

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 1 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_eps1024153.pdf

Most Recent Change

REV NO.	CHANGE SUMMARY	DOCUMENT OWNER	APPROVER	DATE APPROVED	EFFECTIVE DATE
53	Updated sections 6.4 and 7.10 to clarify requirements	Kerry Gwin Scott Arrants	Rick Chapman	7/27/2020	7/27/2020

Calibration System Manual

Keysight Technologies, Inc.

Table of Content

Copyright Notice	2
Foreword	2
1.0 Scope	2
2.0 Normative References	2
3.0 Terms and Definitions	3
4.0 General Requirements	3
4.1 Impartiality	3
4.2 Confidentiality	4
5.0 Structural Requirements	5
6.0 Resource Requirements	6
6.1 General	6
6.2 Personnel	6
6.3 Facilities and environmental conditions	8
6.4 Equipment	10
6.5 Metrological traceability	13
6.6 Externally provided products and services	13
7.0 Process Requirements	14
7.1 Review of Requests, Tenders, and Contracts	14
7.2 Selection, Verification and Validation of Methods	15
7.3 Sampling	17
7.4 Handling of Tests or Calibration Items	17
7.5 Technical Records	18
7.6 Evaluation of Measurement Uncertainty	18
7.7 Ensuring the Validity of Results	19
7.8 Reporting of Results	20
7.9 Complaints	23
7.10 Nonconforming Work	23
7.11 Control of Data and Information Management	24
8.0 Management System Requirements	25

Copyright Notice

© Copyright 2002-2017 Keysight Technologies, Inc. All rights reserved. Reproduction, adaptation, or translation without prior written permission is prohibited, except as allowed under copyright laws.

Foreword

This calibration system manual has been written for all organizations within Keysight Technologies, Inc.

Responsibility for the document contents belong to the Keysight Technologies Business Management System Manager.

1.0 Scope

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

- Calibration Facilities
- Entities that provide calibrations at customer or remote locations
- Manufacturing Test and Calibration Facilities

Organizational processes and procedures will be required to supplement, but not supersede, the Calibration System Manual.

2.0 Normative References

This document describes procedures employed by Keysight Technologies' Calibration Facilities for the calibration of instruments. The paragraph numbering used in this document is consistent with that used in ISO/IEC 17025:2017. Included in the scope of the document are:

- Calibration facilities' policies, procedures, and processes established to meet the requirements of ISO/IEC 17025:2017, ANSI/NCSL Z540.1-1994 (R2002), ANSI/NCSL Z540.3-2006, ISO 10012:2003 and the needs of customers and/or external registration bodies.

-
- Provides a detailed description of how calibration is accomplished at Keysight Technologies.

3.0 Terms and Definitions

This document uses the definitions of the International Vocabulary of Metrology (JCGM 200:2012), ISO/IEC 17025:2017, ANSI/NCSL Z540.1-1994 (R2002) and ANSI/NCSL Z540.3-2006, as well as other terms applied to 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 several categories defined in the [Standard Type Definition](#) document.

Organization

Keysight calibration facilities have varying reporting structures in the corporation for example they may be grouped into regional service organizations, manufacturing organizations, etc. Within this document the term organizations may be used to represent any of these levels or groupings of calibration facilities.

4.0 General Requirements

4.1 Impartiality

4.1.1 Keysight ensures impartiality through organizational structure and alignment and through strategic, customer, operational, and quality driven objectives and goals.

4.1.2 Keysight management ensures impartiality by focusing on the needs and requirements of customers. This is achieved via operational and quality driven reviews and reinforced through mandated training such as [Standards of Business Conduct](#).

4.1.3 As per Keysight Technologies Standards of Business Conduct, Keysight discourages monetary or other compensation that would constitute a conflict of interest and affect the technical judgment of individuals involved in the calibration of measurement and test equipment.

4.1.4 Every effort is made to ensure that employees working within a calibration facility environment are not directly subjected to work related pressures that could compromise the quality of their work and impartiality. Keysight Technologies [Standards of Business Conduct](#) addresses employee integrity, ethics, and conflicts of interest. Keysight employees are required to review these standards annually.

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

4.1.5 If a risk to impartiality is identified it will be addressed in accordance with the Keysight Technologies Standards of Business Conduct.

4.2 Confidentiality

4.2.1 Customer confidential information, proprietary rights, results of calibrations and any special requests regarding customer calibrations are treated as confidential.

4.2.2 If Keysight Technologies is required by law or authorized by contractual arrangements to release confidential information, the associated customer/s will be informed.

4.2.3 Any information obtained from third-parties related to specific customer/s, will be treated as confidential between the customer/s and Keysight. Any third-party information will only be shared with the customer/s if the source of the information provides agreement to do so.

4.2.4 Employees are required to review Keysight Technologies [Standards of Business Conduct](#) annually. The related requirements for Keysight Suppliers can be found on www.keysight.com in the [supplier portion](#) of the quality page.

5.0 Structural Requirements

5.1 All calibration facilities within Keysight Technologies are part of the legal entity [Keysight Technologies, Inc.](#) and legally defined in the various countries of operation.

5.2 The calibration facilities' managers are identified as per associated organization charts and have the necessary authority to ensure that planning, resourcing, directing and controlling of the operation are provided to meet customer, quality, and business objectives.

5.3 Calibration facilities that are accredited to ISO/IEC 17025:2017 maintain a Scope of Accreditation with their respective accreditation body.

5.4 Keysight Technologies Calibration Facilities carry out activities in a way that meet the requirements of ISO/IEC 17025:2017, ANSI/NCSL Z540.1-1994 (R2002), ANSI/NCSL Z540.3-2006, and ISO 10012:2003 as applicable based on customer and contractual requirements. This applies to activities performed at all permanent facilities, at sites away from permanent facilities, in associated temporary or mobile facilities or at customer facilities.

5.5 Keysight Technologies Calibration Facilities maintain the following:

- a) A management structure is depicted in the calibration facilities' organizational charts. These charts demonstrate the interaction of all parts of the calibration facilities and the relationship with the corporate structure.
- b) Organizational charts, detailed job descriptions, various process flow charts and written procedures, indicate the responsibility, authority and connectivity of everyone directly involved in performing calibration activities within the calibration facilities.
- c) Organizational documentation is maintained to ensure the consistent application of calibration facility activities and the validity of laboratory obtained results.

5.6 Calibration activities are supervised by personnel who have extensive 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 understand the objective of

calibration and how to assess the validity of the results obtained. Organizational documentation, such as training records, are utilized to satisfy this requirement.

Each calibration facility has access to at least one person who is technically expert in calibration and metrology. This person may be a metrologist, technical supervisor, technical specialist, engineering support/management or the metrology manager who has the responsibility to make decisions regarding the technical validity of all aspects of the calibration process.

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 for use within quality improvement projects and initiatives.

All calibration personnel have the authority to identify deviations from the management system or procedures and are able to initiate actions to prevent such deviations. This is monitored by the quality representative and facility management.

5.7 All Keysight Calibration Facilities

- a) communicate the effectiveness of the management system and importance of meeting customer and other requirements through the use of newsletters, coffee talks, meetings and other appropriate means and
- b) maintain the integrity of the management system when changes are implemented.

6.0 Resource Requirements

6.1 General

Keysight facilities have the personnel, equipment, systems and support services to perform all their required calibration activities.

6.2 Personnel

6.2.1 All personnel are trained in accordance with the [Keysight Training Process Requirements](#).

The calibration facilities have staff of sufficient size and knowledge to satisfy the capacity and technical capability needed to support their workload. Personnel are hired to fulfill specific job requirements. Formal training may be required as a method of providing employee technical education. On-the-job training (OJT) is utilized when appropriate and gives employees the opportunity to experience new situations or service a broader product range by learning in a controlled environment where assistance is readily available through mentoring. 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 includes, but is not limited to, the following aspects:

- Supervisor knowledge and assessment during qualification,
- Support of a minimum number of products to qualify,
- Previous support of similar products or product lines

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

6.2.3 Under the direction of the manager of the calibration facility, 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.

6.2.4 Job descriptions are located on the [Job Family Matrices](#) website within the HR application.

6.2.5 Procedures and records associated with determining competence, selection and training of personnel, supervision and authorization of personal and monitoring of competence can be found in [SuccessFactors](#) or other locally maintained record keeping systems.

6.2.6 Keysight management identifies and authorizes the appropriate individuals to:

- a) develop, modify, verify and validate calibration methods;
- b) analyse results, including statements of conformity or opinions and interpretations;
- c) report, review and authorize results.

Individuals performing calibrations are authorized to perform calibrations (or repairs), issue calibration certificates or reports, and operate particular types of equipment. This authorization is documented in training or competency records and shall include the date upon which the scope and level of competence was obtained. Historical records shall be kept as evidence of qualification to perform the stated activity at the time of its provision.

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.

6.3 Facilities and environmental conditions

6.3.1 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 facilities are air-conditioned and consideration has been given to cleanliness, temperature and humidity. Where necessary, the facility 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.

6.3.2 Typical environmental requirements for facilities are as follows:

Type of Facility	Temperature Range	Humidity Range
Default Calibration Facility	23 ± 5°C	20 to 80% RH
RF or DC/Low Frequency Standards Facilities	23 ± 1°C	30 to 55% RH

Physical/Dimensional Facilities	20 ± 1°C	20 to 60% RH
---------------------------------	----------	--------------

Some facilities may require tighter limits that will be dictated by the type of calibrations being performed and/or the equipment being used. Should a facility require wider limits a waiver using either the [standard waiver](#) process or a documented waiver process approved by the organization's Metrology shall be in place. Some facilities, such as Hardware Test Centers (HTC), comply with alternate international standards (such as IEC 61010-1 4.3.1) for environmental limits.

6.3.3 Each calibration facility is equipped with an environmental monitoring system. Records are maintained and stored per [Keysight Quality Records Requirements](#).

If at any time the environmental limits are not met, the calibration operation shall be suspended until that condition has been investigated and addressed.

6.3.4 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.

Access to the calibration facilities are controlled. ESD precautions as defined in [Keysight Technologies' ESD Control Manual](#) are taken when handling M&TE and units under test.

Each member of the calibration facilities are responsible for general housekeeping and for complying with all Health & Safety regulations. Common areas and building systems, such as air conditioning, are maintained by a workplace solutions group or contract personnel who shall meet Keysight security and access requirements.

6.3.5 When calibrations are performed at a customer's site, Keysight monitors and records the environmental conditions. Keysight 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, Keysight Technologies requires a [standard waiver](#) by both the customer and Keysight Metrology to complete the calibration activities as needed.

6.4 Equipment

6.4.1 All calibration facilities have the necessary equipment to perform the calibration procedures required to satisfy their customers.

6.4.2 Should it be necessary to borrow equipment, the calibration facilities ensure that equipment on loan from other organizations within Keysight or suppliers (e.g. rented, customer supplied, etc.), are calibrated (if required), traceable to national or international standards and free from viruses (see the [Keysight Anti-Virus Standard](#)).

Arrangements must be made to ensure the calibration integrity of equipment while on loan. Since out-of-tolerance conditions require further investigation, loaned equipment must be uniquely identified in the entity's calibration tracking system.

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

Equipment loaned to organizations outside of Keysight shall be re-calibrated upon return.

6.4.3 Handling, transport, storage, use, and planned maintenance of Keysight owned equipment is performed with the same care as customer equipment. The requirements are covered in Section 7.4 of this document.

6.4.4 All measurement and test equipment that affects measurement accuracy and/or uncertainty is calibrated prior to be placed into service.

6.4.5 Keysight calibration procedures specify the equipment to be used in execution of procedures used to achieve the necessary measurement accuracy and/or uncertainty.

6.4.6 Keysight calibration procedures are designed to provide full metrological traceability. The procedures specify the equipment that is required to support the required metrological traceability for the associated calibration.

6.4.7 All measuring and test equipment having an effect on the accuracy or validity of calibrations is calibrated. M&TE are identified by unique equipment numbers in the entity's calibration tracking system. The effectiveness of the calibration program is evaluated through activities such as the OOT process, reliability reviews, calibration interval management, etc.

6.4.8 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 is 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:

- An indication of the date calibrated,
- An indication of the due date for re-calibration.

If the extent of the calibration or performance of the M&TE is limited, or has other special conditions, a label with the limitation shall be applied.

Equipment that does not need calibration, such as equipment used in Marketing, R&D, and Manufacturing Engineering, may not be subject to periodic calibration. Devices that do not require calibration are labeled with a “Not Subject to Periodic Calibration” (NSPC), “Not Calibrated” (NC), or similarly worded label.

6.4.9 M&TE that is known or suspected to be malfunctioning, out of tolerance, unstable or have intermittent problems shall be removed from use or flagged with an appropriate label, tie on tag, or other suitable means, to guard against unintended use until appropriate corrective action has been taken.

The management of nonconforming work procedure (7.10) shall be initiated. If the out of tolerance or undetermined condition will affect the calibration of other devices, the calibration facilities will identify all suspect calibrations. For more information, see the Keysight Out of Tolerance and Undetermined (OOTU) Procedure Requirements document.

6.4.10 Intermediate checks are made to ensure confidence in a calibration facility’s reference, primary, transfer or working standard’s reliability between calibration intervals. Intermediate checks are not required for all instruments or standards. Other organizationally documented crosscheck processes may be used if needed.

6.4.11 Where correction factors are required to improve measurement accuracy, any standard's factors shall be updated in the associated correction factor management system. In such cases, the process 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 are used, and a record of the validation maintained.

6.4.12 All Keysight-owned 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 organization's calibration processes and procedures.

For specific reasons, seals may be broken to gain access to equipment when it can be shown that such entry does not affect 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.

If Software or Firmware require updates a re-calibration is performed unless the support information states that the update does not affect calibration.

6.4.13 Individual records are maintained by each calibration facility for each item of M&TE or standard they control. These records are either electronic media or hardcopy stored at the facility.

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

- a) Instrument identification (including trace number, and software and firmware version),

- b) Manufacturer's name, model number, serial number, and a description of the item
- c) Most recent calibration record,
- d) Current physical location,
- e) Current calibration interval, date of last calibration, and calibration history,
- f) Period of validity for reference material (if applicable, such as a shelf life),
- g) Maintenance plans and history as applicable,
- h) Repair history as applicable, such as indications of erratic behavior or operational failures.

6.5 Metrological traceability

6.5.1 Keysight maintains metrological traceability of all its measurement results through an unbroken chain of calibration, each contributing to the measurement uncertainty.

6.5.2 Calibrations performed by calibration facilities are traceable to the International System of Units (SI) as described in ISO/IEC 17025:2017. External calibration providers 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 facility that is accredited to ISO/IEC 17025:2017 by an accreditation body that is a signatory on an internationally accepted Mutual Recognition Agreement (such as ILAC or APLAC) for the parameters tested may be accepted as sufficient to meet this requirement.

6.5.3 When traceability to SI units is not technically possible, traceability to appropriate measurement standards shall be documented in the associated uncertainty analysis.

6.6 Externally provided products and services

6.6.1 A documented vendor appraisal/performance monitoring procedure is used to select suitable suppliers that support calibration activities at Keysight Facilities. Each facility must administer a vendor control system that evaluates potential suppliers 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 17025:2017
 - ANSI/NCSL Z540.1-1994 (R2002)
 - ANSI/NCSL Z540.3-2006
 - ISO 9001:2015
 - Specific Keysight or customer criteria

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

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

6.6.2 The procedure and records associated with externally provided products and services are managed and maintained by each calibration facility. These procedures include defining the criteria for evaluating, selecting, monitoring, and re-evaluating external providers.

6.6.3 Calibration facilities communicate to external providers the necessary requirements to ensure quality services are provided. The communication includes the requirements for the products or services provided, the acceptance criteria, any competence requirements, and any requirements associated with activities the laboratory may perform at the external provider's premises.

7.0 Process Requirements

7.1 Review of Requests, Tenders, and Contracts

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

- a) The customer requirements are documented and understood,
- b) The calibration facilities have the required resources, equipment, and personnel,
- c) When an external provider is used the customer is informed and approves the use of that external provider,

- d) The calibration facilities select an appropriate calibration method that meets the needs of the customer.

7.1.2 Keysight facilities maintain capability databases that define the calibration offerings on a per facility basis which are updated to the latest version calibration procedures as appropriate. When requests outside the standard capability or to use out of date procedures are requested those may be negotiated with the individual calibration facilities.

7.1.3 The decision rules utilized by Keysight are defined in the [Keysight Instrument Calibration Report Standard](#). This is clearly communicated to the customer when Keysight confirms a calibration service.

7.1.4 All differences between the customer request and service order are resolved with the customer prior to performing any work. This is documented in the order management system.

7.1.5 The customer is informed of any deviations to the previously agreed-upon contract and this is documented in the order management system.

7.1.6 When a contract requires an amendment, the contract review process is used and changes are communicated to all relevant interested parties.

7.1.7 Customers may be permitted to visit calibration facilities, provided Keysight is given adequate 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.

7.1.8 Records of all reviews 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 Keysight Technologies [General Retention Schedule](#).

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and verification of methods

7.2.1.1 Keysight facilities utilize OEM calibration procedures and methodologies where possible. When an OEM procedure is not available or deemed inappropriate or inadequate,

appropriate methods are developed by qualified Metrologists using industry standard calibration methods.

Note: For Keysight Calibration facilities calibration procedures are considered calibration "methods".

7.2.1.2 All Keysight calibration facilities have a documented method to manage calibration procedures including support documentation such as instructions, standards manuals, etc. and is readily available to technical personnel.

7.2.1.3 All calibration procedures include revision control to ensure that the latest valid version is used.

7.2.1.4 When customers do not specify methods Keysight approved calibration procedures are used.

7.2.1.5 When Keysight develops new calibration procedures they are fully verified to ensure the required performance can be achieved.

7.2.1.6 When calibration procedure development is required it is developed by qualified personnel in accordance with a defined and documented procedure. Changes to calibration procedures follow the same documented procedure.

7.2.1.7 Keysight calibration and verification procedures are documented. Deviation is only authorized by specific customer calibration/verification requirements.

Should a customer request a method or calibration procedure not normally used, the request will be negotiated with the customer.

7.2.2 Validation of Methods

7.2.2.1 All calibration procedures are validated in accordance with a documented procedure. Results of the validation are recorded. As part of the validation process each calibration procedure is assigned a level of use for which it is valid.

7.2.2.2 Changes to calibration procedures are documented and re-validated if necessary.

7.2.2.3 The validation process includes steps to validate the range and accuracy of the calibration procedure as compared to the associated calibration test source.

7.2.2.4 The following is maintained as evidence of calibration procedure validation:

- a) Validation plan or procedure
- b) Reference to specifications/ test source
- c) Validation that the procedure includes the necessary test parameters per the test source
- d) Any applicable validation results obtained
- e) Verification that test method is metrologically sound, including traceability to SI, and level of calibration which indicates its validity of use

7.3 Sampling

Typically, sampling is applicable to testing laboratories, not calibration laboratories. Should a sampling need occur in a calibration laboratory a defined sampling plan will be used.

7.4 Handling of Tests or Calibration Items

7.4.1 Keysight 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 departments use Keysight Technologies' corporate documented shipping and handling procedures in conjunction with their own organization's procedures. A more detailed description of the processes used can be found in each facilities organizationally defined Business Management System documentation.

7.4.2 Keysight calibration facilities maintain a system to identify calibration items when under the facility's control. The system contains sufficient information to uniquely identify and track each calibration item.

7.4.3 All equipment received for calibration are verified or matched to appropriate paperwork such as model number, serial number, etc. In the event of any discrepancy, the appropriate interested parties are notified and the discrepancy resolved, and updated in the order management system.

7.4.4 When calibration items require storage under specific environmental conditions the environment is monitored and recorded.

7.5 Technical Records

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

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.

7.5.2 When mistakes occur on a manually prepared calibration report or test record, the entry shall be crossed-out with a single line and the correct values entered. Individuals making such corrections shall initial or sign alongside each 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.

7.6 Evaluation of Measurement Uncertainty

7.6.1 All Keysight calibration facilities identify the significant contributions when evaluating the measurement uncertainties for calibrations.

7.6.2 Keysight uses the same measurement uncertainty process for both internal and customer calibrations.

7.6.3 The methodology used for deriving the expanded measurement uncertainty is in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (ISO/IEC Guide 98-3) or its supplements. Other methods may have been used for earlier analysis and have been deemed to be acceptable.

7.7 Ensuring the Validity of Results

7.7.1 Keysight monitors the operations of the calibration facilities using one or more of the following techniques. Where applicable statistical techniques are applied to review the results.

- Use of reference materials (in physical/dimensional calibration facilities)
- Functional checks of measuring and test equipment
- Use of check standards with control charts where applicable
- Periodic intermediate checks on measuring equipment
- When calibration results are found to be potentially suspect, reviews are completed by competent personnel
- Intra laboratory comparisons
- Other activities may be performed on a facility by facility basis.

Most calibration facilities use the services of Keysight primary standards laboratories for the calibration of their most accurate working standards.

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

7.7.3 Data from monitoring activities, such as from 7.7.1 and 7.7.2, are analyzed and used to improve the calibration facilities activities. If the results are found to be outside of pre-defined criteria or show suspect results appropriate corrective action is taken.

7.8 Reporting of Results

7.8.1 General

7.8.1.1 A Calibration report includes both a certificate and data report. Each calibration includes specific information based on the type of calibration service rendered and customer specific requirements, if any. For details on the content of calibration reports, refer to the [Keysight Technologies Calibration Certificate Process web site](#).

7.8.1.2 Depending upon the customer contract, 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.

7.8.1.3 The results of tests or calibrations may be reported to the client in a simplified manner. This package shall contain sufficient information to comply with the customers' requirements.

Regardless of customer requirements for a calibration certificate or data report, all information concerning the calibration shall 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.

7.8.2 Common requirements for calibration reports

7.8.2.1 Each calibration report shall, at a minimum, include the following information:

- a) Title, such as "Certificate of Calibration" or equivalent
- b) Name and address of the facility performing the calibration
- c) Location where the calibration occurred. If at a customer site it is acceptable to simply list "customer premises" or equivalent.
- d) Unique identification of the calibration report and that all its parts are recognized as a part of the whole, and on each page an identification in order to ensure that the page is recognized as a part of the report and a clear identification of the end of the report.
- e) Name and address of the customer
- f) Identification of the method (procedure) used
- g) Description and/or unambiguous identification of the item being calibrated
- h) Date of receipt of the calibration item where this is critical to the validity of the results
- i) Date of the performance of the calibration activity

- j) Date of issue of the calibration report
- k) If a sampling plan is used, reference to the sampling plan and procedures
- l) Statement that the results only relate to the items calibrated
- m) Calibration Results with appropriate units of measure
- n) Deviations from standard procedures (if applicable)
- o) Identification of the person authorizing the report
- p) Clear identification when results are from external providers.

A statement indicating the calibration report shall not be reproduced except in full without Keysight approval shall be included on the calibration report.

7.8.2.2 Keysight Technologies maintains responsibility for the information provided in the calibration report. Should measurements be provided by the customer those are clearly identified.

7.8.3 This document applies to Keysight facilities performing calibrations. Should testing be performed the requirements of ISO 17025:2017 are adhered to.

7.8.4 Calibration Reports – additional requirements

7.8.4.1 Calibration Reports shall include:

- a) The measurement uncertainty of the measurement results presented in the same units as that of the measurand or in a term relative to the measurand.
- b) The conditions under which the calibrations were made that have an influence on the measurement results. Environmental monitoring equipment does not provide traceable parameters for calibrations and so the associated 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.
- c) A statement identifying how the measurements are metrologically traceable
- d) The result before and after any adjustment or repair, if available.
- e) Where relevant a statement of conformity with specifications.
- f) Where appropriate, opinions and interpretations.

7.8.4.2 Should sampling activities occur the certificate will meet the requirements of ISO 17025:2017.

7.8.4.3 Calibration certificates or labels shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. Such agreements are documented.

The minimum requirements for a calibration label are:

- Date of calibration
- Identification of the calibration event (service order number or equivalent)
- Unique identification of item being calibrated (asset number or serial number)
- Calibration due date when there is a prior agreement with customer for accredited calibrations. If the calibration is for Keysight owned item a due date is always applied.

7.8.5 Reporting Sampling – specific requirements

Should sampling activities occur the certificate will meet the requirements of ISO 17025:2017.

7.8.6 Reporting statements of conformity

7.8.6.1 For calibrations that include an accrediting body symbol when a statement of conformity to a specification is provided a decision rule is employed taking into account the associated level of risk associated. For further information on decision rules used and how those are documented on calibration reports refer to the [Keysight Instrument Calibration Report Standard Reference](#).

7.8.6.2 When a statement of conformity is reported the statement clearly identifies,

- a) which results the statement of conformity applies to
- b) which specifications are met or not met
- c) the decision rule applied

7.8.7 Reporting opinions and interpretations

7.8.7.1 Keysight Technologies, in general, does not provide opinions and interpretations on calibration services. Should an opinion or interpretation be performed the requirements of ISO 17025:2017 are adhered to.

7.8.8 Amendments to Calibration Reports

7.8.8.1 When an issued report needs to be changed, amended, or re-issued any change of information is clearly identified including the reason for the change.

7.8.8.2 Amendments to calibration reports will be issued as a separate document informing the customer of the amendment/supplement. This document will include the

statement “Supplement to Calibration Report” (or equivalent) 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.

7.8.8.3 When it is necessary to issue a complete new report this is uniquely identified and references the original that it replaces.

7.9 Complaints

7.9.1 Keysight facilities receives, document, evaluate, and make decisions on complaints through the [Customer Issue Resolution](#) (CIR) process.

7.9.2 A customer facing description of the [complaint handling process](#) can be provided to interested parties upon request.

7.9.3 The CIR process includes the following elements:

- a) Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it
- b) Tracking and recording complaints
- c) Ensure that appropriate actions are taken.

7.9.4 Keysight takes responsibility to gather and verify all necessary information to validate the complaint.

7.9.5 The CIR process requires Keysight to keep the customer informed during the progression of the complaint process.

7.9.6 The CIR process has oversight at the Keysight corporate quality level which maintains independence from the individual calibration facilities.

7.9.7 Whenever possible Keysight provides a formal notice of the final complaint resolution.

7.10 Nonconforming Work

7.10.1 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 a standard. When non-conforming work is reported, an evaluation is performed.

Notification of out of tolerance or undetermined conditions must be sent to owners of affected equipment as per the Keysight Out of Tolerance and Undetermined (OOTU) Procedure Requirements document.

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

Should the non-conforming work be identified to impact customer calibrations previously performed, all affected customers shall be notified, advised of the nature and extent of the incident, and given the opportunity to decide the course of action as they evaluate the impact of the non-conforming work on their products, processes, or services.

In cases where customers consider the non-conforming work condition to be significant, as defined in the Keysight Out of Tolerance and Undetermined (OOTU) Procedure Requirements document, the liability of the calibration facility will be limited to a re-calibration of the affected equipment at no charge.

7.10.2 Records shall be retained of nonconforming work and actions.

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

7.11 Control of Data and Information Management

7.11.1 All Keysight calibration facilities are connected to the Keysight network and have access to all the information necessary to facilitate calibration activities.

7.11.2 The Keysight information management system is fundamentally managed by the Keysight Information Technology (IT) team. The information management system includes all aspects of networking and software.

7.11.3 The Keysight IT team manages the process to authorize network access for all employees.

7.11.4 Most information is maintained by the [Keysight Technologies IT team](#). When external providers are used appropriate Confidential Disclosure Agreements and controls are in place and follow the [IT Security and Compliance](#) requirements.

7.11.5 All instructions, manuals, and applicable reference data relevant to Keysight Calibration Facilities are available through the Keysight network and available as needed to appropriate personnel.

7.11.6 Data transfers, such as calibration factors, are subject to appropriate checks when completed manually. Majority of data transfers are automatic through calibration software.

8.0 Management System Requirements

Keysight maintains an ISO 9001 quality system registered through [DEKRA](#). All Keysight Calibration Facilities are included in the scope of the [ISO 9001 quality system](#).

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 26 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_eps1024153.pdf

Document Control Log

REV NO.	CHANGE SUMMARY	DOCUMENT OWNER	APPROVER	DATE APPROVED	Effective Date
Original	First Issue	Ed Tong, Jerry Rorie	Jim Horner	14 Oct. 2002	14 Oct. 2002
A	Updated Coversheet.	Ed Tong Jerry Rorie	Jerry Rorie	3 May 2002	3 May 2002
B	Updated Environment temperature value to "(23 ± 5) deg C".	Ed Tong Jerry Rorie	Jerry Rorie	18 Jun. 2002	18 Jun. 2002
C	Updated Quality Policy to meet currently published information.	Ed Tong Jerry Rorie	Jerry Rorie	16 July 2002	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	14 Feb 2003
E	Various editorial changes	Ed Tong John Grubb	Ed Tong John Grubb	10 July 2003	10 July 2003
F	Clarified equipment status definitions in section 5.5.8.	Ed Tong John Grubb	Ed Tong John Grubb	6 Aug 2003	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	26 March 2004
18	Modified Para. 5.3.4 to reflect the discontinuance of the Agilent ESD Standard. Changed document Owner &	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	22 July 2004	22 July 2004

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 27 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_eps1024153.pdf

	Approver. Changed revision reference to align with the method used by Webdoc.				
19	Modified paragraph 4.7 to clarify client confidentiality requirements.	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	23 Sept 2004	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	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	1 July 2005
22	Changed the reference in the document header from EPSG to Keysight	Kerry Gwin Steven Hughes	Kerry Gwin Steven Hughes	23 Sept 2005	23 Sept 2005
23	Updated Manual to comply with the requirements of ISO 17025:2005	Kerry Gwin	Diana Clark	9 March 2006	9 March 2006
24	Reworded paragraph 5.10.2 to clarify calibration offerings statement	Kerry Gwin	Diana Clark	31 March 2006	31 March 2006
25	Reworded paragraph 5.2.5 to clarify content of training records	Kerry Gwin	Diana Clark	21 April 2006	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	7 August 2006
27	Added ISO 10012:2003(E) to the list of standards to which Keysight complies section 1.0	Kerry Gwin	Diana Clark	1 November 2006	1 November 2006

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 28 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_eps1024153.pdf

28	Corrected the Revision No.	Kerry Gwin	Diana Clark	27 June 2007	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	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	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	March 2009
32	Updated links to the Keysight Calibration Certificate Process Web Page in Section 5.10 and Appendix A	Kerry Gwin	Diana Clark	March 2009	March 2009
33	Removed references to CSG, uncertainty F# and reviewed and updated all sections.	Kerry Gwin	Ted Tucker	31 July 2009	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	September 2010
35	Changed the name of this table to Most Recent Change and corrected error in date column of the document control log.	Kerry Gwin	Ted Tucker	November 2010	November 2010

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 29 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_eps1024153.pdf

36	Skipped as part of the ShareDoc Revision synchronization.	Kerry Gwin	Ted Tucker	January 2011	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 Keysight 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	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	January 2011
39	Updated URL in header section. No content changes.	Kerry Gwin	Ted Tucker	February 2011	February 2011
40	Updated Revision number in header section to match the Revision History. No content changes.	Kerry Gwin	Ted Tucker	May 2011	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	June 2011
42	Updated rev number of document to match actual revision number	Kerry Gwin	Ted Tucker	June 2011	June 2011

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 30 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_eps1024153.pdf

43	Updated Section 5.3.1; Updated links throughout the document.	Kerry Gwin	Ted Tucker	January 2013	January 2013
44	Removed unnecessary signature blocks from copyright page.	Kerry Gwin	Ted Tucker	April 2013	April 2013
45	Converted from Agilent Technologies, Inc. to Keysight Technologies, Inc.	Kerry Gwin	Ted Tucker	7 May 2014	1 August 2014
46	Updated link to previous versions of this document to point to the Keysight instance of ShareDoc.	Kerry Gwin	Ted Tucker	7 July 2014	19 August 2014
47	Updated link to previous versions of this document to point to the Keysight instance of ShareDoc. Also updated various incorrect links throughout the document.	Kerry Gwin	Ted Tucker	1 October 2014	13 October 2014
48	Updated links on pages 5, 33 and 45; deleted inactive link on page 39; removed reference to Keysight Metrology Leadership Team in section 4.1.5.h.	Kerry Gwin	Ted Tucker	January 5015	January 2015
49	Corrected Approval and effective dates; updated document approver; Removed the restriction on the use of Standard Procedures in section 5.4.2; Added text in section 5.2.5 to clarify the authorization of certificates and reports.	Kerry Gwin	Rick Chapman	August 2015	August 2015
50	Updated sections 4.9 and 5.5 to refer to the new OOTU process;;	Kerry Gwin	Rick Chapman	11 Jan 2016	11 Jan 2016
51	Updated text in section 5.4.7.2 regarding ownership of software control	Kerry Gwin	Rick Chapman	24 Mar 2016	24 Mar 2016

Calibration System Manual

Doc # epsg1024153

Revision No: 53

Page 31 of 31

Document URL: http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/Keysight_CSM_epsg1024153.pdf

52	Update entire document to align with ISO 17025:2017 and update to current practices	Kerry Gwin Scott Arrants	Rick Chapman	3/22/2018	3/22/2018
53	Updated sections 6.4 and 7.10 to clarify requirements	Kerry Gwin Scott Arrants	Rick Chapman	7/27/2020	7/27/2020

Note: Revisions of this document prior to number 45 are located at:

http://sharedoc.collaboration.is.keysight.com/sites/EMG-Wide/SD/ISO/ISO%2017025/EMG_CSM_epsg1024153.pdf