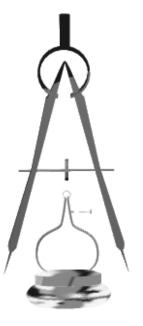


QUALITY MANAGEMENT SYSTEMS MANUAL

0601-000003

REV. A



OFFICIAL TESTWAVE DOCUMENT

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REVISION HISTORY								
REV	DCN#		DESCRIPTION	1	ORIGINATOR	DATE		
Α	05-027-06		INITIAL RELE/	ASE	H.W.LeBas	11/15/04		
	APPROVALS							
ORIGIN		DATE	C.E.O.	DATE	QA, Manager	DATE		
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	FORM 0600-000001-0A 8/01/04							

Calibration and Benefits

- 1. Calibration: A set of operations, performed in accordance with a predefined documented procedure that compares the measurements reported by a given instrument to those made by a more accurate instrument or standard, all for the purpose of detecting and reporting, or minimizing by minor adjustment, errors identified in the given instrument.
- 2. Instruments that do not meet predefined calibration specifications will be issued a Certificate of Calibration showing the failed parameter, and a "Failed Calibration" label will be affixed to the instrument. The client will be invoiced for the quoted calibration, even though their instrument failed calibration.
- 3. The fee for calibration does not include; repair of the instrument, replacement of parts, lamps, batteries, test leads, or major adjustments needed to bring the out-of tolerance instrument back within predefined specifications.
- 4. In the event of a failed calibration, the designated contact at your company will be informed of the nature of the calibration failure, and will be presented with the option of repair or return of the instrument as-is. If the designated contact chooses the repair option, we will proceed with troubleshooting, and a separate repair estimate will be presented. If the repair estimate is declined, there is no additional charge for the repair estimate, and the original calibration fee still applies. If the repair is approved, another calibration will be performed at the conclusion of the repair at no additional charge, and the client will be billed for the initial calibration fee and the repair.

The benefits of purchasing calibrated instrumentation and maintaining it by performing periodic external re-calibration include:

- Assurance of accurate measurements.
- Ability to trace your measurements back to a known and accepted standard.
- Acceptance of your measurements among other countries.
- Tighter site-to-site correlation and a smaller process sigma.
- The meeting of requirements of quality programs such as ISO-9000 & ISO-17025.

Recommended Calibration Intervals

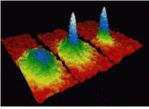
The accuracy of the electronic components used in all instruments drift over time and this equates to instrument error. The effects of time in service, as well as environmental conditions, add to instrument drift. At

guarantee the instrument's measurement integrity. When this happens, you should submit your instrument for calibration. Testwave LLC[™] can recommend a calibration interval that best suits your budgetary requirements and the instrument manufacturer's requirements for

some point in time, the drift causes the instrument's uncertainty to become undefined, meaning, the manufacturer can no longer



SEM of a Charged Diamond Tip



Bose Einstine Condensate

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measurement accuracy.

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External Calibration

When an instrument in service reaches the end of its specified calibration interval, you should return the instrument to a Calibration Laboratory for a calibration service. The instrument's measurement integrity will be compared to external standards of known accuracy. If the results of the measurements do not fall within specified tolerances, adjustments are made to the instrument. In general, the act of external calibration includes:

1. Evaluate the instrument's accuracy to determine if it correlates to a given standard within a given tolerance for accuracy.

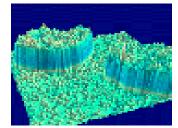
2. If the instrument does not correlate, repeat, or demonstrate linearity within its specified tolerance, make adjustments to the measurement sensor circuitry or internal references.

3. Re-test the instrument to ensure that it operates within its specified tolerance.

4. Issue a calibration certificate, stating that the instrument measures within specification tolerance when compared to a traceable standard. Routine performance of external calibration ensures the measurement accuracy of your instrument.



Topology of a Micro Heater



Chromium on an Atomic Iron Surface

Self-Calibration

Self-calibration is a method whereby an instrument uses onboard (internal) references instead of external references to adjust for optimum measurement accuracy. During self-calibration, the instrument measures the onboard references and adjusts its measurement references to account for changes in accuracy, which may be caused by environmental effects such as temperature, humidity, or altitude.

Self-calibration <u>does not</u> replace external calibration. You must perform a regular external calibration to validate the instrument's internal references used during self-calibration.

Self-calibration and external calibration work together to validate the measurement uncertainty of an instrument.

Please direct questions and comments regarding this Quality Management System Manual to our Quality Assurance Manager:

Mr. Kevin Haddock Testwave LLC 1515 Greg Street Sparks, Nevada 89431-5915 USA Phone (775-356-8378) Fax (775-356-8290)

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Measurement Traceability

One of the most basic requirements of a calibration is proof of traceability to a known and agreed upon standard.

Traceability is defined as an unbroken chain of comparisons, all having stated uncertainties, between your measurement and some national, international, or agreed upon standard. Because standards maintained by national and international bodies are well quantified and maintained, the ability to demonstrate an unbroken chain of comparisons between your measurements and these standards provides advantages such as:

- · Ability to trace your measurement uncertainty back to a known and agreed upon standard.
- Acceptance of your instrument's measurement capabilities between countries.
- Ability to determine the maximum uncertainty associated with your measurements.

Traceability is defined at a number of levels. At the top most level, the Bureau International des Poids et Measures (BIPM) ensures worldwide uniformity of measurements and their traceability to the International System of Units (SI). It does this with the authority of the Convention of the Meter, a diplomatic treaty among 51 nations. The BIPM also takes part in, and organizes, international comparisons of national measurement standards, and carries out calibrations for Member States.

Measurement Uncertainty

The result of any measurement is only an approximate estimate of the "absolute or theoretical" value being measured. In truth, the absolute or theoretical value can never be perfectly measured. This is because there is always some physical limit to how well we can measure a number. For example, the specifications of a digital voltmeter may state that if set to the 10V range, and measuring a signal of 9.5V, the error from the nominal reading may vary by as much as ± 10 mV. Therefore one part of the uncertainty of any measurement taken in the +/-10V DC range is ± 10 mV. We say "one part" because there are other factors that contribute to the total uncertainty of the measurements. These include similar and additional uncertainties associated with all of the devices used to calibrate the digital voltmeter as well as the statistical error associated with the measurement.

If you were to use a digital voltmeter to measure the same value of 9.5V one hundred times, then you would expect to get 100 different answers. The answers would be very close (most likely within ±10mV of each other), but they would not be the same. Many systems will average the returned data and report the average as the measurement. To determine statistical measurement uncertainty, you will need to take the standard deviation of all of the 100 measurements, and this is called the Type A Uncertainty (repeatability). Then, you must locate the instrument manufacturer's published specification for uncertainty, and this is called Type B Uncertainty (reproducibility). Type A and B can be root-squared-summed together to compute Combined Uncertainty. Measurement uncertainty can be reported as Type A only, Type B only, Combined, or Expanded to include a degree of confidence or assurance.

Type A uncertainties are systematic (repeatability) – statistically derived from a series of repeated measurements.

Type B uncertainties are random and systematic (reproducibility) – derived by a variety of other means and conditions.

Expanded Uncertainty - the root-squared sum of Type A and Type B uncertainties, including a coverage factor (k=1.96).

How To Use This Manual

This Manual describes the Quality Management System utilized by Testwave LLC and is organized in accordance to the ISO 17025:1999 (E) Standard, as recommended by the National Institute of Standards and Technology (NIST). This manual describes our general policy and systems of control concerning instrument calibration, while pointing to definitive and specific procedures as required. The structure of this document is designed to parallel the numbering scheme of the ISO 17025:1999 (E) written Standard.

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INTRODUCTION:

Testwave LLC, a premier calibration and metrology laboratory, markets valueadded *calibration and metrology services* to the public and private sectors worldwide. A privately held company since 1999, our mission is to deliver integrity based calibration services, cost effective metrology engineering solutions for individual customer requirements, reputable instrument repair services, sales of industry-known brands of test equipment, and full service test engineering, from integration of hardware and software, to documentation and training. Testwave's engineers and metrologists pioneered the development of their calibration and certification process, which insures the accuracy of your instrument's calibration to NIST traceable working standards. Testwave LLC offers on-site pick-up/delivery, on-site calibration, and expedites services within northern Nevada. Calibrations include a notification recall service that prompts the customer when re-calibration is due. Futhermore, Testwave's shipping and receiving department can handle the packaging and safe delivery of your sensitive instruments via UPS, FedEx, DHL, or other common carrier. We are located at the north end of the Reno-Tahoe International Airport.

Testwave's established calibration disciplines include; pressure, air-flow, temperature, humidity, torque, mass, RPM, vacuum, linear displacement, angular displacement, time-base, acoustical noise, voltage, current, resistance, capacitance, inductance, frequency, and rf power. Our calibration services are designed to meet the exacting standards of manufacturers, water purveyors, weights & measures, ski-lift resorts, aviation service centers, fuel depots, pharmaceutical, assembly, medical laboratories and facilities, telecommunications, commercial broadcast stations, microwave, defense and aerospace. Testwave's calibration disciplines are ISO 17025 accredited and our ISO 17025 Scope of Accreditation is available upon request.

Testwave maintains a sizable reference library of manuals obtained from the original equipment manufacturers. In the event that a customer requests a special test procedure or calibration procedure, or if a procedure does not exist, Testwave's metrologists and test engineers are available to develop a test calibration procedure, or a test specification to accommodate the client's specific requirements. Testwave will not attempt to calibrate an instrument unless an agreed upon calibration procedure is present before the time of calibration. This in part insures the accuracy and integrity of calibrations performed in the Testwave Calibration Laboratory and on-site.

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1. SCOPE:

1.1 Primary Objective:

- 1.1.1 This manual describes the Testwave Quality Management System (QMS) used by Testwave and defines the established criterion used to competently and effectively achieve the quality objectives of the laboratory. The Testwave Calibration Laboratory's Mission Statement is as follows...
 - 1.1.1.1 Maintain all Testwave Calibration standards for pressure, airflow volume, temperature, humidity, torque, mass, RPM, vacuum, linear displacement, angular displacement, timebase, acoustical noise, frequency, voltage, current, resistance, capacitance, inductance, and rf power.
 - 1.1.1.2 Provide reliable metrology measurement services designed to meet or exceed the requirements of the client.
- 1.1.2 Calibration standards have been calibrated by the National Institute of Standards and Technology (NIST), or by an accredited laboratory, and except those derived by ratio techniques and natural physical constants are traceable to the international system of unite (SI). Calibration standards are also validated through internal surveillance, statistical evaluations, and external comparison. Measurements and calibration values produced and recorded by the metrology laboratory are traceable to SI units through NIST.

1.2 Parameters:

- 1.2.1 Measurements, calibrations, and tests performed by the calibration laboratory personnel resulting in ISO 17025 tier certificates, reports, or other summarizing statements are limited to the test parameters listed in the Testwave LLC Scope of Accreditation.
- 1.2.2 The Testwave Quality Management Systems Manual is based on ISO/IEC Guide 17025, used in conjunction with applicable portions of the reference documents maintained in the laboratory, constitute the laboratory's ISO 9001 based quality management system and applicable to the test parameters listed in the Testwave LLC Scope of Accreditation.
 - Testwave LLC Scope of Accreditation: DCO Number 643-000001

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1.3 Application:

The general policies and responsibilities defined in this Quality Systems Manual specify the minimum ISO/IEC 17025:1999 (E) requirements applicable to the critical path of Testwave's Instrument Calibration Processes. This document forms the basis of Testwave's Quality Management System and is used for the development of detailed quality procedures and work instructions. This Quality Manual applies specifically to the Testwave Calibration Laboratory in Sparks Nevada and its field activities. It is the responsibility of all Testwave employees to uphold and support the policies stated in this document. Each Testwave team member is responsible for their quality. Deviations from this manual's requirements require approval of Testwave's Management.

Testwave Management is committed to the customer and the operation of a calibration/test service oriented on quality-based standards such as ISO 9001, ISO 17025 and ANSI/NCSL Z540-1.

The requirements addressed in this manual are intended to meet the international standards described in ISO/IEC Standard 17025:1999 (E) for calibration and test only. Testwave does not provide sampling services and does not reference the subject in this manual.

Testwave LLC Scope of Accreditation: DCO Number 643-000001

2. NORMATIVE REFERENCES:

NOTE: All references described in this quality manual are maintained on file in the laboratory and are accessible to all laboratory staff and management.

- 2.1.1 **ISO/IEC 17025**, 1999 (E), *General Requirements for the Competence of Calibration and Testing Laboratories.*
- 2.1.2 **ANSI/NCSL Z540-1**, 1994, Calibration Laboratories and Measuring and Test Equipment General Requirements.
- 2.1.3 **ANSI/NCSL Z540-2**, 1997 U.S. Guide for the Expression of Uncertainty in Measurement.
- 2.1.4 **NIST HB 44**, 1999, Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices.
- 2.1.5 FLUKE, Calibration: Philosophy In Practice, Second Edition, 1994
- 2.1.6 **ISO 9001**, 2000 (E), *Quality Management Systems Requirements*.

NOTE: This quality manual was written using the references listed in this section. The core of this manual was written following the guidelines in ISO/IEC 17025:1999 (E) and modified to promote a specific quality assurance program for the Testwave Calibration Laboratory.

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3. TERMS & DEFINITIONS:

Refer to Annex A

4. MANAGEMENT REQUIREMENTS:

4.1 **Organization:**

\div Quality Management Systems Manual: DCO Number 0601-000003

Testwave LLC, hereafter referred to as Testwave, is a Quality Measurement Management Organization lead by the Chief Executive Officer (CEO), who is responsible to assume the position of or designate the positions of Business Manager, Lab Manager, Quality Manager, and Technical Manager. As required and with proper expertise, any of those positions may be occupied by the same person. During the absence of key staff, alternates are identified and empowered.

The Testwave Management Team assumes top-down responsibility for its instrument calibration process, repair services, new and used product warranty, and business practices. All Testwave quality procedures are internal practices designed to help the organization meet or exceed its customer's expectations by improving calibration accuracy, reducing calibration cycle time, and offering a wide variety of calibration services. These established practices and procedures are systematically evaluated for continuous improvement and effectiveness over time. The Testwave Management Team has sole responsibility to insure that all employees understand, implement, and maintain the Testwave Quality Management System.

Calibration Practices 4.1.1

DOCUMENT

The testing techniques utilized for measurements reported by Testwave shall ensure accuracy, tolerance, precision, traceability, and/or uncertainty as required by the client.

* (* (* (Lab Standards Calibration Procedure: Customer Pay Calibration Procedure (STD): Customer Pay Calibration Procedure (17025): Dutsource Calibration & Repair Procedure: Calibration Recall Procedure:	DCO Number 0 DCO Number 0 DCO Number 0 DCO Number 0 DCO Number 0	633-000003 633-000004 640-000005			
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4.1.2 Independence

Testwave Management is committed to customer satisfaction and ensures that its calibration laboratory is independent from any commercial, financial, or outside pressure, which might adversely affect the quality of tests and resulting reports.

4.1.3 Accreditation

The Testwave Calibration Laboratory maintains accreditation and demonstrates conformance to the ISO/IEC 17025:1999 (E) Standard. The current certificate of accreditation is prominently displayed on its Internet website and maintained on the wall in the Main Lobby.

4.1.4 Confidentiality

✤ Non-Disclosure Non-Compete Policy: DCO Number 0642-000008

Testwave maintains the confidentiality and proprietary rights of all information including: type of work performed, calibration results, design information, procedures, customer specifications, customer information, purchase orders, and correspondence to the extent allowable by State and Federal Law. All laboratory personnel are informed and bound by this policy. All employees are bound by an agreement of non-disclosure and non-compete. In addition, non-disclosure agreements are required when Testwave engages in the exchange of sensitive information with its clients.

4.1.5 Legal Entity

Testwave is a Limited Liability Company that can be held legally responsible for its activities under the statutes governing the State of Nevada.

4.2 Quality System:

4.2.1 Customer Commitment

Testwave conducts measurements under defined environmental conditions while using calibration techniques and NIST traceable standards that provide evidence of conformity of product to determined requirements. The Testwave Calibration Laboratory follows calibration procedures issued in part by the U.S. Federal Government through the *Government Industry Data Exchange Program* (GIDEP), or the most current manufacturer's specifications, and/or procedures that are signature to the instrument undergoing calibration. Data collected and reported at the time of calibration is reported "as-is", and is protected by Testwave's internal Data Integrity Reporting Policy.

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4.3 Document Control:

- Document Control Template: DCO Number 0600-000001
 Document Control Procedure: DCO Number 0601-000004
- Document Control Proceed
 Part Numbering System:
- Data Integrity Policy:
- DCO Number 0601-000004 DCO Number 0632-000001 DCO Number 0631-000008

4.3.1 DCO Overview

Testwave maintains a formal Document Control Center and a part numbering system. All procedures under document control include a document title, a document number with revision code, a revision history index, a table of contents, page numbers, a confidentiality statement, and a signature approval bar. The Document Control Center is maintained and managed electronically on the company server under the Document Control Center IntraNet. After signature approval, hard copies are embossed with the Testwave Seal, stamped "Original" and placed in the Quality Assurance filing cabinet. Only one hard copy of the original is maintained at all times. Revision history for each document is maintained on the corporate server. The Quality Management Systems Manual is the nucleus of the Document Control Center's architecture and references or calls out satellite procedures needed to reinforce the Quality Manual. These satellite procedures may also reference sub-procedures of their own. All procedures are referenced by title and document control number (DCO number).

4.3.2 Authority

4.3.2.1 Testwave management has the designated authority to modify or update the Quality Management Systems Manual. The Quality Manual is annually reviewed and updated as needed. The Chief Executive Officer is responsible for the final approval of all changes made to the Quality Management Systems Manual, and the revised document takes effect when signed and dated by the Chief Executive Officer.

4.3.2.2 This Quality Management Systems Manual (along with associated appendices and references) is available to laboratory staff and management. Management is responsible for providing the documented quality system and ensuring that all staff familiarize themselves and comply with the policies and procedures established in the Quality Management Systems Manual and its associated documentation.

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4.3.2.3 The Testwave Quality Management Systems Manual is intended to act a method of communication for Testwave's clientele and Testwave personnel. It is Testwave's intention to accurately convey the nature of its processes and business practices to its customers through the use of the Quality Management Systems Manual and to provide a reference to all Testwave employees. The Quality Management Systems Manual should accurately reflect the day-to-day activities of the business to the client.

4.3.3 Controlled Copies

Controlled copies of this Quality Management Systems Manual are issued to Testwave management and are made available to laboratory personnel. Approved copies are made available to customers through the Testwave Internet Website.

4.4 Review of Requests, Tenders, and Contracts:

Calibration Quote Procedure: DCO Number 0640-000006

Testwave establishes and maintains a procedure for the review of requests, tenders, and contracts. The policies for these reviews leading to a contract for testing and/or calibration ensure that:

4.4.1 The determined calibration requirements include adequate methods that are well defined, documented, and understood by the laboratory personnel.

4.4.2 The laboratory has the capability and resources to meet the given requirements from the client.

4.4.3 The appropriate test and/or calibration method is capable of meeting the clients' specified requirements.

4.4.4 Differences between the request or tender and the contract are resolved before work commences. Each contract is acceptable to both the laboratory and the client.

4.5 Subcontracting of Tests and Calibrations:

♦ Outsource Calibration and Repair Procedure: DCO Number 0640-000005

When the Testwave Calibration Laboratory subcontracts work for any reason, (e.g., workload, need for further expertise, temporary incapacity) this work shall be placed with a competent subcontractor. A competent subcontractor is one that complies with the standard(s) required by the customer.

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4.5.1 Testwave advises the client of the arrangement and gains approval of the client, preferably in writing.

4.5.2 The laboratory is responsible to the client for the subcontractor's work, except when it is the client or a regulatory authority that specifies a particular subcontractor.

4.5.3 The laboratory maintains a register of all subcontractors for tests and/or calibrations and a record of the evidence of compliance with the specific standard for the work in question.

4.6 **Purchasing Supplies and Services:**

Purchasing Procedure:	DCO Number 0631-000001
Vendor Approval Procedure:	DCO Number 0631-000004
Vendor CARS Procedure:	DCO Number 0631-000007

Testwave uses the above procedures for the selection and purchasing of supplies and services that affect the quality of its tests and/or calibrations. These procedures apply to the purchase of reagents and laboratory consumable materials relevant to calibrations performed by the laboratory.

4.6.1 Testwave inspects and/or otherwise verifies purchased supplies, reagents, and consumable materials that affect the out-going quality of tests and/or calibrations as complying with standard specifications as defined in the methods for the tests and/or calibrations in which they are intended.

4.6.2 Testwave evaluates suppliers of critical consumables, supplies, and services, which may affect the quality of testing and calibration. Testwave maintains a list of preferred vendors.

4.7 Service to the Client:

Testwave's staff shall afford clients or their representatives' full co-operation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, to the extent in which the laboratory can ensure confidentiality to other clients, or when normal work flow is not unduly impeded or interrupted (by appointment only). Testwave maintains effective communications and feedback to the client during this process.

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4.8 Complaints:

Customer Complaint Procedure: DCO Number 0631-000006

Testwave has a policy and procedures for the resolution of complaints received from clients or other parties. Records of all complaints and of the investigations and corrective actions taken by the laboratory are the responsibility of the Quality Assurance Manager and the Chief Executive Officer. Testwave's policy is to provide the client with excellent service. In the unlikely event of a complaint, we treat it as an opportunity for improvement (Section 4.9 Non-conformity and Section 4.10 Corrective Action).

4.9 Control of Non-Conformities:

*	Incoming Inspection Procedure:	DCO Number 0634-000003
*	Internal Audit Procedure:	DCO Number 0601-000002

Where the identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with the required standards, Testwave's management shall ensure that the appropriate areas of activity are audited in accordance with its own Internal Audit Procedure as soon as possible. Non-conformities are resolved through the corrective action process.

4.10 Corrective Action:

Internal Corrective Action Procedure: DCO Number 0634-000008

Corrective action required by discovery of an error in the herein system or measurement affecting quality is documented, evaluated, and resolved using the Internal Corrective Action Procedure. This procedure utilizes root-cause analysis to identify the true impetus of the problem, selects, and resolves the specific issue to prevent reoccurrence. Corrective actions are consistent with the magnitude and the risk of the problem.

4.11 Preventive Action:

Testwave is committed to its continued improvement through the reduction of uncertainties in our measurement standards, design of error resistant calibration, test procedures, and the use of root-cause analysis. Opportunities for needed improvement and potential sources of non-conformances, either technical or with the quality system, shall be identified formally as part of corrective action and assigned improvement projects informally during normal work duties. Identified opportunities may result in action plans being developed, implemented, and monitored as simple as a "just do it" fix.

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4.12 Control of Records:

Document Control Procedure: DCO Number 0601-000004

- **4.12.1** Testwave retains customer calibration records for a minimum of five (5) years. Calibration interval and test records are retained for two (2) years, or as required by the customer. Internal Calibration Standards records are retained for the life of the standard plus the aforementioned. Calibration and test procedures are retained for the current year plus two (2) years after revision on decommissioning as are general records and internal calibration records of support instruments not effecting calibration results. The records for test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty, and to enable the test or calibration to be repeated under conditions as close as possible to the original. These records shall include the identity of personnel responsible for the performance of each test and/or calibration, and checking of results.
- **4.12.2** The laboratory ensures the safety and security of records. Records include those with information required by regulation, or associated with original test observations, calculations, and reported results. Measurement data is recorded in permanent form, in bound notebooks, or on standard forms. Permanent ink is used to record the actual data and no erasures or whiteouts are made. Corrections are made to data by drawing a single line through the entry and initialing the change, with a note as to why the change was made. Measurement records contain sufficient detail to, if necessary, permit the repetition of measurements.
- **4.12.3** Records are digitized into Testwave's server using Adobe Acrobat PDF format. The server is backed up daily and the results are stored off site.

4.13 Internal Audits:

4.13.1 Outgoing Quality Audits

- Calibration Audit Procedure: DCO Number 0601-000005
- Internal Corrective Action Procedure: DCO Number 0634-000008

Testwave maintains a system of control that supports the outgoing quality of calibrations and/or test reports performed for the client. Audits of the processes, individual tests, calibrations, and documentation are inspected for confirmatory to internal, contractual, and pertinent standards' requirements. Non-conformities identified during the outgoing quality inspection process are referred to the Quality

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Manager, Calibration Lab Manager, and the Metrologist responsible for the nonconformity. Strategies for possible corrective action are proposed at this time. Approved recommendations are fed back to the calibration process through corrective action.

4.13.2 Internal Audits

Internal Audit Procedure: DCO Number 0601-000002

Testwave management or their designate conducts internal audits and periodic checks per a schedule designated in the internal audit procedure. Internal audits are designed to ensure that the laboratory's policies and procedures as set out in the quality manual are being followed. Non-conformities discovered during an internal audit are resolved per sections 4.9 and 4.10 of this manual.

4.14 Management Reviews:

Testwave Management or their designate conducts a review of the laboratory's quality system and calibration activities on a quarterly basis. These reviews are intended to ensure the continuing suitability and effectiveness of the Testwave Quality Management System. In addition, the quarterly review is intended to initiate the necessary changes or improvements needed to retain the calibration laboratory's accreditation. The quarterly review shall take into account...

- **a.** The suitability of present policies and procedures;
- **b.** Incident reports from managerial and supervisory personnel;
- **c.** The outcome of recent internal audits;
- d. Corrective and preventive actions;
- e. Assessments by external bodies;
- **f.** The results of inter-laboratory comparisons;
- **g.** Changes in the volume and type of the work;
- h. Client feedback;
- i. Complaints;
- **j.** Other relevant factors, such as quality control activities, resources and staff training.

Management reviews are done as part of the scheduled internal audits. Compressive customer audits may be use to augment these audits.

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5. TECHNICAL REQUIREMENTS:

5.1 General:

The Testwave Calibration Laboratory recognizes that many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from...

- a. Human factors.
- **b.** Accommodation and environmental conditions.
- c. Test and calibration methods and method validation.
- d. Equipment.
- e. Measurement traceability.
- **f.** Handling of test and calibration items.

The extent to which the above factors contribute to the total uncertainty of measurement differs considerably between the types of tests and between the types of calibrations. The Testwave Calibration Laboratory shall take into account these factors when developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.2 Personnel:

***** Employment Procedure:

DCO Number 0642-000002

Testwave Management ensures the competence of all personnel who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. Testwave Management formulates its training goals with respect to the education, training, and the skills of the particular laboratory personnel. Testwave maintains a training record for each employee affecting the quality of calibrations.

5.3 Accommodations and Environmental Conditions:

SS Housekeeping Procedure: DCO Number 0642-000010

5.3.1 Testwave Laboratory facilities utilized for testing and/or calibration, including, but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of tests and/or calibrations.

5.3.2 Testwave takes steps (e.g., evaluation of temperature specification of standards and devices under calibration) to ensure that environmental

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conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when tests and/or calibrations are undertaken at sites other than the Testwave Calibration Laboratory in Sparks Nevada.

5.3.3 Testwave monitors, controls, and records relevant environmental conditions, as determined in section 5.3.2, in this manual. Tests and calibrations are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations until such time as the condition is alleviated.

5.3.4 Testwave takes special precautions between neighboring areas in which there are incompatible activities. Measures are taken to prevent cross-contamination in these neighboring areas. Testwave's Sparks Laboratory is designed such that no incompatible areas exist. However, when in the field, measures are taken to prevent cross-contamination in these neighboring areas.

5.3.5 Access to and use of all areas affecting the quality of the tests and/or calibrations are controlled from casual access.

5.3.6 It is the responsibility of each team member to maintain the work area in a clean and tidy manner. Daily 5S measures are taken to ensure good housekeeping practices in the calibration laboratory and throughout the business (*Sort, Straighten, Shine, Standardize, & Sustain*).

5.4 Test and Calibration Methods (including uncertainty of measurement):

5.4.1 Unless specifically required by the customer, Testwave uses test and/or calibration methods appropriate for the tests and/or calibrations it undertakes - preferably those published as international, regional or national standards. Testwave ensures that it uses the latest valid edition of a calibration/test method or procedure unless it is not appropriate or not possible to do so. When necessary, the method or procedure shall be supplemented, or adapted to Testwave's methods, with additional details to ensure consistent application. When standard methods or procedure uses different calibration standards than available to Testwave, the resulting method or procedure is confirmed to Testwave's standards.

5.4.2 Unless the client specifies the calibration method to be used, Testwave shall select an appropriate calibration method that has been published in-either international, regional, or national standards. Testwave may also select calibration methods issued by technical organizations, scientific journals, or the original manufacturer's procedure. Testwave developed methods or methods adopted by Testwave may also be used if they are appropriate for the intended use, validated, and confirmed. The

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client is informed as to the method chosen. Testwave confirms that the method or procedure is suitable for its intended use and they can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation is repeated.

5.4.3 Testwave will advise the client when the method proposed by the client is considered to be insufficient, inappropriate, or out of date.

5.4.4 Introduction of Testwave developed test and calibration methods for internal use shall be a planned and assigned to qualified personnel equipped with adequate resources.

5.4.5 When it is necessary to employ calibration methods that are not covered by standard methods, these are subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed is validated and confirmed appropriately before use.

Measurement Uncertainty Calculation Procedure: DCO Number 0633-000006

5.4.6 Testwave utilizes procedure # 0633-000006 when estimating and reporting the uncertainty of measurement for calibrations performed under the ISO 17025 tier of calibration services. When estimating the uncertainty of measurements, uncertainty components, which are of importance in the measurement, are taken into account using appropriate methods of analysis. Reasonable estimation used during the uncertainty calculation method, the measurement scope, and make use of previous experience and validation data.

5.4.7 Testwave validates non-standard methods, laboratory designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation and conformation is as extensive as is necessary to meet the needs in the given application or field of application. The calibration laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

5.4.8 Validation has two meanings in this manual:

- **a.** Assuring that a procedure contains the steps necessary to meet the test/calibration requirements.
- **b.** From ISO 9000: confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

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Testwave observes both of these principles. The second meaning is part of the process that works with uncertainty estimation to assure that Testwave's standard meets the test/calibration requirement.

5.4.9 Techniques used for the determination of the performance of a non-standard method must consider the following:

- **a.** Calibration using reference standards or reference materials;
- **b.** Comparison of results achieved with other methods;
- **c.** Inter-laboratory comparisons;
- d. Systematic assessment of the factors influencing the result;
- e. Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

5.4.10 When changes are made in validated non-standard methods, the influence of such changes carried out should be documented and if appropriate a new validation is to be carried out.

5.4.11 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability, limit of reproducibility, robustness against external influences, and cross-sensitivity against interference from the matrix of the test object) are assessed for the intended use and the clients' needs.

5.4.12 Validation includes the specification of the requirements, determination of the characteristics of the method, a check that the requirements can be fulfilled by using the method and a statement on the validity of the method.

5.4.13 Validation is always a balance between costs, risks, and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness, and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.5 Equipment:

5.5.1 The Testwave Calibration Laboratory is furnished with items of measurement and test equipment required for the correct performance of the tests and/or calibrations (including, preparation, calibration, processing, and analysis of test and/or calibration data). In these cases where the laboratory needs to use equipment outside its permanent control, it ensures that the requirements of this manual are met.

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5.5.2 Testwave ensures that the equipment and its software used for testing and calibration are capable of achieving the accuracy required, and comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs have been established for key quantities or values of the instruments where these properties have a significant effect on the results. Before placed into service (before lab use), equipment is calibrated to establish that it meets its or the laboratory's predetermined requirements.

5.5.3 Equipment is operated by authorized personnel only. Up-to-date instructions on the use and maintenance of equipment (including relevant manuals provided by the manufacturer of the equipment) are readily available for use by laboratory personnel.

5.5.4 When practical, equipment and its software used for testing and calibration significant to the result are uniquely identified. Labels are affixed to instruments that are included in the Testwave Calibration Laboratory system. Labels provide a visual indication of the instrument's status. Calibration labels may be attached to the instrument's case and/or trimmed of non-essential information when required.

5.5.5 Records are maintained for each item of equipment and its software significant to the tests and/or calibrations performed. The records include the following:

- **a.** Identity of the item of equipment and its options;
- **b.** Manufacturer's name, type identification, and serial number or other unique identification;
- c. Checks that equipment complies with the specification;
- **d.** Current location, where appropriate;
- e. The manufacturer's instructions, if available, or reference to their location;
- **f.** Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration;
- **g.** Maintenance plan, where appropriate, and maintenance carried out to date;
- **h.** Damage, malfunction, modification or repair to the equipment.

5.5.6 Testwave maintains a procedure for the safe handling, transport, and storage of laboratory measurement equipment necessary to ensure proper functionality and to prevent contamination or deterioration.

***** Equipment Handling & Storage Procedure: DCO Number 0642-000011

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5.5.7 Calibration Laboratory equipment that has either been subjected to overloading or mishandling, gives suspect results, has been shown to be defective or outside specified limits, taken out of service. It is isolated to prevent its use, or clearly labeled or marked as out of service until it has been repaired and shown by calibration or test to perform correctly.

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration is labeled, coded or otherwise identified to indicate the status of calibration including date calibrated and the date or expiration criteria when recalibration is due. See Section 5.5.4

5.5.9 In the unlikely event that equipment goes outside the direct control of the laboratory, the laboratory ensures that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of a given laboratory instrument or standard, the calibration laboratory verifies the calibration status of the suspect instrument or standard per a designated internal procedure.

5.5.11 Where calibrations give rise to a set of correction factors, the calibration laboratory uses procedures to ensure that copies of lab software and firmware are correctly updated by part number and revision.

5.5.12 Test and calibration equipment, including both hardware and software, are safeguarded from adjustments, which would invalidate the test and/or calibration results. Safe guarding techniques are stated in procedure # 0633-000002.

5.6 Measurement Traceability:

Lab Standards Calibration Procedure: DCO Number 0633-000002

5.6.1 General:

Testwave standards and test equipment that make quantitative measurements, or provide precision sources are calibrated. Such instruments significantly affecting the measurement integrity of tests and calibrations conducted by Testwave are calibrated before being placed into service, and/or monitored for stability as part of the measurement control program. Standards and equipment that are unreliable or that have exceeded the calibration interval, are removed from service until repaired and calibrated.

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5.6.2 Measurement Traceability:

5.6.2.1 The established program of calibration and verification of measuring and test equipment is designed to ensure that the measurements made by Testwave are traceable to SI units through national standards of measurement. All laboratory calibration reports contain a statement that the standards used are traceable to the National Institute of Standards and Technology.

5.6.2.2 To augment evidence of traceability, Testwave participates in measurement control programs, proficiency tests, and other interlaboratory collaborations.

5.6.3 Standards Calibration/Verification:

5.6.3.1 Laboratory standards are calibrated by the National Institute of Standards and Technology or by an accredited laboratory.

5.6.3.2 Laboratory standards are monitored by the measurement control programs established in the Testwave Calibration Laboratory, and are under the control of trained metrologists. These standards are stable and their variability estimated through statistical means.

5.6.3.3 Standard(s) are re-calibrated if damage occurs or if any significant change is observed in the measurement control program.

5.6.4 Standards:

5.6.4.1 Testwave monitors its standards through a measurement control program, which ensures the required measurement integrity of its tests. This monitoring program includes:

- **a.** Statistical data from check standards.
- **b.** Results from inter-laboratory comparisons.

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5.6.5 Measuring and Test Equipment:

5.6.5.1 Testwave laboratory equipment is calibrated internally or by a calibration laboratory whose traceability to NIST has been validated through an accreditation process. A calibration interval is established for all equipment utilized in the Testwave Calibration Laboratory.

5.6.5.2 When appropriate, each item of equipment is labeled, marked, or otherwise identified to indicate its calibration status. See section 5.5.4.

- **a.** All Testwave equipment used with nominal values and corrections are labeled indicating the calibration status.
- **b.** All Testwave equipment used to facilitate comparison between a standard artifact and an unknown is labeled "*Used for Comparisons Only No Calibration Required.*"

5.6.5.3 The calibration of Testwave Laboratory equipment is conducted at a frequency necessary to ensure that the equipment remains within tolerance during its use in the calibration laboratory. Frequency of calibration is based on a review of calibration, maintenance, and repair history. The Testwave Lab Manager conducts reviews and review records that are maintained on the company server.

5.7 Handling of Test and Calibration Items:

*	Shipping Procedure:	DCO Number 0634-000001
*	Receiving Procedure:	DCO Number 0634-000002
*	Material Handling Procedure:	DCO Number 0642-000005
*	Equipment Handling & Storage Procedure:	DCO Number 0642-000011

5.7.1 The above procedures are for the transportation, receipt, handling, protection, storage, retention and disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and the interests of the laboratory and the client.

5.7.2 Testwave has an established "Item Number System" used for identifying items submitted for calibration. The identification of the instrument is retained throughout the entire time that the instrument remains in the laboratory for calibration, and when the instrument returns for calibration recall. This system is designed and operated to ensure that any item submitted for calibration has its own Testwave unique identity, and cannot be confused physically when referred to in records, other documents, or status.

5.7.3 Upon receipt of the test item for or calibration, abnormalities or departures from normal or specified conditions, as described in the test or

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calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding, and shall document the discussion.

5.7.4 The Testwave staging and shipping area is part of the calibration laboratory, and is controlled by procedures. The laboratory personnel follow all handling instructions provided with an item for test and/or calibration. Testwave accommodates provisions for storage and security necessary to protect the condition and integrity of the secured items submitted by the client for test and/or calibration.

5.8 Assuring Test and Calibration Results:

Quality Management Systems Manual:
 Data Integrity Policy:
 Lab Standards Calibration Procedure:
 Customer Pay Calibration Procedure (STD):
 Customer Pay Calibration Procedure (17025):
 Outsource Calibration & Repair Procedure:

Testwave utilizes established quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data are recorded in such a way that trends are detectable, and, where practicable, statistical techniques are applied to the reviewing of the results. This monitoring is planned and reviewed, and may include, but not be limited to the following:

- **a.** Regular use of certified reference materials and/or internal quality control using secondary reference materials;
- **b.** Participation in inter-laboratory comparison or proficiency testing programs;
- c. Replicate tests or calibrations using the same or different methods;
- d. Re-testing or re-calibration of retained items;
- e. Correlation of results for different characteristics of an item.

5.9 **Reporting Results:**

*] * (*] *]	Data Integrity Policy: Lab Standards Calibration Procedure: Customer Pay Calibration Procedure (STD): Customer Pay Calibration Procedure (17025): Measurement Uncertainty Calculation: Outsource Calibration & Repair Procedure: Calibration Recall Procedure:	DCO Number (DCO Number (DCO Number (DCO Number (DCO Number (DCO Number (DCO Number ()633-000002)633-000003)633-000004)633-000006)640-000005		
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5.9.1 General:

The results of each, or series of test(s) or calibration, carried out by Testwave are reported accurately, clearly, unambiguously and objectively; all in accordance with specific instructions stated in the test or calibration methods.

The results reported in a test report or a calibration certificate issued by Testwave, whether hardcopy or electronic, include all of the information requested by the client for the interpretation of the test or calibration results.

In the case of tests or calibrations performed for a client, or in the case of a written agreement with the client, the results may be reported in a simplified way.

5.9.2 Standard Test Reports and Certificates of Calibration:

All standard test reports and standard calibration certificates issued by Testwave shall include the following information:

- **a.** A document title (e.g. "Test Report" or "Report of Calibration");
- **b.** The name and address of the Testwave laboratory and location where the tests and/or calibrations were carried out (e.g. outsourced calibration, on-site calibration);
- **c.** A Testwave Control Number (e.g. 04n-xxxx) used to identify the test report or report of calibration;
- **d.** A page number and the total number of pages used in the test report or report of calibration;
- e. The name and address of the client;
- **f.** A description of the instrument submitted for calibration, including the manufacturer's name, model name or model number, options, client's asset number (if any), instrument serial number, and any attached or included accessories;
- **g.** The date of receipt and the date of test and/or calibration;
- **h.** The agreed upon calibration interval;

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- i. A reference to the calibration procedures and standards used by the laboratory to calibrate the said instrument submitted for calibration, and to include the calibration date of all standards used;
- j. The test and/or calibration results, where appropriate, the units of measure, a test tolerance, and a statement of conformity to specification or compliance (e.g. Within Tolerance $\pm 1.00\%$ of Full Span);
- **k.** The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or report of calibration (e.g. metrologist, quality assurance);
- **I.** Where relevant, a disclaimer to the effect that states that the results of this test and/or calibration relate only to the said instrument under test.
- **m.** Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
- **n.** Additional information which may be required by specific methods, clients, or groups of clients;
- **o.** The environmental conditions (e.g. temperature, humidity, and altitude) under which the calibrations were made which have an influence on the measurement results report of calibration only.
- **p.** A statement of measurement traceability to N.I.S.T. report of calibration only.
- **q.** A statement of Testwave's compliance with requirements and/or specifications to its present accreditations;
- r. Test data as required or contracted.
- **s.** The calibration certificate shall relate only to quantities and the results of functional tests performed and, if a statement of compliance with a specification is made, it shall identify which clauses of the specification are met or not met.

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5.9.3 ISO 17025 Test Reports:

In addition to the requirements listed in section 5.9.2, Testwave's ISO 17025 tier of test reports shall, where necessary for the interpretation of the test results include:

- **a.** Deviations from, additions to, or exclusions from the test method, and information regarding unattainable test conditions;
- **b.** A statement of the report of calibration's compliance to the requirements and/or specifications;
- **c.** When relevant to the validly of the test results, a statement of estimated Uncertainty of Measurement may be required by the client.
- **d.** Where appropriate and needed opinions and interpretations. A graphical line plot of 10 repeated measurements of a given test parameter, where the upper and lower control limits are defined by the \pm limits of the uncertainty of measurement calculation, a measure of central tendency, standard deviation, and the specified instrument tolerance.
- e. Any additional information that may be required by specific methods, clients, and/or groups of clients;

5.9.4 ISO 17025 Calibration certificates:

In addition to 5.9.2, Testwave ISO 17025 calibration certificates contain the following tier requirements when purchased:

- **a.** The environmental conditions under which the calibration was made that influence the measurement results.
- **b.** A statement of estimated Uncertainty of Measurement. This statement can include Type A, and/or Type B uncertainty, or Combined Uncertainty (root-squared-sums of Type A and Type B). All reported uncertainties include a coverage factor (k=2). The Testwave metrologist, for reasons of feasibility, chooses the appropriate method of reporting uncertainty, unless otherwise specified by the client.
- c. A statement of measurement traceability to SI units through N.I.S.T.

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5.9.5 Reporting Adjustment Data (all tiers):

When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported in the test report and/or report of calibration.

5.9.6 Calibration Interval (all tiers):

Testwave internal calibration intervals are calculated and based on the reliability of the instrument or class of instruments. Testwave's reliability is established at 90% in-tolerance at the time of recalibration. If the out-of-tolerance rate is greater than 10% or for any other reason to question the instrument or class of instruments interval is reduced. This knowledge is offered to our clients as an option. However, a certificate of calibration (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client.

5.9.7 Opinions and interpretations (test reports only):

When opinions and interpretations are included in test reports, Testwave documents the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such in the test report.

NOTE: Opinions and interpretations included in a test report may include, but are not limited to the following:

- **a.** An opinion on the statement of conformity of the results with requirements;
- **b.** Fulfillment of contractual requirements;
- **c.** Recommendations on how to use the results;
- d. Guidance to be used for improvements.

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5.9.8 Testing and calibration results obtained from subcontractors:

When the test or calibration report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.

When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.9.9 Electronic transmission of results:

In the case of transferring test reports and/or reports of calibration by facsimile, optical storage media, or other electronic means, Testwave makes transfers in a systematic manner that meets the client's pre-defined protocol. All transferred electronic files are formatted in Adobe PDF and locked to prevent alteration or misuse.

5.9.10 Amendments to test reports and calibration certificates (all tiers):

Amendments made to a test report or calibration certificate after issue are made only in the form of a further document, or data transfer, which includes the statement "*Supplement to Test Report and/or Calibration Certificate*." When it is necessary to issue a completely new test report and/or calibration certificate, it is uniquely identified and contains a reference to the original that it replaces.

5.9.11 Sub-Contracting Conditions:

Testwave subcontracts in the special circumstances where technical, safety, or efficiency issues dictate. Subcontracting is only conducted with ISO/IEC 17025 accredited laboratories, which meet the requirements of NIST HB 143 and/or NIST HB 150. Testwave maintains a list of approved ISO/IEC 17025 subcontract calibration laboratories, and their Scopes of Accreditation. All test reports and/or calibrations which contain data from subcontracted work include the following statement:

"This report contains data which was produced by a subcontracted laboratory Accredited to ISO/IEC 17025 for the purpose of calibration and/or test."

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ANNEX A (Terms & Definitions)

Calibration:	A set of operations that establish under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding known value of a measurand.
Calibration Progr	am: Calibration programs include external calibration providers and internal calibration providers; calibrations performed; and the management, control systems, and procedures defining the calibration program.
NMI:	A National Metrology Institute, considered being the primary source of standards in the country. In the United States, the National Institute of Standards and Technology (NIST) is considered a NMI.
Equivalence:	An acceptance of the competence of NMIs, accreditation bodies, and/or accredited calibration laboratories in other countries as being essentially equal to NMI, accreditation body, and/or accreditation organizations within the United States.
SI Units:	The International System of Units. A series of quantities in two classes.
Base Units:	Regarded as dimensionally independent units (meter, kilogram, second, ampere, Kelvin, mole, and candela).
Derived Units:	Formed as products of the powers of the base units according to the algebraic relations linking the quantities concerned.
Uncertainty of M	easurement: A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.
Traceability:	A property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties of measurement.
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ANNEX B (Credits & Insignias)

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This quality manual was independently audited and evaluated by McCullough Consulting.

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