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Calibration System Manual

Electronic Measurements Group (EMG), Calibration and Repair Laboratories, Standards Laboratories, Worldwide Customer Service and Support (WCSS), and Manufacturing Test and Calibration (Manufacturing Process Centers)

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Copyright Notice

Agilent Technologies
EMG Calibration Facilities

This document constitutes the Calibration System Manual and is integrated into our documented Business Management System. Authority to modify this document in any manner is reserved to be the responsibility of EMG Business Management System Manager and the EMG Calibration Program Manager. Revisions are indicated on page one of this document.

Foreword

This calibration system manual has been written for all organizations within the Electronic Measurements Group (EMG) of Agilent Technologies.

Responsibility for the document contents belong to the EMG Business Management System Manager and the EMG Calibration Program Manager.

1.0 Purpose

This document describes procedures employed by Agilent Technologies' Calibration Facilities for the calibration of instruments. The paragraph numbering used in this document is consistent with that used in ISO/IEC 17025:2005(E).

Section 4 of this document describes the calibration facilities' Business Management System. This document is designed for use in conjunction with both the EMG Business Management System Manual and the local department's documented process and procedures.

Section 5 of this document defines the system to be used for calibrations performed by departments within EMG:

- Describes calibration facilities' policies, procedures, and processes established to meet the requirements of ISO/IEC 17025:2005(E), ANSI/NCSL Z540.1-1994 (R2002), ANSI/NCSL Z540.3-2006, ISO 10012:2003(E) and the needs our customers and/or external registration bodies.
- Provides a common standard upon which EMG facilities' calibration and Business Management Systems are built.
- Provides a detailed description of how calibration is accomplished at Agilent Technologies.

2.0 Scope

This document is used by all facilities providing calibration services that include, but are not limited to:

- Standards Labs
- Calibration Labs
- Manufacturing Test and Calibration Centers (Manufacturing Process Centers)
- WCSS Calibration Operations
    - The scope of Calibration capabilities for Agilent Technologies Service centers is located within the Siebel application
- Hardware Test Centers

Local calibration facility processes and procedures will be required to supplement, but not supercede, the Calibration System Manual.

This manual may be used as a Business Management System Manual in areas of Agilent Technologies that provide calibrations.

3.0 Definitions

This document uses the definitions of International Vocabulary of Metrology (ISO/IEC Guide 99:2007), ISO/IEC 17025:2005(E), ANSI/NCSL Z540.1-1994 (R2002) and ANSI/NCSL Z540.3-2006, as well as other terms applied to our calibration activities described below.

Instruments

Measuring and Test Equipment (M&TE) – This comprises all of the measuring instruments, measurement standards, reference materials, and auxiliary apparatus that are necessary to perform a measurement. This term includes measuring equipment used in the course of testing and inspection, as well as, that used in calibration.

Measurement Standard – A material measure, measuring instrument, reference material or system intended to define, realize, conserve or reproduce a unit or one or more known values of a quantity to serve as a reference. Items used for measuring standards generally fall into one of the four following categories:

- **Primary** - A standard, which has the highest metrological qualities in a specified field. This standard is generally compared directly to national standards.
- **Reference** - A standard, generally in the highest order in a calibration system, which establishes the basic accuracy values for that system. A reference standard is used to link measurement traceability to an external laboratory.
- **Transfer** - Are designated measuring and test equipment used in a calibration system as a medium for transferring the basic values of reference standards to lower echelon transfer standards or measuring and test equipment. In some cases a transfer standard may be used as a working standard.
- **Working Standard** - A material, measuring instrument, reference material or system intended to define, realize, conserve or reproduce a unit or one or more known values of a quantity.

Measuring Instrument – A device intended to make a measurement, alone or in conjunction with, supplementary equipment. Furthermore, all products that meet the following criteria are considered to be a measuring instrument:

- The product has published specifications
- The specified parameters are traceable to national, international or consensus standards
- A periodic calibration interval has been assigned

Measuring System – This consists of one or more measurement devices, and any other necessary system elements, interconnected to perform a complete measurement.

Metrology Operations

Standards Labs – Highest measurement traceability chain within Agilent Technologies.

Calibration and Repair Labs – Typically, measurements are traceable through Standards Labs

Manufacturing Test and Calibration (Manufacturing Process Centers) – Typically, measurements are traceable through Calibration and Repair Labs.

Calibration – The set of operations that establishes, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, and the corresponding standard or known values derived from the standard and then making a qualitative statement as to the measurand's suitability for use.

Standard Method of Calibration – Any calibration method recommended by the manufacturer.

Verification – Evidence by calibration that specified requirements have been met.

> **Note:** The result of verification leads to a decision either to restore to service, adjust, repair, downgrade, or declare obsolete. In all cases, documentation of the verification performed is maintained in the measuring instrument's individual record.

Calibration Service – The comparison of a measurement system or instrument of unknown accuracy to a measurement standard of known accuracy to detect, correlate, report and eliminate inadequate performance through adjustment, if appropriate.

Verification Service – The comparison of a measurement system or instrument to its specifications, followed with a judgment on its compliance with said specifications.

Characterization – The process of comparing a measurement system or instrument to a measurement standard with known accuracy and reporting the values and uncertainties of the measured parameters. There are no accuracy specifications verified or adjustments performed on the instrument.

Functional Test –The purpose of a functional test is to demonstrate that products are operating properly when the products do not meet calibration criteria as specified in the Agilent Calibration Certificate Program Guidelines. This may also apply to instruments that may not make traceable measurements (examples: protocol analyzers, bit error rate analyzers) or to those instrument repairs that do not affect the measurement integrity of the equipment (example: changing the transport tape of an 8510B).

Preventive Maintenance (PM) – Cleaning, electrical safety testing, and mechanical inspection of measuring and test equipment (does not include calibration).

Traceability – The ability to relate individual measurement results to national standards or nationally accepted measurement systems through an unbroken chain of comparisons, all having defined uncertainties.

An accredited calibration is de-facto proof of traceability. Thus, a national standards laboratory certificate number or an accredited calibration certificate number should not warrant further analysis of the traceability path.

> **Note:** Traceability to national standards does not imply that the linkage must necessarily be to the national references of the country in which the Agilent Technologies facility operates.

Calibration Interval – A predefined period of time between successive calibrations.

Approved Signatories –Individuals who are authorized by management to sign laboratory calibration or test reports and certificates. In some cases authorisation by a local accreditation body may also be necessary.

Calibration Condition Received Classifications

As Received and As Shipped (or As Completed) Condition - The condition of the instrument prior to, and on the completion of, the calibration service. The following statements are used to describe these states:

In Specification – This classification applies if all of the instrument's measured parameters are found to not exceed specification.

Out of Specification – This classification applies if one or more of the instrument's measured parameters are found to exceed specification.

Malfunctioning – This classification applies in the event that, upon receipt: 1) catastrophic or operational failure makes it impossible to take data; or, 2) all data taken is found to be within specification, but complete data is not available due to a partial operational failure of the instrument.

Significant Out of Tolerance Condition – An out-of-tolerance condition in a measuring device or standard which causes a corresponding out-of-tolerance condition at the next level down in the calibration chain. A significant out of tolerance condition is defined by either of the following:

1. The out of tolerance standard has caused the degradation of a test uncertainty ratio (TUR) to less than 4:1.

2. An original test uncertainty ratio (TUR) of less than 4:1 (as stated on the performance test record) has been further degraded.

Non-Conforming Work – This is defined as calibration services that are found during an audit or as the result of the detection of a problem with (or using) a procedure, method or equipment, to be faulty.

Use of Guard Bands – See theAGILENT INSTRUMENT CALIBRATION Format for ISO 17025 and ANSI Z540.3 Measurement Reports, Section 4.3.5 located at http://quality.communications.agilent.com/calcert/. See also the WCSS Adjustment & Guardband Policy at http://sharedoc.collaboration.agilent.com/sites/wcss-ssu/sd/ssu%20bqms/quality_metrology/metrology/policy%20documents/adj%20guard%20policy%20-%20epsg1063880.pdf.

Measurement Decision Risk – The probability that an incorrect acceptance decision related to a measurand's As Received or As Shipped/Completed condition will result from a measurement.

4.0 Management Requirements

4.1 Organization

4.1.1 This document applies to EMG, which is an organization within Agilent Technologies. The facilities within EMG are capable of providing or obtaining a complete array of testing and/or calibration services.

4.1.2 The description of how Agilent Technologies has established its calibration program is described in Section 1, "Purpose", in this document.

4.1.3 The laboratory management system for each calibration area covers all work performed by the calibration facilities. Please see Section 2, "Scope", in this document.

4.1.4 The organizational arrangements are such that the calibration facilities operate as an organization; therefore, the organizational arrangements do not adversely affect the quality of the calibration services. Agilent discourages monetary or other compensation that would constitute a conflict of interest and affect the technical judgment of individuals involved in the calibration of product. Engineering, responsible for design of the test process, is generally separated from production (organizationally) and not rewarded on monthly shipment metrics. Agilent Technologies Standards of Business Conduct emphasizes uncompromising integrity. Quality metrics are reviewed by management to evaluate the ongoing quality of work.

4.1.5 General Organizational Requirements

a.) The calibration facilities' managers have the necessary authority and resources to ensure that planning, organizing, directing and controlling the operation is provided to meet quality and business expectations without departing from established procedures. See section 5.2, Personnel, for more information.

b.) Every effort is made to ensure that employees working within the calibration facilities environment are not directly subjected to work related pressures that could compromise the quality of their work (See 4.1.4). Agilent Technologies Standards of Business Conduct addresses employee integrity and ethics. Agilent managers are required to review these standards with their employees every year.

Employees are trained to utilize specific processes to accomplish their tasks and have a clear understanding of what must be done to realize positive results. Those processes have been designed with quality measures in place to ensure conformity of the deliverables.

c.) As noted earlier, employees review Agilent Technologies Standards of Business Conduct each year. Customer confidential information, proprietary rights, and special requests regarding a customer's calibration are not shared.

Example: Normally, customer data regarding their equipment or its calibration information is not transmitted by direct data transmission. When direct data transmission is required, Agilent Technologies provides data security through internal networking systems that are installed behind an Internet firewall. Many layers of computer security are employed. For faxed information, the appropriate customer's employee is notified that a fax will soon be transmitted.

d.) Agilent Technologies Standards of Business Conduct contains company policy regarding conflict of interest situations.

e.) The management structure is depicted in the calibration facilities' organizational charts. These charts demonstrate the interaction of all parts of the calibration facilities. Local documentation is needed to satisfy this requirement.

f.) Organizational charts, detailed job descriptions, various process flow charts and written procedures, clearly indicate the responsibility, authority and connectivity of everyone directly involved in performing calibration activities within the calibration facilities. Local documentation is needed to satisfy this requirement.

g.) Calibration activities are supervised by personnel who have extensive background experience and who are often assisted by team or group leaders as necessary to ensure the quality of the calibrations being performed. The calibration facilities staff understands the objective of calibration and how to assess results. Local documentation, such as training records, is needed to satisfy this requirement.

h.) Each calibration facility has access to at least one person who is technically expert in calibration and metrology. That person may be a metrologist, technical supervisor, technical specialist, engineering support/management or the metrology manager and has the responsibility to make decisions regarding the technical validity of all aspects of the calibration process. That person may call upon resources in the EMG Metrology Leadership Team for consultation on unique problems or those that require escalation to be resolved.

i.) Each calibration facility is supported by a quality representative who is responsible for coordinating all quality functions including auditing, vendor assessments, training recommendations, assessment of the effectiveness of the Business Management System and

the assistance of employees with the concepts and tools necessary to use within quality improvement projects and initiatives.

j.) The calibration facilities will identify and document alternate or backup personnel to the technical and quality management positions. As is common in many companies and organizations, management from another area may be asked to temporarily assume the tasks of an absent manager.

k.) Personnel are made aware of the relevance and importance of their activities through the use of a system of cascading business priorities and objectives. These business priorities are communicated to personnel in various ways at the discretion of the group's general manager.

4.1.6 EMG management communicates the effectiveness of the management system through the use of newsletters, coffee talks, meetings and other appropriate means.

4.2 Business Management System

4.2.1 This document, in conjunction with the EMG Business Management System Manual and the calibration facility's policies, procedures, guidelines, processes, manuals and other locally defined documentation, comprise the documented Business Management System employed by the EMG calibration facilities.

4.2.2 a), b), c) Refer to the quality policy below:

Agilent Technologies designs and manufactures test, measurement and monitoring instruments, systems and solutions, and semiconductor and optical components. The company serves markets that include communications, electronics, and life sciences. We are committed to building on a foundation of more than 60 years of manufacturing experience and the Hewlett-Packard heritage of excellence in all that we do. Agilent Technologies will work with partners, customers, and employees, to produce quality products and services that make a clear contribution to our customers, using clear standards of business conduct and total quality management practices.

Agilent Technologies Quality Policy Statement

All Agilent Technologies managers and employees support implementation of this policy in accordance with their roles and responsibilities in the organization.

d.) All calibration facilities personnel are required to become familiar with the quality documentation in order to implement its processes and procedures.

e.) This document demonstrates management's commitment to the implementation of the requirements of ISO/IEC 17025:2005, as well as other applicable standards as outlined in Section 1, and to the continual improvement of the effectiveness of the business management system that it describes.

4.2.3 EMG has established a business management system that is administered at the highest level within this group and is described in the EMG Business Management System Manual. The management's commitment to the establishment and continual improvement of this system is described in this manual and its supporting documentation.

4.2.4 EMG's top management communicates to all employees through several methods including, but not limited to, coffee talks, newsletters and direct presentations. Through these methods, all employees are made familiar with Agilent Technologies' Quality Policy which expresses the importance of meeting customer, statutory and regulatory requirements.

4.2.5 The calibration facilities' Business Management System is composed of various levels of documentation that include quality policy and objectives, information on the many processes utilized in the calibration facilities, and key work instructions necessary to complete assigned tasks. The aggregate combination of quality documentation, policy, responsibilities, processes, work instructions, technical manuals, and procedures, form the documented Business Management System.

4.2.6 The responsibility of the technical management is to ensure that sound metrological practices are followed. The technical manager is designated as the technical specialist, engineering support/management or the metrology manager. These personnel are competent in making decisions concerning metrological practices, procedures, and results.

The responsibility of the quality manager/supervisor to ensure that the Business Management System is implemented and maintained in compliance with the standards listed in the "Purpose" section of this document.

4.2.7 When changes to the management system are planned and implemented, the integrity of the system is taken into account. This activity is monitored and assured through diligent review of the system by management as described in the EMG Management Review Process.

4.3 Documentation Control

The Business Management System is comprised of many internal policies, procedures, guides, processes, user reference materials, manuals, and other locally defined documentation that is strategically placed within the organization. The intention is to maintain a system that is professional and of real value. A bureaucratic approach is actively discouraged. Details of the document management program are contained in the EMG Document Control Procedure (Document # E100)

4.4 Review of requests, tenders and contracts

4.4.1 Procedures are in place to review requests, tenders and contracts. These procedures ensure that:

a) The laboratory has appropriate methods and procedures,

b) The laboratory has the needed resources in equipment and personnel,

c) The laboratory selects an appropriate calibration method that meets the needs of the customer.

4.4.2 Records of each review are maintained and include any customer paperwork and notes of conversations with the customer during and after the formal Contract Review phase of the process. These records shall be maintained in accordance with Agilent Technologies General Retention Schedule.

4.4.3 Customer paperwork for instruments that are subcontracted to another vendor for calibration is also reviewed. Particular attention is given to the following:

- The selected subcontractor must be approved by the local calibration facilities quality personnel,
- The customer must be informed that a subcontractor will be utilized.

4.4.4 The customer is informed of any deviations to the previously agreed-upon contract.

4.4.5 When a contract must be amended, the contract review process is used and changes are communicated to the appropriate personnel.

4.5 Subcontracting of tests and calibrations

4.5.1 As with selection of a suitable subcontractor for calibration of Agilent Technologies own equipment, a documented vendor appraisal/performance monitoring procedure is used. Each entity must administer a vendor control system that evaluates potential subcontractors on the basis of criteria suitable for the work being requested. Such criteria may come from one or more of the following sources:

- ISO/IEC 17025:2005
- ANSI/NCSL Z540.1-1994 (R2002)
- ANSI/NCSL Z540.3-2006
- ISO 9001:2008
- Specific Agilent or customer criteria

Accredited vendors will not be subject to appraisals, audits or surveys if they have accreditation for the parameters being calibrated.

4.5.2 Provided it is not contrary to contracted conditions (with particular regard to shipment to another country), the calibration facility may transfer customer instruments requiring standard Agilent Calibration to another Agilent facility without prior notification of the customer. In the case of equipment needing Standards Compliant or Accredited Calibration, the customer shall be notified prior to its shipment to any other Agilent facility. The customer shall also be advised of an intention to ship to any subcontractor (i.e. non-Agilent facility) for any service-type.

4.5.3 The calibration facilities are responsible for work performed by a subcontractor unless a regulatory agency or the customer specifies the subcontractor to be used.

4.5.4 Records of evaluation/audit of external calibration sources are maintained locally or with the calibration facility's Quality department. Copies of individual audits may be available on a networked server while the originals reside within the calibration facility's Quality department.

4.6 Purchasing services and supplies

4.6.1 Through a working relationship with our suppliers, the calibration facilities ensure that materials, products, and services purchased in support activities for customer equipment, conform to specified requirements. Should it be necessary to purchase parts or supplies from vendors outside of Agilent Technologies that will be used in support of customer equipment, a supplier approval against contractual and quality requirements will be made. Vendor assessments, as required, will be conducted with the assistance of Agilent Technologies quality personnel. When it is necessary to purchase calibration services from external suppliers, only vendors who meet established requirements as listed in section 4.5.1, and have been approved by the Agilent Technologies quality personnel will be utilized.

4.6.2 Consumable materials that affect the quality of calibration, such as mineral oil for baths or saturated salt compounds for humidity calibrations, are inspected and/or verified prior to use. Records of the inspection or verification are maintained. (It should be noted that not all calibration facilities use these types of consumable materials.)

4.6.3 Purchasing documents for items that affect quality are reviewed to ensure that the requirements of the Business Management System are met.

4.6.4 Records of approved suppliers are on file. (See 4.5.4)

4.7 Service to the Customer

4.7.1 Customers are permitted to visit our calibration facilities, provided we are given adequate scheduling notice. These visits may be in the form of a formal audit of our calibration processes or to observe particular calibration procedures. Appropriate measures are taken to ensure the confidentiality of all client equipment, materials and information present in the calibration facility.

Customers are routinely notified of delays in the originally scheduled finish date for services.

4.7.2 Feedback is obtained from our customers through various methods (see section 9 of the EMG Business Management System Manual).

4.8 Complaints

Upon receipt of a complaint, the quality or technical manager or appointed person will conduct an investigation of the complaint. If the complaint is related to the processes in the laboratory, it will be communicated to the management team for possible process improvement action. If the complaint is calibration results related, the technical manager or appointed person will investigate the cause. If the investigation result casts doubt on past calibrations of customer instruments, the customer will be advised of the particulars and given the option to return the affected instrument to the laboratory for a no-charge, re-test, re-calibration or verification as necessary.

The quality manager/supervisor is responsible for ensuring that complaints are resolved in a timely manner. Such complaints and corrective actions are reviewed in the quality management review. Refer to section 4.15 of this document.

4.9 Control of nonconforming testing and/or calibration work

4.9.1 In addition to the policies, processes and procedures outlined in the EMG Control of Nonconforming Product document (doc # 103), which applies to all EMG entities, those performing calibrations must also abide by the following:

4.9.1.1 When non-conforming work is reported, an evaluation is performed as described in the paragraphs below. Non-conforming work can be the discovery of an improper calibration method, a mistake in a calibration procedure, an out of limit condition of the environment, or an out of tolerance condition of one of the standards. Out of tolerance (OOT) conditions are the most common form of non-conforming work. If the out of tolerance condition will significantly affect the calibration of other devices, the calibration facility will identify all suspect calibrations. For more information, see the EMG Out of Tolerance Procedure document.

a.) The production supervisor, lead technician, manager, or quality representative, has the responsibility to halt work, or withhold calibration certificates or reports when nonconforming work is identified.

b.) Problems identified that relate to procedure, method, environment, or audit, will be evaluated as prescribed in the corrective action section of this Calibration System Manual.

c.) Notification of out of tolerance conditions or other sources of nonconforming work must be sent to owners of affected equipment. It is the responsibility of the equipment owner or designated functions with technical expertise to determine the impact on their processes and to resolve the out of tolerance conditions of their own equipment. See the EMG Out of Tolerance Procedure document.

Should the non-conforming work be significant as defined in section 3 of this document, the customer is notified, advised of the nature and extent of the incident, and given the opportunity to decide his course of action as he evaluates the impact of the non-conforming work on his product or service. In cases where the customer considers the non-conforming work condition to be significant to his process, the liability of the calibration facility will be limited to a re-calibration of the affected equipment at no charge.

d.) The personnel identified in paragraph 4.9.1.a will make the decision when to resume calibration after a significant nonconforming event. Should there be any disagreement between production and quality, the decision will be escalated to the next level of management. Until a decision is reached, all affected work will be terminated.

4.9.1.2 If the nonconforming work shows evidence that the event may recur, corrective or preventive action will be implemented as described in the EMG Corrective and Preventive Action Requirements document (Doc # E101).

4.10 Improvement

The EMG Business Management System, of which this calibration system is a part, is continually improved through the use of Agilent's quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review as described in the EMG Business Management System Manual. A map of all of the processes and their interrelationships can be found on the EMG BMS Website at: http://epsg.communications.agilent.com/quality/bms/040318_docMap.asp .

4.11 Corrective action

4.11.1 General Procedures for dealing with corrective action are contained in the EMG Corrective and Preventive Action Requirements document (Doc # E101) and supplemented by

the calibration facility's Business Management System documentation describing compliance to "Corrective Action".

4.12 Preventive action

4.12.1 General Procedures for dealing with preventive action are contained in the EMG Corrective and Preventive Action Requirements document (Doc # E101) and supplemented by the calibration facility's Business Management System documentation describing compliance to "Preventive Action".

4.13 Control of records

4.13.1 General Procedures for handling of general records produced by the calibration facilities are contained in the EMG Quality Records Requirements document (Doc # E104) and are supplemented by the calibration facility's Business Management System documentation describing the control of quality records.

4.13.2 Technical Records

4.13.2.1 In addition to the requirements stated above, the control of technical records must also conform to the following:

Calibration records, specifically derived data (where applicable), original observations, and certificates of calibration, are generated for each calibration performed. Original observation is interpreted to mean measured values or pass/fail results, as appropriate. The personnel involved in the process of performing the calibration are identified on these records by appropriate means. Copies of these records are retained by the laboratory in either paper or electronic form. This allows replication of the calibration for the customer if needed. The laboratory manages its M&TE calibration records in an identical manner.

The laboratory retains calibration records for a period consistent with corporate guidelines. For more information concerning corporate record retention guidelines, refer to the General Retention Schedule produced by Records and Information Management (RIM).

4.13.2.2 Records of each calibration and associated data are recorded at the time of the calibration event. This information is identifiable to each calibrated device by a unique equipment identification number or service order number.

4.13.2.3 When mistakes occur on a manually prepared calibration report or test record, the entry is crossed-out with a single line and the correct value is entered. The person making the correction will initial or sign by the entry. Both the correction and the signature must be in ink. Changes to electronically stored records will be subject to similar measures to avoid loss of the original data.

In the case of automated calibrations, data is generated by the software and is considered to be error free. Quality records stored electronically are routinely backed up.

4.14 Internal audits

The purpose of the Audit Program is to assure that the Quality and Metrology systems are fully implemented and the integrity of the systems are maintained. The audit frequency for various facilities will be documented on audit schedules. Detailed procedures for audits are contained in the EMG BMS Assessment Program Manual.

4.15 Management reviews

4.15.1 The calibration facilities perform a program of reviews conducted by the entity's executive management that conforms to the requirements set forth in the EMG Management Review Process document (Doc # E106).

5.0 Technical Requirements

This section defines the calibration system for business entities within EMG.

5.1 General

Appropriate factors affecting calibration results are accounted for when:

- Developing and validating calibration methods and procedures
- Designing facilities
- Establishing qualifications for personnel
- Developing training for personnel
- Selecting standards

5.2 Personnel

5.2.1 All personnel are trained in accordance with the EMG Training Process Requirements.

The laboratory has a staff of sufficient size and knowledge to satisfy the capacity and technical capability needed to support its workload. Personnel are hired to fulfill specific job requirements. Some formal training may be required as a method of providing employee technical education. Some entities utilize on-the-job training (OJT). OJT gives the employee the opportunity to experience new situations or service a broader product range by learning in a controlled environment where assistance is readily available through a mentor. Implementation of OJT is per management discretion and continues until a mentor is satisfied that the required level of competence has been attained.

Acquired experience is also valuable in supporting specific products and, if substantiated, can be a training qualifier for those products. Qualification criteria include, but are not limited to, the following aspects:

- Supervisor knowledge and assessment during qualification,

- Support of a minimum number of products to qualify,
- Previous support of related products or product lines

5.2.2 Training and education goals for the calibration facilities personnel are reviewed each year as part of the employee job performance process. Available training may include formal training classes, attendance of metrology conferences, etc. Training records are available for each member of the calibration facilities.

Under the direction of the Technical Manager and/or Manager of the lab, the technicians can develop technical areas of specialization. The calibration facilities technicians are responsible for creating and continuously improving processes, procedures, and software in the assigned area(s) of responsibility. These activities form much of the basis for technician technical training. The technician with primary responsibility for an area also oversees any day-to-day cross training of other technicians in that technical area.

5.2.3 Temporary and/or contract technicians or other personnel are subject to the same requirements as permanent employees depending on work responsibilities. These personnel work under the direct supervision of a mentor until appropriately trained.

5.2.4 Job descriptions are located on the Job Family Matrices website within the Meidas application.

5.2.5 Technicians are authorized by management to perform calibrations (or repairs) or operate particular types of equipment. This authorization is documented in training or competency records which must include the date upon which the scope and level of competence was decided. Historical records must be kept as evidence of qualification to perform the stated work at the time of its provision.

5.3 Accommodation and Environmental Conditions

5.3.1 In the design of the calibration environment, consideration has been given to the operating specifications of the required M&TE and the operating specifications of the unit under test. The facility is air-conditioned and consideration has been given to cleanliness, temperature and humidity. Where necessary, the laboratory power line supply is regulated with proper line conditioning to ensure proper operation of the measurement and test equipment. Consideration will be given to the environmental requirements of the most sensitive measurement performed. Environmental conditions are reported as a range of acceptable values. Generally, the required

operating temperature range for the calibration facilities is **(23 ± 5) Deg C**. The required relative humidity is **(5 to 80) % and non-condensing**. Options for these requirements are: 1) as stated above, 2) tighter than stated limits above, 3) range of product specifications which requires actual temperature or humidity to be reported.

Note: Some facilities, such as primary standards laboratories will require tighter limits that will be dictated by the type of calibrations being performed and/or the equipment being used.

Note: When calibration is performed at a customer's site, Agilent monitors and records the environmental conditions, Agilent requires a typical set of conditions in which to perform the calibrations. If the customer is unable to provide an area that meets these conditions, Agilent Technologies will not perform the calibration.

5.3.2 Each calibration facility is equipped with an environmental monitoring system. Data is maintained by a department with the necessary capability to demonstrate conformance with locally defined ambient conditions. For example, this may be site facilities engineering. This evidence is retained for a period that complies with the EMG Quality Records Requirements.

If at any time the temperature or humidity limits are exceeded, the calibration operation shall be suspended until that condition has been investigated and corrected.

5.3.3 Activities are effectively separated when the failure to do so could compromise the integrity of the calibrations being performed. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to the calibration facility is controlled. Proper ESD precautions are taken when handling M&TE and the unit under test. ESD requirements are set forth in the Agilent Technologies ESD Control Manual.

5.3.5 Each member of the calibration facility is responsible for the area's general housekeeping and for complying with all Health & Safety regulations. Common areas and building systems, such as air conditioning, are maintained by a workplace services group or contract personnel who shall meet Agilent security and access requirements.

5.4 Calibration Methods and Method Validation

5.4.1 General Calibration and verification procedures shall be maintained and followed in the calibration facilities. Procedures may consist of the performance tests contained in the

instrument's Operating and Service Manual, for Agilent Technologies equipment, or its equivalent. Also, procedures may originate and be written by the manufacturing process center or calibration/standards lab. Calibration procedures may also be contained entirely in software.

Instructions for calibrating or verifying measuring and test equipment are maintained as part of each calibration facility's locally defined Business Management System documentation, where applicable.

Agilent calibration and verification procedures are documented and we do not deviate from the methods described in those procedures unless required by specific customer calibration/verification requirements.

5.4.2 Selection of Methods Most calibration procedures are developed by Agilent Technologies calibration/standards labs and instrument manufacturing process centers using established measurement techniques. Each calibration procedure will be uniquely identified.

Published generic standards (calibration procedures) such as those distributed by ASTM, ASME or ANSI are not normally used for calibration in EMG.

Should a customer request a method of calibration not normally used the request will be negotiated with the customer.

5.4.3 Laboratory-Developed Methods If a procedure doesn't exist, or special calibrations are required which are not covered by a procedure, the technical manager or quality manager will administer a program to write a calibration procedure, which will properly verify the instrument to specification, accuracy, and resolution.

5.4.4 Non-Standard Methods If it is necessary to utilize a non-standard method for calibration, the method will be validated before use.

5.4.5 Validation of Methods When it becomes necessary for the laboratory to develop or modify a calibration procedure, a validation process will be used. See the EMG Measurement Method/Measurement Uncertainty Validation Process Requirements [http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_measurement_method__mu_validation_requirements%20-%20epsg1059922.pdf] and the EMG Guideline for introducing option 1A7 & A6J [http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_guideline_on_the_introduction_of_options_1a7_a6j_1038158%20-%20epsg1038158.pdf]

5.4.6 Estimation of Uncertainty of Measurement The preferred methodology used for deriving the collective uncertainty of measurements is in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" or derivative documents (such as EA–4/02). Other methods have been used for earlier analysis and are deemed to be acceptable.

5.4.7 Control of Data

5.4.7.1 When written calculations are performed as a part of the calibration, or data is hand scribed, the technician performing the calibration will review the data for correctness before completing the calibration procedure. A second party may also make a review as part of a sample inspection process if implemented by the entity.

Data reports printed by a computer will be reviewed for correctness by the technician making the measurement at the completion of the calibration procedure.

5.4.7.2 Software used for the calibration of instruments is controlled using the procedures in the entity's locally defined Business Management System documentation.

Automated calibration programs do not necessarily duplicate the data points in the manual procedures, but are metrologically correct and verify the instrument. Master and working software copies are controlled.

Basic principles are:

- Software is documented and a validation procedure is used to ensure its adequacy.
- Access to the program code or data is controlled by the laboratory supervisor. The systems used in the support of calibration are password protected and have a hierarchical level of access.

5.5 Equipment

General All measuring and test equipment having an effect on the accuracy or validity of calibrations are calibrated. The M&TE are identified by unique equipment numbers in Emerald, CATS or another suitable tracking system.

The Emerald and CATS and other systems also generate management reports such as, Overdue, Due This Month and Due Next Month listing of standards and M&TE. These reports may be run on any interval desired.

Calibration due reports should be run periodically to ensure all instruments due for calibration are calibrated by the due date. These reports can be run by the calibration lab or the equipment owner. All past due measurement and test equipment or standards are removed from use or flagged with appropriate labels, tie-on tags or other suitable means, to guard against inadvertent use. Additionally, the calibration label 'due dates' of the M&TE being used for calibration will be checked before use.

5.5.1 The calibration facilities have the necessary equipment to perform the calibration procedures used within its facility.

Should it be necessary to borrow equipment, the calibration facilities ensure that equipment on loan from other manufacturing divisions or other suppliers (e.g. rented, customer supplied, etc.), is calibrated (if required) , traceable to national or international standards and free from viruses (see the EMG Anti-Virus Requirments Document).

Arrangements must be made to ensure calibration integrity of such items while on loan. Since out-of-tolerance conditions require further investigation, loaned equipment must be uniquely identified in Emerald, CATS or another suitable tracking system.

5.5.2 The calibration facility is supported by a system of standards at an accuracy level, resolution, stability, and calibration range that satisfies the requirements imposed by measuring and test equipment specifications as well as product requirements. Instruments are calibrated to a level needed to meet the calibration requirements of the customer (e.g. instruments used to perform a "Standards-Based Calibration", see the Agilent Calibration Services website, such as ISO 17025 or ANSI/NCSL Z540, will themselves have received a "Standards-Based Calibration" of equal or higher level). If an instrument does not meet that performance specification, it will be repaired or receive a limited use label. As appropriate, all instruments are calibrated prior to being placed into service. Not all devices require calibration. The results of the calibrations are recorded in Emerald, CATS or another suitable tracking system.

5.5.3 Personnel authorized to operate specific equipment are identified as in section 5.2 of this document. The documents necessary to operate or maintain specific equipment can be found in the entities' Business Management System documentation.

5.5.4 Each item of calibration equipment is assigned a unique trace (traceability) number.

5.5.5 Individual records are maintained in the entity for each item of M&TE or standard. These records are in paper form (hardcopy), through electronic media or a combination of both. The entity's service manuals, which contain manufacturer's instructions regarding test equipment, can be found in the entity's local library.

The records for M&TE or standards contain the following information:

- Instrument identification (including manufacturer's name, model number, serial number, trace number and a description of the item),
- Physical location,
- Current calibration interval,
- Documentation for interval adjustment using the Calibration Interval Guidelines document (or similar document) if different from manufacturer's recommended interval,
- Date of last calibration,
- Calibration source(s), (where the unit was calibrated)
- Calibration procedure used,
- Results of previous calibrations,
- Corrective action taken, as documented on the Out of Tolerance (OOT) Procedure document (or similar document),
- Indications of erratic behavior or operational failures,
- Calibration certificate or report number

5.5.6 Procedures for handling, transport and storage are described in section 5.8 of this document.

5.5.7 M&TE that is known or suspected to be broken, out of tolerance, unstable or have intermittent problems is removed from use or flagged with an appropriate label, tie on tag or other suitable means, to guard against inadvertent use until appropriate corrective action can be taken.

5.5.8 Proper control of the use and distribution of standards and M&TE requires consistent and reliable identification of each unit. The calibration facility uses an assortment of labels to achieve the required control. Each standard or M&TE item will be labeled or coded to indicate its calibration or preventative maintenance status. In so far as possible, labels or coding shall be affixed to the front of the unit without obscuring other information.

If the standard or M&TE is of a size which precludes application of a calibration label, the label is applied to its container or an attached tag.

Internal M&TE calibration labels will have as a minimum the following requirements:

- Each label will be distinctly identified with the Agilent Technologies logo, name or both,
- Each label will indicate the date calibrated,
- Each label will indicate the date DUE for re-calibration.

If extent of calibration or performance of the item is limited, or have other special conditions, it will be stated on the label.

Equipment that DOES NOT need calibration, such as the equipment used in Marketing, R&D, and Manufacturing Engineering, may not be subject to periodic calibration. Devices that do not require calibration must be labeled with a valid "Not Subject to Periodic Calibration" (NSPC) or "Not Calibrated" (NC) label.

5.5.8.1 Changing the status of measurement equipment.

5.5.8.1.1 Owners are responsible to monitor the status of each piece of equipment for possible change of calibration status.

5.5.8.1.2 If an owner wants to change the status of a piece of equipment to NSPC, the owner needs to contact the Electronic/Mechanical Maintenance Department, or responsible party, who will take appropriate steps to inactivate the equipment in the calibration recall tracking system and provide the owner with an NSPC label to be affixed to the device.

5.5.8.1.3 If an owner wants to change the status of a piece of equipment from "Not Calibrated" to "Calibrated," the owner must contact the Electronic/Mechanical Maintenance Department, or responsible party, who will take appropriate steps to activate the equipment in the calibration recall tracking system and provide the owner with the information they need to have the item properly calibrated.

5.5.8.1.4 If EMG-Owned M&TE is to be retired or transferred to another entity, (i.e. one that tracks its equipment and usage records using a different system) the sending entity must first determine that it has had no detrimental effect on any calibrations in which it was previously used. This check is made by either:

a. Running a report showing that the unit had not been used since its last calibration.

b. If the unit had been used, it must be calibrated prior to release to determine if it is within specification. Equipment that does not meet specification is processed using the procedures detailed in section 4.9 of this document.

Regardless of the outcome of the investigation above, the results of the report and any subsequent calibration must be kept as a record and retained with the equipment's file.

5.5.9 Equipment loaned to another facility will be given a functional and physical check prior to being returned to service. Should the verification check indicate a potential problem, a full calibration will be performed.

Equipment loaned to organizations outside of the calibration facility will be re-calibrated upon return.

5.5.10 Procedures for intermediate checks (cross-checks) between calibration intervals are described in section 5.9 of this document.

5.5.11 Calibration facilities that require correction factors to improve measurement accuracy may do so by entering their standard's calibration data into computer data files. In such cases, procedures for updating these data files must ensure the accuracy of correction factor data. In cases where data is entered manually, some means of validating the data entry must be used, and a record of the validation kept.

5.5.12 All calibrated measuring and test equipment shall be sealed with tamper-resistant seals to preclude any tampering with calibration controls or adjustments.

Seals shall be applied in quantity and location as necessary to prevent tampering with any calibration controls or adjustments that are not specified as part of an operator's normal operating procedure for the unit. As a general procedure, seals shall be applied to seal the largest unit assembly (i.e. unit's outer covers are sealed). If such sealing is not applicable, then the next larger subassembly shall be sealed or, if necessary, individual controls or adjustments may be sealed to achieve the objective.

Units with broken tamper-resistant seals, when discovered on calibration facility standards or measuring and test equipment shall immediately be corrected in accordance with the local calibration facility's processes and procedures.

For specific reasons, seals may be broken to gain access to a unit when it can be stated that such entry in no way affects the calibration status of the item, (i.e. removing covers to gain access to the GPIB or IEEE488 Interface Bus (HPIB) address switches). The item shall then be re-sealed. In cases where the unit is a main frame and it is necessary to calibrate plug-ins without the covers in place, all accessible calibration controls or adjustments shall be sealed.

Control of calibration software is described in section 5.4.7.2 of this document.

5.6 Measurement Traceability

5.6.1 General All equipment subject to periodic calibration, including environmental monitoring equipment, will be calibrated prior to being placed into service.

NOTE: Environmental monitoring equipment does not provide traceable parameters for calibrations and so this equipment does not need to be listed on the calibration certificate. The environmental conditions provided by this equipment are typically accounted for in the uncertainty analysis.

Review of Recently Calibrated M&TE Any standard whose measured or predicted characteristics are used (rather than simply its specifications) to enhance the accuracy of calibrations performed using it, must be periodically assessed for stability.

Stability is assessed by statistically comparing the difference between data points of the latest and previous calibrated values using locally defined procedures.

Note: A simplistic approach which may be used; if the difference is more than the Root Sum Square (RSS) of the uncertainties reported by the calibrating lab(s), the device is considered to be unstable and inadequate for this type of critical application and must be repaired or replaced.

Trending of Standards Certain “measurement critical” applications may require the use of trended standards as a means of obtaining better than spec performance, without resorting to impractically frequent calibration intervals. In cases where trending is used, the uncertainty associated with trending must be accounted for in the total uncertainty budget of any calibration procedure which makes use of the trended values.

5.6.2 Specific Requirements

5.6.2.1 Calibration

5.6.2.1.1 Traceability Calibrations performed by the calibration facilities are traceable to the International System of Units (SI) as described in the ISO/IEC 17025:2005(E). External calibration sources shall comply with the requirements of ISO/IEC 17025:2005(E), ANSI/NCSL Z540.1-1994 (R2002) and/or ANSI/NCSL Z540.3-2006. Calibration sources shall demonstrate traceability and compliance to appropriate metrological specifications via accreditation, or surveys and audits, as appropriate. A calibration certificate bearing the logo of a lab that is accredited to ISO/IEC 17025:2005(E) by an accreditation body that is a signatory on an internationally accepted Mutual Recognition Agreement (such as ILAC or APLAC) for the parameters tested will be accepted as sufficient to meet this requirement.

Test reports and certificates for equipment calibrated by external laboratories are reviewed for content and accuracy before being placed into service.

5.6.2.1.2 For calibrations that cannot be strictly made to SI units, traceability to appropriate measurement standards shall be used.

5.6.2.2 Testing

Testing is applicable only to testing laboratories, and does not apply to the calibration facility activities.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards All calibration facilities use reference standards. Reference standards shall only be used for calibration (e.g., not for diagnostics). If adjusted, reference standards will be calibrated before and afterwards. However reference standards are not normally adjusted.

5.6.3.2 Reference Materials The calibration facilities do not typically use reference materials. If reference materials are used, e.g., salt solutions for humidity calibrations, they shall be traceable to certified reference materials, or otherwise traceable to SI units of measure where possible.

5.6.3.3 Intermediate Checks Crosschecks are made to ensure confidence in a calibration facility's reference, primary, transfer or working standard's reliability between calibration intervals. Crosschecks are not required for all instruments or standards. The Cross-check Guidelines document describes the crosscheck process in more detail. Other locally documented crosscheck processes may be used if needed.

5.6.3.4 Transport and Storage Procedures for handling, transport, and storage are described in section 5.8 of this document.

5.7 Sampling

Typically, sampling is applicable to testing laboratories, not calibration laboratories. However, some areas may use a reduced test procedure (fewer data points) as appropriate. If sampling is required, it shall be documented locally.

5.8 Handling of Test and Calibration Items

5.8.1 Agilent instruments, reference standards, and customer equipment shall be handled, stored and transported in a manner which shall not adversely affect the calibration or physical condition of the equipment or its measurement integrity. The shipping and receiving department uses Agilent Technologies' corporate documented shipping and handling procedures in conjunction with its own local procedures. A more detailed description of the processes used can be found in the entity's locally defined Business Management System documentation.

If instruments contain hazardous materials, they shall be handled in accordance with local environmental health and safety requirements and are shipped using the guidelines in the Agilent Technologies "Dangerous Goods Transportation Program".

5.8.2 Documented instructions to control and identify all calibration items are included in the entity's locally defined Business Management System documentation

5.8.3 All products received for calibration are verified or matched to appropriate paperwork as to model number, serial number, etc. In the event of any discrepancy, the appropriate people are notified and the discrepancy resolved, using local calibration facility processes and procedures, where applicable.

5.8.4 For information concerning facilities and security refer to sections 5.3 of this document.

SSU facilities must comply with the guidelines set forth in the WCSS Guide for Safe Handling and Storage of Test Equipment.

5.9 Assuring the Quality of Test and Calibration Results

Agilent Technologies, Inc, where appropriate, utilizes the following quality control programs for monitoring the validity of test and calibrations. Where the analysis of data resulting from these programs is found to be outside acceptable limits, appropriate EMG Corrective and Preventive Action Requirements are completed.

5.9.1 Inter-laboratory Comparisons and Proficiency Testing

Standards laboratories participate in a program of inter-laboratory comparisons and proficiency testing as necessary to maintain confidence in their measurements. Where the laboratories are accredited, participation in proficiency testing and inter-laboratory comparisons is a function of the regional accreditation activity.

Most calibration facilities use the services of Agilent primary standards laboratories within Agilent Technologies' manufacturing divisions or major customer support centers for the calibration of their most accurate working standards. Primary laboratories participate, as necessary, in inter-laboratory comparisons and proficiency testing programs and are directly traceable to recognized national standards laboratories.

5.9.2 Cross-checks

Calibration facilities will develop a crosscheck process to ensure the reliability of the standards and instruments used for calibration. The Cross-check Guidelines document describes the crosscheck process in more detail. Other locally documented crosscheck processes may be used if needed.

5.9.3 Maintenance of Calibration Intervals

Measurement equipment is required to be calibrated at established intervals with the intent that the desired accuracy and quality level is maintained. Details regarding the establishment and

adjustment of calibration intervals are contained in the Calibration Interval Guidelines document.

5.9.4 Computation of the Reliability Target

The calibration laboratory's overall M&TE reliability for a given period is computed by dividing the number of units that passed calibration by the sum of the number of units that passed and the number that failed. For example, if a lab had 50 units calibrated in a given quarter, 45 passed and 5 failed, then the lab's reliability percentage for the quarter would be 90%. The computed percentage shall be equal to or greater than the reliability target, which is 85 percent. (If less than 85 percent, corrective action, such as modification of the calibration interval review and adjustment algorithm, shall be taken as necessary.)

5.10 Reporting the Results

5.10.1 General Depending upon the contract with the customer, a calibration documentation package may contain a certificate of calibration, test data, a copy of a work order and/or any other attachments as necessary. The results of tests or calibrations may be reported to the client in a simplified manner. This package will contain sufficient information to comply with the customer's requirements.

Regardless of a customer's requirement for a calibration certificate or data report, all information concerning the calibration will be recorded and maintained except under special circumstances initiated by the customer and explicitly stated as a custom calibration deliverable in a written agreement. This includes all "As Received" and "As Shipped / As Completed" data.

5.10.2 Test Reports and Calibration Certificates

Each test report or calibration certificate includes specific information based on the type of calibration service rendered and the customer's specific requirements, if any. For more information, refer to the Agilent Technologies Calibration Certificate Process web site.

5.10.2 For a description of how Agilent Technologies calibration facilities meet the requirements of sections 5.10.2 a) thru k) of the 17025 standard, refer to the

Calibration Certificate Content and Explanations (Business rules) document listed on the Agilent Technologies Calibration Certificate Process web site.

5.10.3 Test Reports This is applicable to testing laboratories, not calibration laboratories.

5.10.4 Calibration Certificates and Measurement Uncertainty

For a description of how Agilent Technologies calibration facilities meet the requirements of sections 5.10.4.1 thru 5.10.4.4 of the 17025 standard, refer to the Calibration Certificate Content and Explanations (Business rules) document listed on the Agilent Technologies Calibration Certificate Process web site.

a) Z540.1 compliant products and services:
Confidence in the integrity of measured values (and specification status) is achieved by taking the collective uncertainty into account through the use of a "Test Uncertainty Ratio" (TUR).

This ensures the standards and techniques are adequate for measurements being made. Agilent defines TUR as the ratio obtained by dividing the specification of the calibrated item by the uncertainty of the standards and methods used.

A TUR of 4:1 will be maintained where possible to ensure that, when claiming compliance to a published specification, the measurement decision risk will be less than 0.8%.

Where it is not possible to meet a 4:1 ratio (and for single-sided measurements), the collective measurement uncertainty for each corresponding measurement is reported.

Either the Measurement Uncertainty (MU) or the Test Uncertainty Ratio (TUR) shall be included with the test report.

b) Z540.3 and ISO 17025 compliant products and services:

Requirements for Z540.3 and ISO 17025 compliant products and services are contained in Section 3 of the Agilent Instrument Calibration format for ISO 17025 /Z540.3 Measurement Report (Document# epsg1037921).

5.10.5 Opinions and Interpretations This is applicable to testing laboratories, not calibration laboratories.

5.10.6 Testing and Calibration Results Obtained from Subcontractors The Agilent Technologies certificate of calibration will identify those services performed by a subcontractor. The subcontractor's certificate and supporting documentation will be included with the calibration documentation to the customer. For more detailed information see the Instructions for 3rd Party Certificates of Calibration document (Doc# epsg1040023).

5.10.7 Electronic Transmission of Results Electronic transfers shall be made upon agreement with the customer. Information will only be transmitted to the original customer. (Issues of customer confidentiality are further addressed in Agilent's Standards of Business Conduct manual.)

5.10.8 Format of Reports and Certificates The format for calibration certificates is contained in Emerald, CATS or another suitable tracking system and complies with the requirements of ISO/IEC 17025:2005(E). The format of certificates issued by accredited laboratories is prescribed or otherwise agreed to by the accreditation agency. (See the Agilent Technologies Calibration Certificate Process web site.).

5.10.9 Amendment to Test Reports and Calibration Certificates Material amendments are issued as follows:

- Amendments to test reports or calibration certificates will be issued as a separate document informing the customer of the amendment/supplement. This document will include the statement "Supplement to Test Report (or Calibration Certificate)" referencing the original that it replaces.

- Test Reports and Calibration Certificates are available for reprint/reissue. These documents will be reprint/reissues of the originals that they replace.

Appendix A – Process Documentation Showing Compliance to ISO/IEC 17025

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These documents describe the EMG Calibration Quality System.

ISO 17025 SECTION	SUPPORTING DOCUMENT	FURTHER INFORMATION
4 Management requirements		
4.1 Organization		
4.1.1	**Local Documentation**	
4.1.2, 4.1.3, 4.1.4	**CSM** Organization	
	Local Training records.	
4.1.5 a)	**Agilent** Training Requirements: **Section 3.0 Responsibility**	http://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007820.doc
	CSM General Organizational Requirements.	
	Local Training and Authorization records.	
b)	**Agilent** Standards of Business Conduct	http://sbc.corporate.agilent.com/
	Local Documentation, Training Records and Authorization Documents.	
c)	**Agilent** Standards of Business Conduct **1.2.1 General Policy**	http://sbc.corporate.agilent.com/
d)	**Agilent** Standards of Business Conduct **1.1.2 Outside Employment and Other Activities**	http://sbc.corporate.agilent.com/
e), f), g)	**Local Organization, Training and Authorization records.**	
h), i), j)	**Local Documentation should name the Technical Manager, Quality Manager, and backup.**	
4.2 Business Management System		
4.2.1	**Agilent Business Management System Manual:** Our Approach to Quality	http://www.agilent.com/quality/qualityman.pdf
	CSM	
	Local Documentation	
4.2.2	**Agilent's Quality Policy**	**http://emg.communications.agilent.com/quality/policy.asp**

a)	**Agilent Business Management System Manual -** Management Responsibility	http://www.agilent.com/quality/qualityman.pdf
b)	**Local Documentation**	
c)	**Agilent Business Management System Manual -** Agilent's Quality Framework	http://www.agilent.com/quality/qualityman.pdf
	EMG BMS Manual	**http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_bms_manual%20-%20epsg1026386.pdf**
	Local Documentation	
d), e)	**Local Documentation**	
4.2.3	**CSM**	
	Local Documentation	
4.2.4	**Local Documentation**	
4.3 Document control		
4.3.1 General	**Agilent** Document Control Requirements	**HTTP://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007799.doc**
	EMG Document Control Requirements	http://sharedoc.collaboration.agilent.com/sites/emg-wide/sd/no%20prog/nps/emg%20doc%20control%20requirements%20[e100]%204-21-09%20-%20epsg1028732.pdf
	Local Documentation	
4.3.2 Document approval and issue		
4.3.2.1	**Local Documentation**	
4.3.2.2 a), b), c), d)	**Local Documentation**	
4.3.2.3	**CSM** Document approval and issue	
	Local Documentation	
4.3.3 Document changes		
4.3.3.1	**Agilent** Document Control Requirements - **7.3 Document Changes or Revisions**	**HTTP://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007799.doc**
	EMG Document Control Requirements	http://sharedoc.collaboration.agilent.com/sites/emg-wide/sd/no%20prog/nps/emg%20doc%20control%20requirements%20[e100]%204-21-09%20-%20epsg1028732.pdf
4.3.3.2, 4.3.3.3, 4.3.3.4	**Local Documentation**	
4.4 Review of requests, tenders and contracts		
4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5	**Local Documentation**	

4.5 Subcontracting of tests and calibrations		
4.5.1	**SoCo** calibration supplier approval process:	http://www.soco.agilent.com/org/cal-labs/supplier/excal.htm
	Local Documentation	
4.5.2, 4.5.3	**Local Documentation**	
4.5.4	**CSM** Subcontracting of tests and calibration	
	Local Processes and Records.	
4.6 Purchasing services and supplies		
4.6.1	**CSM** Purchasing Services and Supplies	
	Local Documentation	
4.6.2, 4.6.3, 4.6.4	**Local Documentation**	
4.7 Service to the client	**Local Documentation**	
4.8 Complaints	**Local Documentation**	
4.9 Control of nonconforming testing and/or calibration work	**Agilent** Control of nonconformity requirements	http://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007818.doc
	EMG Control of Non-conforming product	http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_control_of_nonconforming_product_e103_1028735%20-%20epsg1028735.pdf
4.9.1 a), b), c), d)	**Local Documentation**	
	OOT Procedure document	
4.9.2	**Local Documentation**	
4.10 Improvement	**Agilent** Corrective and Preventive Action Requirements	**HTTP://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007804.doc**
	EMG Corrective and Preventive Action Requirements	**http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_corrective_and_preventive_action_requirements_e101%20-%20epsg1028733.pdf**
4.11 Corrective action		
4.11.1 General	**Local Documentation**	
4.11.2 Cause analysis	**Local Documentation**	
4.11.3 Selection and implementation of corrective actions	**Agilent** Corrective and Preventive Action Requirements	**HTTP://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007804.doc**
	EMG Corrective and Preventive Action Requirements	**http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_corrective_and_preventive_action_requirements_e101%20-**

		%20epsg1028733.pdf
	Local Documentation	
4.11.4 Monitoring of corrective actions	**Local Documentation**	
4.11.5 Additional audits	**Local Documentation**	
4.12 Preventive action	**Local Documentation**	
4.12.2	**Agilent** Corrective and Preventive Action Requirements	**HTTP://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007804.doc**
	EMG Corrective and Preventive Action Requirements	**http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_corrective_and_preventive_action_requirements_e101%20-%20epsg1028733.pdf**
	Local Documentation	
4.13 Control of records		
4.13.1 General	**Agilent** Quality Records Requirements	http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_quality_records_requirements_e104%20-%20epsg1028767.pdf
4.13.1.1	**Agilent** Record Retention:	http://legal.agilent.com/rim/index.shtm
4.13.1.2, 4.13.1.3, 4.13.1.4	**Local Documentation**	
4.13.2 Technical records		
4.13.2.1, 4.13.2.2, 4.13.2.3	**Local Documentation**	
4.14 Internal audits	**EMG** -Under development	
4.14.1	**EMG** BMS Internal Audit Process	http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_bms_audit_program_manual_e102%20-%20epsg1028734.pdf
4.14.2, 4.14.3, 4.14.4	**Local Documentation**	
4.15 Management reviews		
4.15.1, 4.15.2	EMG Management Review Process	**http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_mgmnt_review_process_e106_epsg1028737%20-%20epsg1028737.pdf**
5 Technical requirements		
5.1 General		
5.1.1, 5.1.2	**Local Documentation**	
5.2 Personnel	**Agilent** Training Process and Requirements	http://wcosedoc.cos.agilent.com/stellent/groups/quality/documents/end_users/007820.doc
	EMG Training Program Requirements	**http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/e**

		mg_training_process_and_requirements_e105%20-%20epsg1028736.pdf
5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5	**Local Documentation, Training Records and Authorization Documents.**	
5.3 Accommodation and environmental conditions		
	EMG ESD Control Program	http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/esd%20control%20docs/esd_control_manual%20-%20epsg1039112.pdf
5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5	**Local Documentation**	
5.4 Test and calibration methods and method validation		
5.4.1 General	**Local Documentation**	
5.4.2 Selection of methods	**Local Documentation**	
5.4.3 Laboratory-developed methods	**Local Documentation**	
5.4.4 Non-standard methods	**Local Documentation**	
5.4.5 Validation of methods	EMG Measurement Method/Measurement Uncertainty Validation Process Requirements	http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_measurement_method__mu_validation_requirements%20-%20epsg1059922.pdf
	EMG Guideline for introducing option 1A7 & A6J	http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_guideline_on_the_introduction_of_options_1a7_a6j_1038158%20-%20epsg1038158.pdf
5.4.5.1, 5.4.5.2, 5.4.5.3	**Local Documentation**	
5.4.6 Estimation of uncertainty of measurement		
5.4.6.1, 5.4.6.2, 5.4.6.3	**Local Documentation**	
	WCSS Measurement Uncertainty Analysis Guidelines	http://sharedoc.collaboration.agilent.com/sites/WCSS-SSU/SD/SSU%20BQMS/Quality_Metrology/Metrology/Policy%20Documents/mu_analysis_guidelines-110330%20-%20epsg1062693.doc
5.4.7 Control of data		
5.4.7.1, 5.4.7.2 a), b), c)	**Local Documentation**	
5.5 Equipment		
5.5.1, 5.5.2, 5.5.3, 5.5.4, 5.5.5, 5.5.6, 5.5.7, 5.5.8, 5.5.9,	**Local Documentation**	

5.5.10, 5.5.11, 5.5.12		
5.6 Measurement traceability		
5.6.1 General	**Local Documentation**	
5.6.2 Specific requirements		
5.6.2.1 Calibration		
5.6.2.1.1, 5.6.2.1.2	**Local Documentation**	
5.6.2.2 Testing		
5.6.2.2.1, 5.6.2.2.2	**Local Documentation**	
5.6.3 Reference standards and reference materials		
5.6.3.1 Reference standards	**Local Documentation**	
5.6.3.3 Intermediate checks	**Local Documentation**	
5.6.3.4 Transport and storage	**Local Documentation**	
5.7 Sampling		
5.7.1, 5.7.2, 5.7.3	**Local Documentation**	
5.8 Handling of test and calibration items		
5.8.1, 5.8.2, 5.8.3, 5.8.4	**Local Documentation**	
5.9 Assuring the quality of test and calibration results	**Local Documentation**	
5.10 Reporting the results		
5.10.1 General	**Local Documentation**	
5.10.2 Test reports and calibration certificates	**Agilent** Calibration Certificate Program Guidelines	**http://quality.communications.agilent.com/calcert/**
	Local Documentation	
5.10.3 Test reports		
5.10.3.1, 5.10.3.2	**Local Documentation**	
5.10.4 Calibration certificates	**EMG** Calibration Certificate Program Guidelines	**http://quality.communications.agilent.com/calcert/**
5.10.4.1, 5.10.4.2, 5.10.4.3, 5.10.4.4	**Local Documentation**	
	WCSS Adjustment & Guardband Policy	**http://sharedoc.collaboration.agilent.com/sites/wcss-ssu/sd/ssu%20bgms/quality_metrology/metrology/policy%20documents/adj%20guard%20policy%20-%20epsg1063880.pdf**
5.10.5 Opinions and interpretations	**Local Documentation**	
5.10.6 Testing and calibration results obtained from subcontractors	**Local Documentation**	
5.10.7 Electronic transmission of results	**Local Documentation**	
5.10.8 Format of reports and certificates	**EMG** Calibration Certificate Program Guidelines	**http://quality.communications.agilent.com/calcert/**

	EMG Measurement Report Guidelines	
	Local Documentation - Data Reports	
5.10.9 Amendments to test reports and calibration certificates	**Local Documentation**	

Appendix B - Supporting Material

Agilent Technologies Quality Policy
http://customer.quality.agilent.com/qual_mgt_systems/qpolicy_translations.htm

Standards of Business Conduct
http://sbc.corporate.agilent.com/

EMG Business Management System Manual
http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/emg%20required%20docs/emg_bms_manual%20-%20epsg1026386.pdf

EMG Calibration System Manual
http://sharedoc.collaboration.agilent.com/sites/EMG-Wide/SD/ISO/ISO%2017025/EMG_CSM_epsg1024153.pdf

Agilent Technologies Calibration Services Website
http://www.home.agilent.com/en/pc-1000002301%3Aepsg%3Apgr/calibration-services-repair?nid=-35734.0&cc=US&lc=eng

Agilent Job Family Matrices
https://meidas.hr.agilent.com/java/ehr.Home?Page=/manager/compensate_and_reward/wage_planning/job_family_matrice_pd.xml&Geography=ususa&LanguageCode=en

Shipping hazardous material
http://wps.service.agilent.com/global_trade/dg/

General Retention Schedule for records
http://legal.agilent.com/rim/retention_schedule.shtm

Workmanship Specification for Electrostatic Discharge Control
http://sharedoc.collaboration.agilent.com/sites/emg-quality/sd/emg-bms/esd%20control%20docs/esd_control_manual%20-%20epsg1039112.pdf

EMG Home page
http://emg.communications.agilent.com/

EMG Quality Home Page
http://epsg.communications.agilent.com/quality/

Service Notes *(note: log in and then click on the Service Notes tab at the top of the page)*
https://litstation.marketing.agilent.com/litapp/

Agilent Technologies Corporate Quality
http://customer.quality.agilent.com/qual_mgt_systems/qms.shtml

Agilent Calibration Certificate Program Guidelines
http://quality.communications.agilent.com/calcert/

Worldwide Customers Service and Support (WCSS) Home Page
http://emg.communications.agilent.com/wcss/

WCSS Quality Home Page
http://ssuweb.business.agilent.com/ssuquality/

WCSS Software Quality Assurance
http://www-ist.scs.agilent.com/sw_qa/index.shtml

Document Control Log

REV NO.	CHANGE SUMMARY	DOCUMENT OWNER	APPROVER	DATE APPROVED
Original	First Issue	Ed Tong, Jerry Rorie	Jim Horner	14 Oct. 2002
A	Updated Coversheet.	Ed Tong Jerry Rorie	Jerry Rorie	3 May 2002
B	Updated Environment temperature value to "(23 ± 5) deg C".	Ed Tong Jerry Rorie	Jerry Rorie	18 Jun. 2002
C	Updated Quality Policy to meet currently published information.	Ed Tong Jerry Rorie	Jerry Rorie	16 July 2002
D	Submitted for review through WebDoc.	Ed Tong Jerry Rorie	Steve Hughes Harold Julander John Grubb Ed Tong Bill Eyler Joe Lang Jerry Rorie Ley-Choo Lim Bob Brown Jim Gurney	14 Feb 2003
E	Various editorial changes	Ed Tong John Grubb	Ed Tong John Grubb	10 July 2003
F	Clarified equipment status definitions in section 5.5.8.	Ed Tong John Grubb	Ed Tong John Grubb	6 Aug 2003
G	Modified 5.10.4 regarding TUR and TAR to separate Z540 vs. 17025. Modified 5.10.1 regarding simplified reports.	Ed Tong Steven Hughes	Ed Tong Steven Hughes	26 March 2004
18	Modified Para. 5.3.4 to reflect the discontinuance of the Agilent ESD Standard. Changed document Owner & Approver. Changed revision reference to align with the method used by Webdoc.	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	22 July 2004
19	Modified paragraph 4.7 to clarify client confidentiality requirements.	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	23 Sept 2004
20	Removed all references to the now defunct ISO 10012-1-1992 Standard.	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	3 December 2004
21	Added section 5.5.8.1.4 that stipulates what must be done when removing a calibrated item from service and removed the term "TAR" from the second paragraph of section 5.10.4.	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	1 July 2005
22	Changed the reference in the document header from EPSG to EMG	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	23 Sept 2005

23	Updated Manual to comply with the requirements of ISO 17025:2005	Kerry Gwin	Diana Clark	9 March 2006
24	Reworded paragraph 5.10.2 to clarify calibration offerings statement	Kerry Gwin	Diana Clark	31 March 2006
25	Reworded paragraph 5.2.5 to clarify content of training records	Kerry Gwin	Diana Clark	21 April 2006
26	Removed references to CSG throughout the document. Changed "Support Solutions Unit" to "Service Solutions Unit" throughout the document and corrected all URL references to the GRS.	Kerry Gwin	Diana Clark	7 August 2006
27	Added ISO 10012:2003(E) to the list of standards to which EMG complies section 1.0	Kerry Gwin	Diana Clark	1 November 2006
28	Corrected the Revision No.	Kerry Gwin	Diana Clark	27 June 2007
29	Clarified language usage in sections 4.5.1, 5.10.1 and 5.10.4. Added definition of Measurement Decision Risk to section 3. Added "where applicable" to references to local documentation in sections 5.4.1 and 5.8.3	Kerry Gwin	Diana Clark	April 2008
30	Edited paragraph 4.5.2 to clarify that when a customer must be notified prior to transshipment of a unit to be calibrated. Edited paragraph 5.5.2 to clarify internal ETE calibration level requirements.	Kerry Gwin	Diana Clark	Feb 2009
31	Re-publication of the changes in Rev 30, specifically paragraph 4.5.2 which was inadvertently left out of Rev 30.	Kerry Gwin	Diana Clark	March 2009
32	Updated links to the EMG Calibration Certificate Process Web Page in Section 5.10 and Appendix A	Kerry Gwin	Diana Clark	March 2009
33	Removed references to CSG, uncertainty F# and reviewed and updated all sections.	Kerry Gwin	Ted Tucker	31 July 2009
34	Amended paragraph 2 of section 5.10.1 regarding custom calibration deliverables. Corrected hyperlink to Siebel in section 2.0	Kerry Gwin	Ted Tucker	September 2010
35	Changed the name of this table to Most Recent Change and corrected error in date column of the document control	Kerry Gwin	Ted Tucker	November 2010

	log.			
36	Skipped as part of the ShareDoc Revision synchronization.	Kerry Gwin	Ted Tucker	January 2011
37	Updated link to Siebel in Section 2. Replaced the term "Quality System" with "Business Management System" throughout the document. Renamed section 4.7. Clarified the reference in section 4.9.1.d to refer to 4.9.1.a. Corrected reference in section 4.9.1.2 to point to the EMG CA & PA Process. Updated the link to the Agilent Calibration Services web page in section 5.5.2 and Appendix B. Added text to Section 5.6.1 to clarify instruments to appear as traceable standards.	Kerry Gwin	Ted Tucker	January 2011
38	Updated to tie Rev Number with ShareDoc Rev after file name change – no content change. (Andrew Soulsby)	Kerry Gwin	Ted Tucker	January 2011
39	Updated URL in header section. No content changes.	Kerry Gwin	Ted Tucker	February 2011
40	Updated Revision number in header section to match the Revision History. No content changes.	Kerry Gwin	Ted Tucker	May 2011
41	Updated web links throughout the document in order to accommodate the migration from WebDoc to ShareDoc	Kerry Gwin	Ted Tucker	June 2011
42	Updated rev number of document to match actual revision number	Kerry Gwin	Ted Tucker	June 2011
43	Updated Section 5.3.1; Updated links throughout the document.	Kerry Gwin	Ted Tucker	January 2013
44	Removed unnecessary signature blocks from copyright page.	Kerry Gwin	Ted Tucker	April 2013