-developed methods and standard methods used outside their intended scope or otherwise modified. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 17 of 31

7.2.2.2 When changes are made to a validated method, the influences of such changes are determined and where they are found to affect the original validation, a new method validation is performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, are ensured to meet the relevant needs of the customers and are consistent with specified requirements.

7.2.2.4 TSCL retains the following records of validation:

- a) the validation procedure used;
- b) specification of the requirements;
- c) determination of the performance characteristics of the method;
- c) results obtained;
- d) statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling: *TSCL does not currently perform sampling. The guidelines provided in this section will apply to any future sampling activities, should the need arise.*

7.3.1 TSCL ensures that a sampling plan and method is in place when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method addresses the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method is available at the site where sampling is undertaken. Sampling plans are, whenever reasonable, based on appropriate statistical methods.

7.3.2 The sampling method describes:

- a) the selection of samples or sites;
- b) the sampling plan;
- c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

7.3.3 TSCL retains records of sampling data that forms part of the testing or calibration that is undertaken. These records include, where relevant:

- a) reference to the sampling method used;
- b) date and time of sampling;
- c) data to identify and describe the sample (e.g. number, amount, name);
- d) identification of the personnel performing sampling;
- e) identification of the equipment used;

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		

Page 18 of 31

- f) environmental or transport conditions;
- g) diagrams or other equivalent means to identify the sampling location, when appropriate;
- h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of test or calibration items

7.4.1 *TSCL* has a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of *TSCL* and the customer. Precautions are taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item are followed.

7.4.2 *TSCL* has a system for the unambiguous identification of test or calibration items. The identification is retained while the item is under the responsibility of *TSCL*. The system implemented ensures that items are not confused physically or when referred to in records or other documents. The system appropriately, accommodates a sub-division of an item or groups of items and the transfer of items.

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, *TSCL* consults with the customer for further instructions before proceeding and records the results of the consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, *TSCL* includes a disclaimer in the report indicating which results are affected by the deviation.

7.4.4 When an item needs to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded by *TSCL*.

Supporting Documents: *Handling of Reference Standards and Calibration Items (CL-3011)*

7.5 Technical records

7.5.1 *TSCL* ensures that technical records for each *TSCL* activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty that enable the repetition of *TSCL* activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each *TSCL* activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

7.5.2 *TSCL* ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 19 of 31

Supporting Documents: *Control of Records Procedure (QS-4007), Calibration Recall Procedure (CL-3009), Calibration Certificate Preparation and Approval Procedure (CL-3008)*

7.6 Evaluation of measurement uncertainty

7.6.1 TSCL identifies the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, are taken into account using appropriate methods of analysis.

7.6.2 TSCL evaluates the measurement uncertainty for all calibrations, including of its own equipment.

7.6.3 TSCL evaluates test measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimate is made based on an understanding of the theoretical principles or practical experience of the performance of the method.

7.7 Ensuring the validity of results

7.7.1 TSCL has a procedure for monitoring the validity of results. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but is not limited to the following:

- a) use of reference materials or quality control materials;
- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replicate tests or calibrations using the same or different methods;
- g) retesting or recalibration of retained items;
- h) correlation of results for different characteristics of an item;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) testing of blind sample(s).

7.7.2 TSCL monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but may not be limited to, either or both of the following:

- a) participation in proficiency testing;

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 20 of 31

b) participation in interlaboratory comparisons other than proficiency testing.

7.7.3 Data from monitoring activities is analyzed, used to control and, if applicable, improve *TSCL*'s activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported.

Supporting Document: *Proficiency Testing: Monitoring the Validity of Results (CL-3010)*

7.8 Reporting of results

7.8.1 General

7.8.1.1 *TSCL* reviews the test and calibration results and authorizes them prior to release.

7.8.1.2 The results are provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports are retained as technical records.

7.8.1.3 When agreed with the customer, *TSCL* may report the results in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer is retained and readily available.

Supporting Document: *Calibration Certificate Preparation and Approval (CL-3008)*

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 Each report includes at least the following information, unless *TSCL* has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

- a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");
- b) the name and address of *TSCL*;
- c) the location of performance of *TSCL* activities, including when performed at a customer facility or at sites away from *TSCL*'s permanent facilities, or in associated temporary or mobile facilities;
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e) the name and contact information of the customer;
- f) identification of the method used;
- g) a description, unambiguous identification, and, when necessary, the condition of the item;

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 21 of 31

- h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- i) the date(s) of performance of *TSCL* activity;
- j) the date of issue of the report;
- k) reference to the sampling plan and sampling method used by *TSCL* or other bodies where these are relevant to the validity or application of the results;
- l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
- m) the results with, where appropriate, the units of measurement;
- n) additions to, deviations, or exclusions from the method;
- o) identification of the person(s) authorizing the report;
- p) clear identification when results are from external providers.
- q) a statement specifying that the report shall not be reproduced except in full without approval of *TSCL* that provides an assurance that parts of a report are not to be taken out of context.

7.8.2.2 *TSCL* is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where *TSCL* has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it indicates on the report that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports, where necessary for the interpretation of the test results, include the following:

- a) information on specific test conditions, such as environmental conditions;
- b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
- c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
 - o it is relevant to the validity or application of the test results;
 - o a customer's instruction so requires, or
 - o the measurement uncertainty affects conformity to a specification limit;
- d) where appropriate, opinions and interpretations (see 7.8.7);
- e) additional information that may be required by specific methods, authorities, customers or groups of customers.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 22 of 31

7.8.3.2 When *TSCL* is responsible for the sampling activity, test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates include the following:

- a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

NOTE: According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

- b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
- c) a statement identifying how the measurements are metrologically traceable;
- d) the results before and after any adjustment or repair, if available;
- e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
- f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where *TSCL* is responsible for the sampling activity, calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3 A calibration certificate or calibration label does not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

Supporting Documents: *Calibration Certificate Preparation and Approval (CL-3008), Reporting Statements of Conformity (CL-3019)*

7.8.5 Reporting sampling – specific requirements

Where *TSCL* is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports include the following, where necessary for the interpretation of results (In some cases sampling activity/plan is included in the appropriate method):

- a) the date of sampling;
- b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
- c) the location of sampling, including any diagrams, sketches or photographs;
- d) a reference to the sampling plan and sampling method;

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 23 of 31

- e) details of any environmental conditions during sampling that affect the interpretation of the results;
- f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, *TSCL* documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and applies the decision rule.

7.8.6.2 *TSCL* reports on the statement of conformity, such that the statement clearly identifies:

- a) to which results the statement of conformity applies;
- b) which specifications, standards or parts thereof are met or not met;
- c) the decision rule applied (unless it is inherent in the requested specification or standard).

Supporting Documents: *Calibration Certificate Preparation and Approval (CL-3008), Reporting Statements of Conformity (CL-3019)*

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, *TSCL* ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. The *TSCL* documents the basis upon which the opinions and interpretations have been made.

7.8.7.2 The opinions and interpretations expressed in reports are based on the results obtained from the tested or calibrated item and are clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained by *TSCL*.

Supporting Documents: *Calibration Certificate Preparation and Approval (CL-3008), TSCL Table of Authorizations (QS-5003)*

7.8.8 Amendments to reports

Refer to *Calibration Certificate Preparation and Approval (CL-3008)* for specific instructions on how to document changes/corrections to issued calibration certificates.

Supporting Documents: *Calibration Certificate Preparation and Approval (CL-3008)*

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 24 of 31

7.9 Complaints

7.9.1 *TSCL* has a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the handling process for complaints is available to any interested party on request. Upon receipt of a complaint, *TSCL* confirms whether the complaint relates to activities for which *TSCL* is responsible and, if so, shall deal with it. *TSCL* is responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints includes at least the following elements and methods:

- a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken.

7.9.4 *TSCL* is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the *TSCL* acknowledges the receipt of the complaint, and provides the complainant with progress reports and the outcome.

7.9.6 The outcome(s) to be communicated to the complainant is made by, or reviewed and approved by, individual(s) not involved in the original *TSCL* activities in question.

7.9.7 Whenever possible, *TSCL* shall give formal notice of the end of the complaint handling to the complainant.

Supporting Documents: *Control of Nonconforming Product and Services (QS-4002)*, *Customer Complaint Processing (QS-4010)*

7.10 Nonconforming work

7.10.1 *TSCL* has a procedure that is implemented when any aspect of its activities or results of its work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure ensures that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by *TSCL*;
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 25 of 31

- d) a decision is made on the acceptability of the nonconforming work;
- e) where necessary, the customer is notified and work is recalled;
- f) the responsibility for authorizing the resumption of work is defined.

7.10.2 TSCL retains records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of TSCL's operations with its own management system, TSCL implements the appropriate corrective action.

Supporting Documents: *Control of Nonconforming Product and Services (QS-4002), Corrective Action Procedure (QS-3001)*

7.11 Control of data and information management

7.11.1 TSCL has access to the data and information needed to perform its activities.

7.11.2 TSCL information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces within its information management system(s) by TSCL before introduction. Whenever there are any changes, including TSCL software configuration or modifications to commercial off-the-shelf software, they are authorized, documented and validated before implementation.

7.11.3 TSCL information management system(s):

- a) is protected from unauthorized access;
- b) is safeguarded against tampering and loss;
- c) is operated in an environment that complies with provider or TSCL specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- d) is maintained in a manner that ensures the integrity of the data and information;
- e) includes recording system failures and the appropriate immediate and corrective actions.

7.11.4 When TSCL information management system is managed and maintained off-site or through an external provider, TSCL ensures that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 TSCL ensures that instructions, manuals and reference data relevant to its information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers are checked in an appropriate and systematic manner.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 26 of 31

Supporting Documents: *Data Protection and Backup (IT-3000), Calibration Certificate Preparation and Approval Procedure (CL-3008), Electronic Transmission Procedure (CL-3018)*

8 Management system requirements

8.1 Options

8.1.1 General

TSCL has established, documented, implemented and maintains a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 and assuring the quality of its results. In addition to meeting the requirements of Clauses 4 to 7, TSCL implements a management system in accordance with Option A of ISO/IEC 17025.

8.1.2 Option A

As a minimum, the management system of the TSCL shall address the following:

- management system documentation (see 8.2);
- control of management system documents (see 8.3);
- control of records (see 8.4);
- actions to address risks and opportunities (see 8.5);
- improvement (see 8.6);
- corrective actions (see 8.7);
- internal audits (see 8.8);
- management reviews (see 8.9).

8.1.3 Option B (Not applicable to TSCL)

8.2 Management system documentation (Option A)

8.2.1 TSCL management has established, documented, and maintains policies and objectives for the fulfillment for the purposes of ISO/IEC 17025 and ensures that the policies and objectives are acknowledged and implemented at all levels of TSCL's organization.

8.2.2 The policies and objectives address the competence, impartiality and consistent operation of TSCL.

8.2.3 TSCL management supports the commitment to the development and implementation of the management system and to continually improving its effectiveness.

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 27 of 31

8.2.4 All documentation, processes, systems, records, related to the fulfillment of the requirements of ISO/IEC 17025 are included in, referenced from, or linked to the management system.

8.2.5 All personnel involved in *TSCL* activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

Supporting Documents: *Laboratory Access Policy (CL-2001), Calibration Laboratory Quality Policy (CL-2000), Confidentiality Policy (HR-2000), Gifts and Gratuities Policy (HR-2001), Good Housekeeping Policy (SAF-2000), NVLAP Term/Logo and ILAC MRA Mark Control Policy (CL-2002), NVLAP Term/Logo and ILAC MRA Mark Control Procedure (CL-3017), Software Development Policy (SW-2001), Thunder Scientific Software Development Overview (SW-2000)*

8.3 Control of management system documents (Option A)

8.3.1 *TSCL* controls the documents (internal and external) that relate to the fulfillment of ISO/IEC 17025.

8.3.2 *TSCL* ensures that:

- a) documents are approved for adequacy prior to issue by authorized personnel;
- b) documents are periodically reviewed, and updated as necessary;
- c) changes and the current revision status of documents are identified;
- d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- e) documents are uniquely identified;
- f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

Supporting Documents: *Control of Documents Procedure (QS-4006), Calibration Work Instructions (CL-4xxx), Management Review Process (QS-4005), Quality Document Numbering System (QS-5001)*

8.4 Control of records (Option A)

8.4.1 *TSCL* establishes and retains legible records to demonstrate fulfillment of the requirements if ISO/IEC 17025.

8.4.2 *TSCL* implements the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. *TSCL* retains records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality commitments, and records are readily available (see 7.5.).

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 28 of 31

Supporting Documents: *Control of Records Procedure (QS-4007), Control of Records Matrix (QS-5004), Quality Document Numbering System (QS-5001)*

8.5 Actions to address risks and opportunities (Option A)

8.5.1 TSCL considers the risks and opportunities associated with its 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 TSCL;
- c) prevent, or reduce, undesired impacts and potential failures in its activities;
- d) achieve improvement.

8.5.2 TSCL plans:

- a) actions to address these risks and opportunities;
- b) how to:
 - integrate and implement these actions into its management system;
 - evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities are proportional to the potential impact on the validity of TSCL results. Risks and opportunities are normally addressed through management reviews (see 8.9). TSCL addresses risk and opportunities at the annual Management Review Meetings, recording issues identified/discussed at the meeting and assigning follow-ups through the QT9™ QMS ISO Functions>Management Review and Management Review Meeting Issues sections. Risks/opportunities identified between annual meetings will be added into the QT9 notes for the next annual meeting, and will be communicated in the next scheduled bi-monthly Mini Management Review.

Supporting Documents: *Management Review Process (QS-4005)*

8.6 Improvement (Option A)

TSCL associates at all levels approach their work with a mind for continuous improvement, as noted in the 'Thunder Scientific Mission Statement' in *Calibration Laboratory Quality Policy (CL-2000)*. Actions for improvement can be initiated, tracked and documented through either the Management Review Process or the Preventive Action tabs in QT9™ QMS' ISO Functions module.

8.6.1 TSCL identifies and selects opportunities for improvement and implements any necessary actions.

THUNDER SCIENTIFIC CALIBRATION LABORATORY					
Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 29 of 31

8.6.2 TSCL seeks feedback, both positive and negative, from its customers. The feedback is analyzed and used to improve the management system, TSCL activities and customer service.

Supporting Documents: *Calibration Laboratory Quality Policy (CL-2000), Management Review Process (QS-4005), Feedback Process (CL-3015)*

8.7 Corrective actions (Option A)

Corrective actions are initiated, tracked and documented through QT9™ QMS' ISO Functions module.

8.7.1 When a nonconformance occurs, TSCL:

- a) reacts to the nonconformance and, as applicable:
 - takes action to control and correct it;
 - addresses the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformance, in order that it does not recur or occur elsewhere, by:
 - reviewing and analyzing the nonconformance;
 - determining the causes of the nonconformance;
 - determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the management system, if necessary.

8.7.2 Corrective actions implemented are appropriate to the effects of the nonconformities encountered.

8.7.3 TSCL retains records as evidence of:

- a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
- b) the results of any corrective action.

Supporting Documents: *Corrective Action Procedure (QS-3001), Control of Nonconforming Product and Services (QS-4002), Data Protection and Backup (IT-3000), Management Review Process (QS-4005)*

8.8 Internal audits (Option A)

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		
					Page 30 of 31

- TSCL uses the services of an external, independent auditing consultant to perform TSCL's annual internal audits. Any consultant used for this function must be, at a minimum, certified through a nationally recognized quality organization to perform quality audits specific to ISO/IEC 17025 activities.
- TSCL schedules, documents and tracks Internal audits through QT9™ QMS' ISO Functions Module.
- TSC Quality Manager (or designee) is the primary point of contact for internal audits and is responsible for ensuring the internal audit schedule is met.

8.8.1 *TSCL* conducts internal audits at planned intervals (at least once per year) to provide information on whether the management system:

a) conforms to:

— The requirements of ISO/IEC 17025;

---*TSCL's* own requirements for its management system, including its activities;

b) is effectively implemented and maintained.

8.8.2 *TSCL*:

- plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of its activities concerned, changes affecting *TSCL*, and the results of previous audits;
- in conjunction with their audit consultant, defines the audit criteria and scope for each audit;
- ensures that the results of the audits are reported to relevant management;
- implements appropriate correction and corrective actions without undue delay;
- retains records as evidence of the implementation of the audit program and the audit results.

Supporting Documents: *Internal Audit Process (QS-4003)*

8.9 Management reviews (Option A)

All facets of the Management Review are addressed through QT9™ QMS' ISO Functions> Management Review Module.

8.9.1 *TSCL* management reviews its management system at planned intervals (at least once per year) in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of ISO/IEC 17025.

8.9.2 The inputs to management review are recorded and include information related to the following:

THUNDER SCIENTIFIC CALIBRATION LABORATORY

Document Reference:	CL-1000	Revision:	3	Publish Date:	06/04/2020
Document Name:	Thunder Scientific Calibration Laboratory Quality Manual				
APPROVER	Jarred Crouse	Job Title	Calibration Laboratory Manager		
APPROVER	Jeri Thompson	Job Title	Quality Manager		

Page 31 of 31

- a) changes in internal and external issues that are relevant to the *TSCL*;
- b) fulfillment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcome of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the work or in the range of *TSCL* activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review and all decisions and actions related to it are recorded, including:

- a) the effectiveness of the management system and its processes;
- b) improvement of *TSCL* activities related to the fulfillment of the requirements of ISO/IEC 17025;
- c) provision of required resources;
- d) any need for change

Supporting Documents: *Management Review Process (QS-4005)*