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Note: Changes made in revision 1 are highlighted.

1 Introduction

Davis calibration laboratories provide an array of support services for test, measurement and control instrumentation. Calibration services to customers include several choices of where calibrations may be performed such as pick-up/return, on-site, on-premises and mobile. In addition, customers are offered certification options, repair services, asset leasing/rental, asset management, service recall, transit cases and warranty management.

Capabilities include the following areas:

- Communications
 - Electrical/Electronics
 - Fiber Optics
 - Flow
 - High Voltage/Current
 - X-Ray/Radiography
 - Physical Dimensional
 - Pipette
 - Precision Mass
 - Pressure
 - RF/Microwave
 - Temperature & Humidity
- Refer to www.daviscalibration.com/calibration-capabilities webpage for more information on capabilities.

Note: Changes made in Revision 1 are highlighted.

2 Scope

The Davis Calibration quality management system covers requirements of ISO 9001:2008, ISO 17025:2005 and ANSI Z540.1-1994. Applicable requirements from 10 CFR 21 and 10 CFR 50 Appendix B are also included.

Besides the permanent locations, the quality management system (QMS) covers work carried out at sites away from permanent locations, **satellites**, or in associated temporary or mobile facilities.

ISO 9001:2008

There is an exclusion to **ISO 9001:2008**. Section 7.3 does not apply to the Davis Calibration laboratories since there is no design or manufacturing of products.

ISO 17025:2005

Scopes of accreditation to ISO 17025 are unique to each location based on its abilities.

- Refer to the following link to view scopes by location:
www.daviscalibration.com/quality/calibration-certifications.asp

3 Definitions

Note: The normative references of definitions are the latest editions of the following: ISO 9000, *Quality management systems—Fundamentals and vocabulary*, ISO 17000, *Conformity assessment—Vocabulary and general principles*, and VIM, *International vocabulary of basic and general terms in metrology*, unless otherwise redefined in the quality manual.

4 Management Requirements

4.1 Organization

The calibration laboratories are part of an organization that can be held legally responsible. The legal name of the organization is Davis Inotek Instruments LLC. **Davis Calibration is the trade name or dba (doing business as).**

It is the responsibility of the laboratory to carry out its activities in such a way as to meet the applicable requirements of ISO 17025:2005 , **ISO 9001:2008**, **ANSI Z540.3-2006**, 10 CFR 21 and/or 10 CFR 50 Appendix B and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

Processes needed for the quality management system and their application throughout the organization are defined in procedures and instructions. The sequence and interaction of these processes are defined in procedures, presentations and guides. Basic processes of Davis Calibration laboratories includes: receiving, calibration, data entry and shipping. Refer to “Guide to Process Approach” for more information.

- Refer to Appendix B for list of SOPs
- Refer to Appendix C for basic overview of sequence and interaction of processes

If the laboratory is part of an organization performing activities other than calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the calibration activities of the laboratory is defined in order to identify potential conflicts of interest.

- Refer to corporate and laboratory organizational charts

The laboratory has managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the quality management system, and to identify the occurrence of departures from the QMS or from the procedures for performing calibrations, and to initiate actions to prevent or minimize such departures.

The laboratory has arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

The laboratory has procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.

- Refer to SOP CO-1003

The laboratory has policies to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

- Refer to the following policies in the HR Handbook:
 - "Confidentiality"
 - "Conflict of Interest"

The laboratory defines its organizational and managerial structure of the laboratory, its place in the organization, and the relationships between quality management, technical operations and support services.

- Refer to corporate and laboratory organizational charts

The laboratory specifies the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of calibrations.

The laboratory provides adequate supervision of laboratory staff, including trainees, by persons familiar with methods and procedures, purpose of each calibration, and with the assessment of the calibration results.

The laboratory has technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.

- Laboratory management designates a technical manager who has overall responsibility for the technical operations. This is documented on the "Multi-Role Designations Form."
- Identified laboratory approved signatories are documented on the "Multi-Role Designations Form."

The quality representative at the corporate level is the Quality Director, who has direct access to the highest level of management at which decisions are made on laboratory policy or resources. Responsibilities and authority for ensuring that the management system related to quality is implemented and followed at all times is defined.

The Laboratory Manager designates a quality representative and a deputy **for their location from members of their staff**. This is documented on the "Multi-Role Designations Form".

The laboratory ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the quality management system.

Top management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system.

4.2 Management System

The laboratory establishes, implements and maintains a quality management system appropriate to the scope of its activities. The laboratory documents its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the calibration results. The system's documentation is communicated to, understood by, available to, and implemented by the appropriate personnel.

The quality policy statement is issued under the authority of top management and implemented by appropriate personnel.

Quality Policy

Davis Calibration management and personnel are committed to:

- providing high quality calibrations in compliance with the requirements of ISO 17025, ISO 9001 and our customers
- meeting or exceeding our customer's expectations
- being familiar with the Davis Calibration quality management system and implementing quality procedures in their work
- the continual improvement and effectiveness of the Davis Calibration quality management system requirements.

Quality Objectives

Quality objectives for Davis Calibration laboratories are:

Basic Quality Data

Acceptance rate of calibration certificates and supporting documentation at final inspection step is > 99%.

Turn Around Times

Perform high quality calibrations that meet an average turn around time of 6 working days from the point of receipt into calibration software system.

External Audit Findings

A laboratory does not receive a major non-conformance from an accreditation/registration body during a calendar year.

Each quality objective is reviewed annually during management review.

Quality Manual

The quality manual:

- Defines the laboratory's quality management system policies, including a quality policy statement.
- Includes or makes references to the supporting procedures including technical procedures.
- Outlines the structure of the documentation used in the quality management system.

- Defines the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance of the quality management system.

Top management:

- Provides evidence of commitment to the development and implementation of the quality management system and to continually improving its effectiveness.
- Communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.
- Ensures that the integrity of the quality management system is maintained when changes to the QMS are planned and implemented.

4.3 Document Control

The quality management system is documented using a tier structure that consists of the following:

- Tier 1: Quality Policy & Quality Objectives
- Tier 2: Quality Manual
- Tier 3: Quality Procedures
- Tier 4: Quality Work Instructions, Forms & Records

The laboratory establishes and maintains procedures to control all documents that form part of its quality management system (internally generated or from external sources). The following control measures are defined in standard operating procedures:

- approvals for adequacy prior to issuance
- review, update, and re-approval
- change controls
- identification of current revision status
- availability of relevant versions at points of use
- legibility, unique identification and retrievability
- identification and distribution of external documents
- identification and management of obsolete documents
- assurance that appropriate personnel are informed of revisions
- periodic reviews for continuing suitability
- how changes in documents maintained in computerized systems are made and controlled

➤ Refer to SOP CO-2000

4.4 Review of Requests, Tenders and Contracts

The laboratory establishes and maintains procedures for the review of requests, tenders and contracts. The review also covers any work that is subcontracted by the laboratory.

The procedures for these reviews ensure that:

- The requirements, including the methods to be used, are adequately defined, documented, and understood.
- The laboratory has the capability and resources to meet the requirements.
- The appropriate calibration method is selected and capable of meeting the customers' requirements.

➤ Refer to SOP CO-3000

Any differences between the tender or request and the contract are resolved before any work commences. Each contract is acceptable both to the laboratory and the customer before any work is done. The customer is informed of any deviation from the contract.

Records of reviews, including any significant changes, are maintained. Records are maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the periods of execution of the approved contract.

If a contract needs to be amended after work has commenced, the same review process is repeated and any amendments are communicated to all affected personnel.

4.5 Subcontracting of Calibrations

When a laboratory subcontracts work, whether because of unforeseen reasons or on a continuing basis, this work is placed with a competent subcontractor.

The laboratory advises the customer of the arrangement in writing and, when appropriate, gains the approval of the customer, preferably in writing. In addition, the laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

The laboratory maintains a register of all subcontractors that it uses for calibrations and records the evidence of compliance for the work in question.

➤ Refer to approved vendor list (AVL) for subcontractors

4.6 Purchasing Services and Supplies

The laboratory has procedures for the selection and purchasing of services and supplies it uses that affect the quality of the calibrations. Procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the calibrations.

➤ Refer to SOP CO-4000

The laboratory ensures that purchased supplies and reagents and consumable materials that affect the quality of calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the calibrations concerned. These services and supplies used are to comply with specified requirements. Records of actions taken to check compliance are maintained.

Purchasing documents for items affecting the quality of laboratory output contain information describing the services and supplies ordered. These purchasing documents are reviewed and approved for technical content prior to release.

The laboratory evaluates suppliers of critical consumables, supplies and services which affect the quality of calibration, and maintains records of these evaluations and list those approved.

4.7 Service to the Customer

The laboratory willingly cooperates with customers or their representatives in clarifying the customer's requests and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

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

4.8 Complaints

The laboratory has a procedure for the resolution of complaints received from customers or other parties. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

- Refer to SOP CO-3001

4.9 Control of Nonconforming Calibration Work

The laboratory has a procedure to follow when any aspect of its calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.

The procedure ensures that:

- The responsibilities and authorities for the management of nonconforming work are designated and actions are defined and taken when nonconforming work is identified.
- An evaluation of the significance of the nonconforming work is made.
- Corrective action is taken immediately, together with any decision about the acceptability of the nonconforming work.
- Where necessary, the customer is notified and work is recalled.
- The responsibility for authorizing the resumption of work is defined.

- Refer to SOP CO-8001

The customer is notified when the identification of defective calibration equipment casts doubt on the validity of results and/or when any customer's equipment is found significantly out of tolerance during the calibration process. Out of tolerance measurement data is reported to the customer so appropriate action can be taken.

When the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratories operations within its own policies and procedures, the corrective action procedures given in 4.11 are promptly followed.

4.10 Improvement

The laboratory continually improves the effectiveness of its quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.11 Corrective Action

The laboratory has a procedure for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality management system or technical operations have been identified.

The procedure includes:

- To start with an investigation to determine the root cause(s) of the problem.
 - Who is an appropriate authority for implementing a corrective action.
 - When corrective action is needed, the laboratory identifies potential corrective actions.
 - The appropriate authority selects and implements the action(s) most likely to eliminate the problem and to prevent recurrence.
 - Corrective actions are made based on the degree appropriate to the magnitude and the risk of the problem.
 - The laboratory documents and implements any required changes resulting from corrective action investigations.
 - The laboratory monitors the results to ensure that the corrective actions taken have been effective.
- Refer to SOP CO-8000

When the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with ISO 17025:2005 and/or ISO 9001:2008, the laboratory ensures that the appropriate areas of activity are audited in accordance with its internal audit program as soon as possible.

4.12 Preventive Action

Needed improvements and potential sources of nonconformities, either technical or concerning the quality management system are identified. When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented, and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement. The procedure for preventive actions includes the initiation of such actions and the application of controls to ensure that they are effective.

- Refer to SOP CO-8000

4.13 Control of Records

The laboratory has procedures that describe the controls needed for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.

- Refer to SOP CO-2002

All records shall be legible, stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records are established. All records are held secure and in confidence.

The laboratory has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

- Refer to SOP CO-2003

The laboratory retains sufficient information to establish an audit trail, calibration records, staff records and a copy of each calibration certificate issued, for a defined period. The records for each calibration contains sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for sampling, performance of each calibration and checking of results.

Observations and calculations are recorded at the time that they are made and are identifiable to the specific task.

When mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations in records are signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

4.14 Internal Audits

The laboratory periodically, and in accordance with a predetermined schedule and procedure, conducts internal audits of its activities to verify that its operations continue to comply with the requirements of the quality management system and applicable standards such as ISO 17025:2005, ISO 9001:2008 and ANSI Z540.1-1994. The internal audit program addresses all elements of the quality management system, including the calibration activities.

It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Such audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's calibration results, the laboratory takes timely corrective action, and notifies customers in writing if investigations show that the laboratory results may have been affected.

- Refer to SOP CO-5000

The area of activity audited, the audit findings and corrective actions that arise from them are recorded. Follow-up audit activities are verified and the implementation/effectiveness of the corrective action taken is recorded.

4.15 Management Reviews

In accordance with a predetermined schedule and procedure, the laboratory's top management periodically conducts a review of the laboratory's quality management system and calibration activities to ensure the continuing suitability and effectiveness of the QMS, and to introduce necessary changes or improvements.

- Refer to SOP CO-1001

The management review takes into account: the suitability of policies and procedures; reports from managerial and supervisory personnel; the outcome of recent internal audits; status of corrective and preventive actions; assessments by external bodies; the results of interlaboratory comparisons or proficiency tests; changes in the volume and type of the work; process performance and product conformity; customer feedback; complaints; follow-up actions from previous management reviews; changes that could affect the QMS; and recommendations for improvement.

The output from the management review includes any decisions and actions related to: improvement of the effectiveness of the QMS and its processes; improvement of product related to customer requirements; and resource needs. Findings from management reviews and actions that arise from these reviews are recorded. The management ensures that those actions are carried out within an appropriate and agree timescale.

5 Technical Requirements

5.1 General

Many factors determine the correctness and reliability of the calibrations performed by a laboratory. These factors include contributions from, but not limited to: human factors; accommodation and environmental conditions; calibration methods and method validation; equipment; measurement traceability; sampling; and the handling of calibration items.

The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) calibrations. The laboratory takes into account those factors in developing calibration methods and procedures, in the training and qualification of personnel and in the selection and calibration of the equipment it uses.

5.2 Personnel

The laboratory management ensures the competence of all who operate specific equipment, perform calibrations, evaluate results, and sign calibration certificates. When using staff that

is undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

The laboratory management formulates the goals with the respect to the education, training and skills of the laboratory personnel. The laboratory has a procedure for identifying training needs and providing training of personnel. The training program is relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken is evaluated.

- Refer to SOP CO-7000

The laboratory may use personnel who are employed by, or under contact to, the laboratory. Where contracted and additional technical and key support personnel are used by the laboratory, the laboratory ensures that such personnel are supervised and competent and that they work in accordance with the laboratory's quality management system.

The laboratory maintains current job descriptions for managerial, technical and key support personnel involved in calibrations.

The management authorizes specific personnel to perform particular types of sampling, calibrations, issuing calibration reports, giving opinions and interpretations and operating particular types of equipment. The laboratory maintains records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.

5.3 Accommodation and Environmental Conditions

Laboratory facilities for calibration, including but not limited to energy resources, lighting and environmental conditions, are such as to facilitate correct performance of calibrations.

The laboratory ensures that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when sampling and calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of calibrations are documented.

The laboratory monitors, controls and records environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention is paid, as appropriate to the technical activities concerned. Calibrations are stopped when the environmental conditions jeopardize the results of the calibrations.

There are effective separations between neighboring areas in which there are incompatible activities. Measures are taken to prevent cross-contamination.

Access to and use of areas affecting the quality of calibrations is controlled. The laboratory determines the extent of control based on its particular circumstances.

Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary.

➤ Refer to SOP CO-9000

5.4 Test Methods and Method Validation

Selection of Methods

The laboratory uses appropriate methods and procedures for all calibrations within its scope. These include handling, transport, storage and preparation of items to be calibrated, and where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of calibration data.

The laboratory has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for calibration, where the absence of such instructions could jeopardize the results of the calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up-to-date and are readily available to personnel. Deviation from calibration methods may occur only if the deviation has been documented, technically justified, authorized and accepted by the customer.

The laboratory uses calibration methods which meet the needs of the customer and are appropriate for the calibrations it undertakes. Methods published in international, regional or national standards are preferably used. The laboratory ensures that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

When the customer does not specify the method to be used, the laboratory selects appropriate methods. Methods developed or adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer is informed as to the method chosen. The laboratory confirms that it can properly operate standard methods before introducing the calibrations. If the standard method changes, the confirmation is repeated. The laboratory informs the customer when the method proposed by the customer is considered to be inappropriate or out of date.

Laboratory Developed Methods

The introduction of calibration methods developed by the laboratory for its own use is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and effective communication amongst all personnel involved is ensured.

Non-standard Methods

When it is necessary to use methods not covered by standard methods, these methods are subject to agreement with the customer and includes a clear specification of the customer's requirements and the purpose of the calibration. The method developed is validated appropriately before use.

Validation of Methods

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

The range and accuracy of the values obtained from validated methods are assessed for the intended use, and relevant to the customers' needs.

Estimation of Uncertainty of Measurement

The laboratory applies procedures for estimating uncertainty of measurement for all calibrations and types of calibrations. When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation are taken into account using appropriate methods of analysis. **The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected.**

- Refer to SOP CO-9003

Control of Data

Calculations and data transfers are subject to appropriate checks in a systematic manner.

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, the laboratory ensures that:

- Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.
- Procedures are established and implemented for protecting the data; such procedures include, but not limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of calibration data.

- Refer to SOPs CO-1003, CO-2003

5.5 Equipment

The laboratory furnishes all items of sampling, measurement equipment required for the correct performance of the calibrations. In those cases where the laboratory needs to use equipment outside its permanent control, it ensures that the requirements of ISO 17025:2005 and/or **ISO 9001:2008** are met.

Equipment and its software used for calibration and sampling is capable of achieving the accuracy required and complies with specifications relevant to the calibrations concerned. Calibrations programs are established for key quantities or values of the instruments where

these properties have a significant effect on the results. Before being placed into service, equipment is calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It is checked and/or calibrated before use.

Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment are readily available for use by the appropriate laboratory personnel.

Each item of equipment and its software used for calibration and significant to the result, when practicable, are uniquely identified. Records are maintained of each item of equipment and its software significant to the calibrations maintained. The records include at least the following:

- The identity (name) of the item of equipment and its software.
- The manufacturer's name, type identification, and serial number or other unique identification.
- Checks that equipment complies with the specification.
- The current location, where appropriate.
- The manufacturer's instructions, if available, or reference to their location.
- Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration.
- The maintenance plan, where appropriate, and maintenance carried out to date.
- Any damage, malfunction, modification or repair to the equipment.
- Where relevant, measured value observed for each parameter found to be out of tolerance during calibration.

The laboratory has procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

- Refer to SOP CO-6000

Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. The equipment is isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration to perform correctly. The laboratory examines the effect of the defect or departure from specified limits on previous calibrations and institutes the "Control of Nonconforming Work" procedure.

- Refer to SOP CO-8001

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

When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory ensures that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks are carried out according to a defined procedure.

- Refer to SOP CO-9005

Where calibrations give rise to a set of correction factors, the laboratory has procedures to ensure that copies are correctly updated.

- Refer to SOP CO-6000

Test and calibration equipment, including both hardware and software, are safeguarded from adjustments which would invalidate the calibration results. For example, tamper resistant seals are affixed to operator accessible controls or adjustments on equipment which, if moved, would invalidate the calibration,

5.6 Measurement Traceability

All equipment used for calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the calibration is calibrated before being put into service. The laboratory has an established program and procedure for the calibration of its equipment. The program includes the procedures to ensure recall or removal from service of any standard which has exceeded its calibration interval or is otherwise judged to be unreliable.

- Refer to SOP CO-9002

The program for calibration of equipment is designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).

When using external calibration services, traceability of measurements are assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration provides confidence in measurements by establishing traceability to appropriate measurement standards such as: the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; and the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable program of interlaboratory comparisons is required where possible.

Reference Standards and Reference Materials

The laboratory has a program and procedures for the calibration of its reference standards. Reference standards are calibrated by a body that can provide traceability. Such reference standards of measurement held by the laboratory used for calibration only and for no other

purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards are calibrated before and after any adjustment.

Reference materials, where possible, are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

- Refer to SOP CO-6000

The laboratory has procedures for the safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

- Refer to SOP CO-6000

5.7 Sampling

The calibration laboratories do not sample items prior to calibration.

The laboratory has a plan and a procedure for sampling during the final inspection process.

- Refer to SOP CO-9004

Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these are recorded in detail with the appropriate sampling data and is included in all documents containing calibration results, and communicated to the appropriate personnel.

The laboratory has procedures for recording relevant data and operations relating to sampling that forms part of the calibration that is undertaken. These records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identifying the sampling location as necessary and, if appropriate the statistics the sampling procedures are based upon.

5.8 Handling Calibration Items

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

- Refer to SOP CO-6001

The laboratory has a system for identifying calibration items. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other

documents. The system, if appropriate, accommodates a sub-division of groups of items and the transfer of items within and from the laboratory.

Upon receipt of the calibration item, abnormalities or departures from normal or specified conditions, as described in the calibration method is recorded. When there is doubt as to the suitability of an item for calibration, or when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail, the laboratory consults the customer for further instructions before proceeding and records the discussion.

The laboratory has procedures and appropriate facilities for avoiding deterioration, loss or damage to the calibration item during storage, handling and preparation. Handling instructions provided with the item are followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded. Where a calibration item or a portion of an item is to be held secure, the laboratory has arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

- Refer to SOP CO-6001

5.9 Assuring the Quality of Calibration Results

The laboratory has quality control procedures for monitoring the validity of calibrations undertaken. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results.

- Refer to SOP CO-9005

The monitoring of the validity of calibration is planned and reviewed, and may include, but not limited to, the following:

- Regular use of certified reference materials and/or internal quality control using secondary reference materials.
- Participation in interlaboratory comparison or proficiency-testing programs.
- Replicate calibrations using the same or different methods.
- Recalibration of retained items.
- Correlation of results for different characteristics of an item.

Quality control data is analyzed and, where they are found to be outside pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.

5.10 Reporting the Results

Calibration Certificates

The results of each calibration, or series of calibrations carried out by the laboratory is reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration methods.

Calibration certificates include at least the following information, unless the laboratory has valid reasons for not doing so:

- Title
- Name and address of the laboratory, and the location where the calibrations were carried out, if different from the address of the laboratory
- Unique identification of the calibration certificate and of each page
- Name and address of the customer
- Identification of the method used
- Description of, the condition of, and unambiguous identification of the item(s) calibrated
- **Date of receipt of the calibration item(s) where this is critical to the validity and application of the results**
- Date of the performance of the calibration
- Reference to the procedure used
- Calibration results with, where appropriate, the units of measurement
- Name, function and signature or equivalent identification of person(s) authorizing the calibration certificate
- Where relevant, a statement to the effect that the results relate only to the item calibrated
- Where necessary, the conditions under which the calibrations were made that have an influence on the measurement results
- Where necessary, the uncertainty of measurement
- Where necessary, evidence that the measurements are traceable
- A statement that the certificate shall not be reproduced except in full, without the written approval of the laboratory
- Where necessary, special limitations of use
- Where necessary, any deviation from, additions to or exclusions from the calibration method, and any other information relevant to a specific calibration

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

- Refer to SOP CO-2007

Opinions and Interpretations

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

Results from Subcontractors

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

Electronic Transmission of Results

In the case of transmission of calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of ISO 17025:2005 are met.

Format of Calibration Certificates

The format is designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse.

Amendments to Calibration Certificates

Material amendments to a calibration certificate after issue is made only in the form of a further document, or data transfer, which includes the statement:

“Supplement to Calibration Certificate, serial number...[or otherwise identified]”, or an equivalent form of wording.

Such amendments meet all the requirements of ISO 17025:2005.

When it is necessary to issue a complete new calibration certificate, it will be uniquely identified and contain a reference to the original that it replaces.

Document Review

Name	Title	Review Date
E. Doughty	Quality Manager	

Approval

Name	Title	Approval Date
S. Hopkins	VP of Operations	

Revision History

Revision history is kept on file at Davis Calibration headquarters.

Appendix A

Procedural Requirements Referenced to Davis SOP Number

Refers to	ISO 17025 Clause	SOP Number
Customer confidentiality	4.1.5(c)	CO-1003
Protection of results	4.1.5(c)	CO-1003
Customer confidence	4.1.5(d)	HR "Confidentiality" & "Conflict of Interest" Policies
Document control	4.3	CO-2000
Contract review	4.4.1	CO-3000
Purchasing	4.6.1	CO-4000
Customer complaints	4.8	CO-3001
Control of nonconforming testing/calibration work	4.9.1	CO-8001
Corrective actions	4.11	CO-8000
Preventive actions	4.12	CO-8000
Control of quality records	4.13	CO-2002
Internal quality audits	4.14.1	CO-5000
Management review	4.15.1	CO-1001
Training	5.2.2	CO-7000
Estimation of measurement uncertainty	5.4.6	CO-9003
Data protection and security	5.4.7.2(b)	CO-2003
Equipment	5.5.6, 5.5.10, 5.5.11	CO-6000
Measurement traceability	5.6.1	CO-9002
Reference Standards (Masters)	5.6.3	CO-6000
Sampling	5.7	CO-9004
Handling of test and calibration items	5.8	CO-6001
Quality Control (MAPS & intermediate checks)	5.9.1, 5.6.3.3	CO-9005

Procedure	ISO 9001 Clause	SOP Reference
Control of documents	4.2.3	CO-2000
Control of records	4.2.4	CO-2002
Internal audit	8.2.2	CO-5000
Control of nonconforming product	8.3	CO-8001
Corrective action	8.5.2	CO-8000
Preventive action	8.5.3	CO-8000

Appendix B

Davis Calibration SOPs

SOP Number	SOP Title	ISO 17025 Clauses
CO-1000	Organizational Roles and Responsibilities	4.1, 4.2, 5.2
CO-1001	Management Reviews	4.10, 4.15
CO-1002	Use of Accreditation Body Symbol	NA
CO-1003	Communication Practices	4.1, 4.7, 5.4
CO-2000	Document Control Program	4.3
CO-2001	Control of External Documents	4.3
CO-2002	Control of Quality Records	4.13, 5.4
CO-2003	Backup of Electronic Records	4.13
CO-2004	Control of Automated Test Procedures	5.4
CO-2005	Label Control	4.3
CO-2006	Measurement Data	4.13
CO-2007	Calibration Certificates	4.3, 5.10
CO-3000	Contract Review and Amendment	4.4
CO-3001	Handling Customer Complaints	4.8
CO-4000	Purchasing	4.5, 4.6
CO-4001	Supplier Evaluation Program	4.5, 4.6
CO-5000	Internal Audit Program	4.14
CO-5001	Supplier Audits	4.5, 4.6
CO-6000	Control of IMTE	5.4, 5.5, 5.6
CO-6001	Handling Calibration Items	5.5, 5.6, 5.8
CO-7000	Qualifications Program	5.2
CO-8000	Corrective and Preventive Action Program	4.11, 4.12
CO-8001	Control of Nonconforming Product	4.9
CO-8002	Out-of-Tolerance Conditions	4.9, 5.4
CO-8003	Deviations	4.1, 5.4
CO-9000	Accommodations and Environmental Conditions	5.3
CO-9001	Calibration Procedures	5.4
CO-9002	Measurement Traceability	5.6
CO-9003	Estimation of Uncertainty Measurement	5.4
CO-9004	Inspections	5.7, 5.8
CO-9005	Measurement Assurance Program	5.5, 5.6, 5.9
CO-9006	Onsite and Mobile Calibration Activities	4.1
CO-9007	Interlaboratory Transfers	4.1
CO-9008	Use of Equipment Labels	5.5
10000 series	Calibration Software System Specific	5.4

Appendix C

Basic Process Example

