

Midwest Metrology, LLC  
341 Smith Drive  
Clayton, Ohio 45315

**Management System Manual LEVEL 1**

Doc. No. MSM

Rev. No. F

Date: 12/28/06

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MIDWEST METROLOGY, LLC

**ISO/IEC 17025  
Management System Manual**

Approved:  
Document Author

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General Manager

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**Distribution List**

*Company Intranet*

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# Introduction to Midwest Metrology, LLC

## COMPANY OVERVIEW

Midwest Metrology, LLC is a multi-parameter and device calibration laboratory. Offering services both in its laboratory and in the field.

## MANAGEMENT SYSTEM MANUAL

The Quality Manager is responsible for reviewing, revising and maintaining this manual as necessary. This manual contains no confidential information. The Corporate Director of Laboratory authorizes the Quality Manager to approve this manual, including any revisions and to authorize its release. Uncontrolled copies of this manual are available to customers. The identification of the status of this manual is identified in the footer of any particular page within the manual.

The release of a controlled copy follows Internal Procedures, which requires a Distribution Sign-off Sheet to be signed by the recipient. The sign-off sheet also identifies the collection of the obsolete controlled copy, where applicable. All distributed controlled copies are logged on the "Distribution List". The Quality Manager maintains the Sign-off Sheets and the Distribution Lists in the Quality Office. Upon the release of a new revision, the Quality Manager contacts all relevant Controlled Copy holders and arranges for the collection of their "Obsolete Copy" and the issue of the revised copy.

Due to the strict requirements of releasing "Controlled Copies" of this manual, it is the policy of Midwest Metrology, LLC to provide only "Uncontrolled Copies" to customers unless special arrangements are made with the MM Quality Manager.

Holders of Uncontrolled Copies can contact the Quality Manager periodically to verify their Revision as being current. (Standard Operating Procedures are for internal use only and can be viewed by customers for auditing purposes at MM.)

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## QUALITY POLICY

Midwest Metrology, LLC is a supplier of calibration and repair services to a large number of industries involving all types of quality requirements. Our success in large part has been based on understanding, promoting, and delivering the highest quality products and services to our customers. Our "Quality First" philosophy applies to every aspect of our business. Each Midwest Metrology, LLC employee is empowered to resolve all quality and customer service issues promptly by completely utilizing any and all resources necessary.

It is recognized that in a service business our entire organization must be committed to the solitary goal of providing our customers with unparalleled service.

Midwest Metrology, LLC is committed to providing customers with unsurpassed quality in calibration and system maintenance services. Our management system is designed to provide good professional practices by utilizing recognized and approved methods and procedures to support our customer's quality requirements.

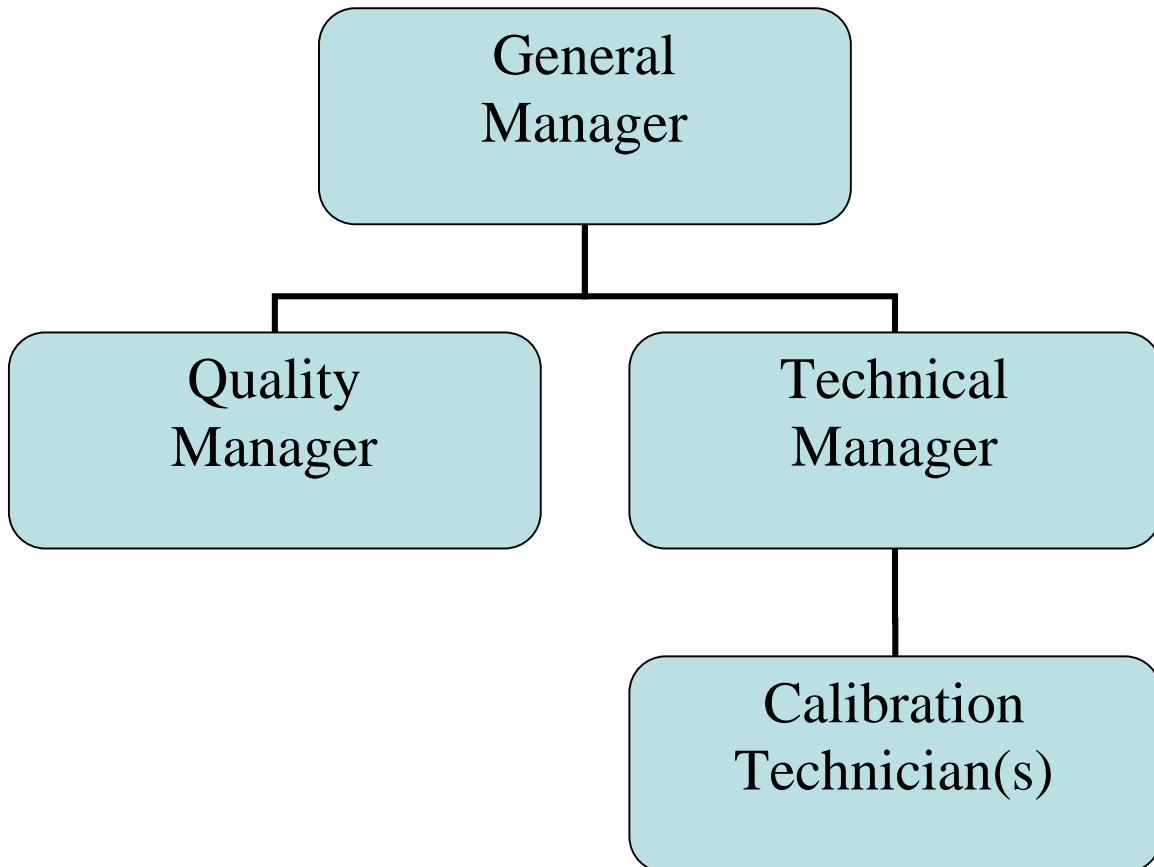
In order to fulfill our customer's needs, Midwest Metrology, LLC evaluates all requirements and systems pertinent to the customer's quality and testing programs. Recommendations for changes in procedures, sample handling and preparation, maintenance, environmental, and/or utilities are provided where needed to ensure a high probability for accurate and valid results for the customer.

All Midwest Metrology, LLC employees are required to familiarize themselves with our Management system and implement the given policies and procedures in their work

Midwest Metrology, LLC maintains a controlled Management system Manual with the objective of ensuring our commitment to continuous improvement in our services and compliance to ISO/IEC17025 along with A2LA's additional requirements needed to maintain our laboratory accreditation.

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## Midwest Metrology, LLC Organization Chart



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## 1. Purpose

- To establish and implement a management system compliant to ISO9002, ANSI/NCSL Z-540-1, MIL STD 45662A, and ISO/IEC 17025.

## 2. Scope of Management system

This manual and the management system of which it refers to applies to all calibration operations of Midwest Metrology, LLC. See section 4.2 for details of Management system structure.

## 3. Responsibilities

### General Statement

Responsibilities and job descriptions are defined in the Standard Operating Procedures and associated forms. Linked text in this document only function within the complete management system.

**Management** supports the organizational freedom and authority to:

- ◆ Identify and record any service quality problems.
- ◆ Initiate, recommend or provide solutions through designated channels.
- ◆ Verify the implementation of solutions.
- ◆ Control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

**Management** defines the responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality. Management identifies in-house verification requirements, provides adequate resources, and assigns trained personnel for verification activities.

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## **4.0 Management Requirements**

### **4.1 Organization**

#### **4.1.1 Laboratory**

The legal name of this Laboratory (Organization) is “Midwest Metrology, LLC”. It may henceforth be referred to as “MM”. Its current operating location is at:

*Location:*  
341 Smith Drive  
Clayton, Ohio 45315

Midwest Metrology, LLC additionally provides on-site calibration services to customers. The requirements as given in this Management system Manual are fully applied to these on-site calibration activities.

#### **4.1.2 Compliance**

MM carries out its calibration activities in compliance with this Management system and to satisfy the needs of the customer.

#### **4.1.3 Operations**

All operations, in-house and on-site, conducted by MM are performed in compliance to this Management system.

#### **4.1.4 Organization**

Midwest Metrology, LLC provides calibration services and no other services that could place Midwest Metrology, LLC or its personnel in a position where conflicting interest could be a concern.

#### **4.1.5 Processes**

See [4.1SOP01](#) for details of responsibility pertaining to the management system and organization of Midwest Metrology, LLC. An Organizational Chart is given in this manual.

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#### 4.1.6 Communication

**GEN MGR** has overall responsibility for ensuring that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system. This is accomplished through a regularly scheduled shop meeting. Topics covered in the shop meetings include, but are not limited to:

- customer, statutory and regulatory requirements
- any changes to management system documents
- **internal and/or external audit results**

## 4.2 Management system

### 4.2.1 Management system

All employees are responsible for compliance to the Management system. The individual documents define specific employee responsibilities.

Responsibility is assigned for the establishment, implementation, and the maintaining of the Management system appropriate to the scope of its activities, including the type, range, and volume of calibration activities it undertakes. The Management system includes the identification and references to the laboratories documented policies, systems, programs, procedures, and instructions to the extent necessary to enable the laboratory to assure the quality of the test and/or calibration results it generates.

Responsibility is assigned for ensuring that documentation used in this Management system is communicated to, understood by, available to, and implemented by the appropriate personnel.

### 4.2.2 Quality Policy & Objectives

The fundamental objective for this Management system is to provide documentation, which ensures compliance to all

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standards as given in “Section 1” of this manual. Additional objectives include the provision of documented procedures ensuring consistency in our processes, giving us a bar by which continuous improvement can be verifiably achieved. Other specific objectives are identified in the individual procedures.

The overall objectives are set out in the Quality Policy statement in this management system manual, issued by top management, stating the standard of performance to be obtained and maintained, and are reviewed during management review.

**4.2.3** Top management is responsible for the development and implementation of the management system and to continually improving its effectiveness. Evidence of continual improvement is indicated by revision history of management system documents, internal audit results, and corrective and preventive actions.

**4.2.4** Top management is responsible for communicating to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements. This is accomplished during the shop meeting, as discussed in [4-1SOP01](#).

#### **4.2.5 Supporting Procedures**

Supporting procedures including technical procedures utilized by MM are controlled by the Management system.

The Management system is maintained and up to date.

#### **4.2.6 Quality and Technical Management**

**QUAL MGR and TECH MGR** are responsible for ensuring that the laboratory operations and documented management system are in compliance with the standards referenced in the level 1 of this management system, as well as with customer requirements. This is accomplished during shop meetings, as required.

Quality and Technical management roles and responsibilities are defined in the job description documents QUALMAN and TECHMAN controlled within this quality system. Additionally, roles and responsibilities are defined throughout the Management system.

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#### **4.2.7 Changes to the Management System**

**4.7.1** Top management is responsible for ensuring that the integrity of the management system is maintained when changes to the management system are planned and implemented. This is done by ensuring adherence to present management system documents until revised, and then communicating any changes to all employees.

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

#### **4.2.8 Quality Manual and System Structure**

Through a formal documented system of planned activities, the Management system meets:

- jurisdictional regulations, codes, and standards
- contractual specifications and drawings
- corporate quality objectives

This program complies with the applicable sections and elements of standards established and recognized by the governmental agencies and the customers served.

The quality manual is current and up-to-date to reflect changes to the system, simply stated, easy to use, and fully approved by all affected functional groups.

Procedures and instructions are implemented as written.

#### **STRUCTURE**

**LEVEL 1 Management system Manual** (This Manual)

**LEVEL 2 Standard Operating Procedures:** Identified and linked to this manual by structure of document number, e.g. 4.1SOP01 is the first document in the series of Standard

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Operating Procedures (SOP) relative to section (element) 4.1 of this manual. Additional documents in the 4.1 series would be referenced in either the preceding document or the 4.1SOP **01** document and would have the document number 4.1SOP02, 03, etc., as applicable, relative to the given example.

**LEVEL 3 Work Instructions and Calibration Procedures:** May have various document numbers and formats, linked to system by reference in the applicable LEVEL 2 SOP section 5 "Related Documents". May be linked through a controlled list containing applicable document numbers and one or more of the following; revision dates or revision levels.

**LEVEL 4 Quality Records :** Documents and completed forms as described by the system and maintained in conformance to the system.

### 4.3 Document Control

#### 4.3.1 General

MM establishes and maintains procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, calibration methods, as well as drawings, software, specifications, instructions, and manuals.

##### 4.3.1.1 Types of Documents

See [4.3SOP01](#) for list of types of documents under control.

#### 4.3.2 Document Approval and Issue

##### 4.3.2.1 Approval and Issue

Only the latest revisions of controlled documents are available at all locations where operations essential to the effective functioning of the laboratory are performed.

Documents are approved by designated personnel .

##### 4.3.2.2 Identification of Document Status

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“Draft Copy” and “Obsolete” markings override any other markings. Stamped markings override other markings.

“Draft Copy” documents are not to be implemented or used until status is changed.

#### **4.3.2.3 Identification of Document Status**

Management system documents generated by the laboratory are be uniquely identified. Such identification includes the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

### **4.3.3 Document Changes**

Any employee can initiate a change to a document by completing a “Document Change Request” form. Change requests are logged in the “Document Change Request” log.

Individual identified as “Document Author” on first page of the Level 1 & 2 documents are responsible to author the requested changes when approved.

#### **4.3.3.1 Review and Approval**

Change requests are reviewed and either approved or disapproved by the same function (individuals identified on first page of Level 1 & 2 documents) that performed the original review. The designated personnel have access to pertinent background information upon which to base their review and approval. If the change is approved, the document is updated.

#### **4.3.3.2 Change Record**

Change records are maintained which identify the changes made to controlled documents or a copy of the document is maintained as an obsolete copy.

#### **4.3.3.3 Amendments**

Authority is given to certain individuals for hand pen changes to documents in the event that an emergency change needs to be employed. The change is considered temporary and must be clearly marked,

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initialed and dated. A formal re-issue of the document is performed as soon as practical.

#### **4.3.3.4 Computerized Documents**

A procedure exists that describe how changes in documents maintained in computerized systems are made and controlled, as applicable. See *Digital Document Control Procedure* [4.3SOP02](#)

### **4.4 Review of Requests, Tenders, and Contracts Procedure**

#### **4.4.1 General**

All new work is reviewed to ensure that the laboratory has the appropriate facilities and resources before commencing such work.

Quotes are generated for the following products:

- Calibration Services.
- Repair, installation, and preventative maintenance of various types of equipment.
- Providing personnel for assistance in technical support.

Service rates are priced on an item-by-item basis, consisting of flat rates, hourly rates, and discounts relating to customer volume and requirements.

Contracts are reviewed ensuring:

- The requirements, including the methods to be used are adequately defined, documented, and understood (See 5.4.2).
- The laboratory has the capability and resources to meet the requirements.
- The appropriate calibration method is selected and capable of meeting the customers' requirements.
- Any differences between the request or tender and the contract are resolved before any work commences. Each contract must be acceptable to both the laboratory and the customer.

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#### **4.4.2 Records of Review**

Records of such 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 period of execution of the contract.

#### **4.4.3 Review of Subcontracted Work**

Subcontracted work is reviewed for the same requirements as for work performed by MM. This is done by communication with the selected subcontractor. Records of this review are maintained in the customers job file. (See [4.5SOP01](#) for details)

#### **4.4.4 Contract Deviations**

The customer is informed of any deviations from the contract.

#### **4.4.5 Contract Amendments**

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

### **4.5 Subcontracting of Tests and Calibrations**

#### **4.5.1 Subcontractor Selection**

When the laboratory has to subcontract work, it is placed with a competent subcontractor.

#### **4.5.2 Customer Approval**

The laboratory advises and obtains approval from the customer, preferably in writing, when the laboratory intends to subcontract to another laboratory specific tests and/or calibrations, or a part of a test and/or calibration.

#### **4.5.3 Responsibility of Subcontracted Work Quality**

The laboratory is always responsible to its customer for the work the subcontractor performs, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

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#### **4.5.4 Records of Subcontractor Assessments**

The laboratory maintains a register of all subcontractors that it uses for tests and/or calibrations and a record of the assessments it has made of them and of all subcontracted tests and/or calibrations.

### **4.6 Purchasing Services and Supplies**

#### **4.6.1 Purchasing Policies and Procedures**

The laboratory has policies and 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 consumable materials relevant to the calibrations.

#### **4.6.2 Consumable Compliance Verification**

The laboratory ensures that purchased supplies, 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 tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

#### **4.6.3 Purchasing Documents for Consumables**

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

#### **4.6.4 Critical Service Suppliers**

Critical services are identified as requiring ISO/IEC17025 accredited services. The laboratory evaluates suppliers of critical consumables, supplies, and services that affect the quality of calibration and maintain records of these evaluations and list those approved.

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## 4.7 Service to the Customer

The laboratory affords customers or their representative's co-operation to facilitate clarification of the customer's request and to monitor the performance of the laboratory in relation to the work performed.

**4.7.2** Customer satisfaction is reviewed at least annually during the management review meeting. QA procedure 4.7SOP02 defines the method of distribution and review of results. Goals have been established for

### 4.7.3

## 4.8 Complaints

**POLICY:** *All complaints from customers and /or other parties must be documented on the appropriate form and resolved typically within 30 days from receipt, unless there is exceptional reason for requiring a longer time period. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).*

The procedure 4.8.1SOP01 is followed when a complaint is received.

## 4.9 Control of Nonconforming Calibration Work

**POLICY:** *Any situation involving the discovery of non-conforming work must be addressed, documented, and resolved within 30 days of discovery. This includes the identification and determining of a resolution to correct for such a situation. This also includes notification to affected recipients of calibration work performed by the laboratory.*

The procedure [4.9SOP01](#) is followed when any aspect of calibration work is performed, or the results of this work do not conform to the procedures designated to be used in performing the calibration by internal processes or by requirements agreed upon with the customer.

## 4.10 Improvement

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Midwest Metrology, LLC continually improves the effectiveness of its 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**

### **4.11.1 General**

**Policy:** *When nonconforming work or conditions occur in the process, services, quality management system, or when customer complaints or returns are received, employees take immediate and appropriate corrective action according to documented Quality Procedure 4.11SOP01. The laboratory has the policy that corrective actions be documented on the appropriate form and resolved typically within 30 days of the identification.*

Procedure 4.11SOP01 defines those managers with responsibility and authority for corrective action when products or processes become noncompliant with specified requirements.

Any required changes to the operational procedures resulting from corrective action investigations are documented and implemented.

### **4.11.2 Cause Analysis**

Root cause analysis is performed and may be assigned to the applicable manager.

### **4.11.3 Selection and Implementation of Corrective Actions**

The actions most likely to eliminate the problem and to prevent recurrence are selected and implemented. Any corrective action taken to eliminate the cause(s) of nonconformity's or other departures are to a degree appropriate to the magnitude of the problem to commensurate with the risks encountered.

### **4.11.4 Monitoring of Corrective Actions**

Follow-up of the corrective action are performed within a designated timeframe of implementation of the corrective action.

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The objective of the follow-up is to assess the success of the corrective action in achieving its objective.

#### **4.11.5 Additional Audits**

Where the identification of nonconformity's or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with stated International Standards, the appropriate areas of activity are promptly audited in accordance with [4.13SOP01](#).

This additional audit may be scheduled to follow implementation of the corrective actions to confirm their effectiveness.

An additional audit is mandatory when a serious issue or risk to the business is identified.

### **4.12 Preventive Actions**

#### **4.12.1 General**

Any potential need for preventive action from various sources such as internal or external audit observances, management reviews, feedback from customers and staff observations are evaluated.

Any required changes to the operational procedures resulting from identified improvement opportunities or preventive action investigations are documented and implemented.

#### **4.12.2 Preventive Actions**

The actions most likely to eliminate the potential problem are selected and implemented. Preventive actions are followed up. The objective of the follow-up is to assess the success of the preventive action in achieving its objective.

### **4.13 Control of Records**

#### **4.13.1 General**

##### **4.13.1.1 Procedure Authority and Requirements**

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Procedure(s) for identification, collection, indexing, access, storage, maintenance, and disposal of quality and technical records are established and maintained.

#### **4.13.1.2 Storage**

Quality records are stored in designated areas throughout the facilities of Midwest Metrology, LLC under control and maintained by designated individuals. They are legible and stored 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. The length of time is indicated in [4.12SOP01](#).

#### **4.13.1.3 Security and Confidence**

All records are held secure and in confidence.

#### **4.13.1.4 Computerized Records**

Where computerized, Quality records follow an established backup procedure.

### **4.13.2 Technical Records**

#### **4.13.2.1 Performance of Calibration Records**

The laboratory maintains original observations, derived data and 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 contain 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 identity of personnel responsible for sampling, performance of each calibration and checking of results.

#### **4.13.2.2 Observations, Data and Calculations**

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

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### **4.13.2.3 Mistakes and Corrections in Records**

When mistakes occur in records, each mistake is crossed out, not erased, made neither illegible nor deleted, and the correct value is entered alongside. All such alterations to 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 the original data.

## **4.14 Internal Audits**

### **4.14.1 General**

Predetermined audit plans and schedules are established. The schedule and audit plan ensures that the operations are audited for compliance to the management system and procedures and address all elements of the management system, including the calibration activities. This plan meets the requirements as dictated by management. These requirements include:

- Carried out by trained and qualified personnel.
- Wherever resources permit, the personnel are independent of the areas being audited by them.
- The cycle is completed within one year.

### **4.14.2 Corrective Actions**

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's calibration results, corrective actions are timely and customers are notified in writing if investigation shows that the laboratory results may have been affected.

### **4.14.3 Records**

Areas audited are documented along with findings and corrective actions that arise from the audit.

### **4.14.4 Follow-up**

Follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken.

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## 4.15 Management Reviews

### 4.15.1 Management Review

See *Internal Audits and Records*.

Top management reviews the results of internal audits, plans and schedules audits of quality processes and procedures according to the Internal Audits procedure.

According to a defined schedule, the management system is reviewed. This review includes:

- The suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- The outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- The results of interlaboratory comparisons or proficiency tests;
- Changes in the volume and type of work;
- Customer feedback;
- Complaints;
- Site calibration activities;
- Other relevant factors, such as quality control activities, resources, and staff training;
- Recommendations for improvement.

The review takes into account reports from managerial and supervisory staff.

This review feeds into the laboratory planning system and includes the goals, objectives and action plans for the upcoming year.

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This review may be supplemented by consideration of related subjects at regular management meetings.

#### **4.15.2 Records of Management Review**

Management review meetings are documented and maintained. This record contains findings and actions taken as a result of this meeting. The actions are discharged within an appropriate and agreed upon timescale.

#### **4.15.3 Management Representative**

The Quality Manager is designated as the company's Management Representative of Quality.

## **5. Technical Requirements**

### **5.1 General**

**5.1.1** Many factors determine the correctness and reliability of the calibrations performed by a calibration laboratory. This procedure identifies known factors in order to assist in ongoing assessment, control, and improvement of these problematic components of measurement. These factors include contributions from:

- **Human factors (See 5.2)**
- **Accommodation and environmental conditions (5.3)**
- **Calibration methods and method validation (5.4)**
- **Equipment (5.5)**
- **Measurement Uncertainty (5.6)**
- **Sampling (5.7)**
- **Handling of calibration items (5.8)**

**5.1.2** The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) calibrations. Midwest Metrology, LLC takes account of these factors in developing calibration methods and procedures, in the

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training and qualifications of personnel, and in the selection and calibration of the equipment it uses.

## 5.2 Personnel

### 5.2.1 Technical Qualifications

**5.2.1.1** Only qualified personnel are utilized in operating specific laboratory equipment, performing calibrations, evaluating results, and signing calibration reports. The “Employee Training Record” is the evidence of competency of personnel for these specific tasks that can affect quality. Personnel performing these tasks while in training are supervised.

**5.2.1.2** The “Employee Training Record” identifies the employee as being “***In Training***”, “***Qualified***”, or “***Qualified to Train***” for specific tasks affecting quality. It also identifies the requirements of appropriate education, training, experience, and/or demonstrated skills, as required.

### 5.2.2 Training Goals and Training Needs Identification

**5.2.2.1** Management formulates goals and requirements with respect to the education and training and skills required for personnel performing tasks affecting quality. These goals and requirements are identified in the “Employee Training Record”.

**5.2.2.2** Management identifies training needs and provides training, as applicable. Management evaluates the effectiveness of the training actions taken.

### 5.2.3 Permanent and Contracted Personnel

**5.2.3.1** Management is responsible for ensuring the following policy is followed:

**Policy:** *It is the policy of this laboratory to only use personnel who are permanently employed by, or under contract to, the laboratory. Where additional key support personnel are contracted and used, such personnel are supervised and competent and*

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*work in accordance with the laboratory's management system.*

## 5.2.4 Job Descriptions

5.2.4.1 Management is responsible for ensuring that job descriptions are maintained current for managerial, technical, and key support personnel involved in calibrations.

## 5.2.5 Employee Training Records

5.2.5.1 The “**Employee Training Record**” is used to identify level of qualification and the specific technical task, including sampling, where required, and issuing reports of calibration, giving opinions and interpretations, and operating specific equipment.

5.2.5.2 The “**Employee Training Record**” form includes procedural content and is under document control by revision date.

5.2.5.3 The “**Employee Training Record**” is maintained by management and readily available. It includes the date on which authorization is based and the identification of the confirming authority.

## 5.3 Accommodation and Environmental Conditions

5.3.1 Management ensures that the laboratory facilities for calibration, including but not limited to, energy sources, lighting, and environmental conditions are maintained to facilitate correct performance of calibrations. This includes calibrations performed at a customer’s facility.

5.3.1.1 The laboratory ensures that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. This includes work performed at customers’ facilities as well as within MM laboratory.

## 5.3.2 Environmental Monitoring

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**5.3.2.1** Environmental conditions that can significantly affect measurement quality are monitored, controlled, and recorded, as necessary. The technical requirements for accommodation and environmental conditions that can affect the results of calibrations are documented.

**5.3.2.2** Environmental conditions for the performance of specific calibrations are identified and posted.

**5.3.2.3** All employees are responsible for stopping calibrations when the acceptable environmental range is exceeded and notifying management. Calibrations do not resume until management determines that the calibration can resume without the results being jeopardized by the environmental conditions.

**5.3.3** There is effective separation between neighboring areas in which there are incompatible activities and taking measures to prevent cross-contamination.

**5.3.4** Access to and use of areas affecting quality are restricted to applicable personnel. Unauthorized personnel can access these areas under escort.

**5.3.5** Good housekeeping is maintained in the laboratory. Special procedures are prepared where necessary.

## **5.4 Calibration Methods and Method Validation**

### **5.4.1 General**

**5.4.1.1** The laboratory uses appropriate methods and provides procedures for all calibrations, including sampling, handling, transport, storage, and preparation of items to be calibrated and where appropriate, the estimation of the measurement uncertainty as well as statistical techniques for analysis of calibration data.

**5.4.1.2** 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 calibration results.

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**5.4.1.3** All instructions, standards, and manuals are kept up to date and readily available to applicable personnel.

**5.4.1.4** Deviations from calibration methods only occur if the deviation has been documented on the calibration report. It must be deemed technically justified and authorized by management and accepted by customer.

#### **5.4.2 Selection of Methods**

**5.4.2.1** The laboratory uses calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the calibrations it undertakes. Methods published in international, regional, or national standards are used. The laboratory uses the latest edition of standards, where possible and appropriate. When necessary, the standard may be supplemented with additional details to ensure consistent application.

**5.4.2.2** Where the customer does not specify the method to be used, the laboratory selects appropriate methods that have either been published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.

**5.4.2.3** Laboratory-developed methods or methods adopted by the laboratory can be used if deemed appropriate and validated.

**5.4.2.4** The customer is informed as to the method chosen and is informed when the method proposed by customer is considered to be inappropriate or out of date.

#### **5.4.3 Laboratory-Developed Methods**

**5.4.3.1** Introduction of calibration methods developed by the laboratory for its own use is a planned activity by qualified personnel equipped with adequate resources.

#### **5.4.4 Non-Standard Methods**

**5.4.4.1** When it is necessary to use methods not covered by standard methods, they are subject to agreement with the

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customer and include a clear specification of the customer's requirements and the purpose of the calibration. The method is validated appropriately before use.

#### **5.4.5 Validation of Methods**

- 5.4.5.1** Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
- 5.4.5.2** The laboratory validates non-standard methods, standard methods used outside their intended range and amplification of standard methods to confirm that the methods are fit for the intended use. That the validation is as extensive as necessary to meet the needs of the given application or field of application. And that 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.
- 5.4.5.3** The range and accuracy of the values obtainable from validated methods as assessed for the intended use are relevant to the customers needs .

#### **5.4.6 Estimation of the Uncertainty of Measurement**

- 5.4.6.1** The laboratory has a procedure to calculate its estimation of the uncertainty of measurement. (See [5-4SOP02](#)) These calculations are available for specified ranges and for all quantities/measurements in its scope.
- 5.4.6.2** This section of the standard is not currently applicable to MM, as MM does not perform testing.
- 5.4.6.3** 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.

#### **5.4.7 Control of Data**

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

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**5.4.7.2** Where computers or automated equipment is used for the acquisition, processing, recording, reporting, storage, or retrieval of calibration data, the laboratory ensures that:

**5.4.7.2.1** Computer software developed by the laboratory is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use.

**5.4.7.2.2** Procedures and/or policies are established and implemented for protecting the integrity of data.

**5.4.7.2.3** 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 .

## **5.5 Equipment**

**5.5.1** The laboratory is furnished with all items of sampling, measurement and test equipment required for the correct performance of the calibrations it performs, including sampling, preparation of calibration items, processing and analysis of calibration data, as applicable. In cases where the laboratory needs to use equipment outside its permanent control, it ensures that the requirements of this procedure are met.

**5.5.2** 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. Calibration 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, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with [5-6SOP01](#) before use.

**5.5.3** 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.

**5.5.4** Each item of equipment and its software used for calibration and significant to the results is, when practical, uniquely identified.

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- 5.5.5** Records are maintained of each item of equipment and its software significant to the calibrations performed.
- 5.5.6** The laboratory has policies and/or 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.
- 5.5.7** Equipment that has been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly labeled or marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly. Management examines the effect of the defect or departure from specified limits on previous calibrations and institutes the **“Control of Non-Conforming Work”** procedure.
- 5.5.8** Whenever practicable, all equipment under the control of the laboratory is labeled, coded or otherwise identified to indicate the status of calibration including the date when last calibrated and the date of expiration criteria when recalibration is due.
- 5.5.9** 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 is checked and shown to be satisfactory before the equipment is returned to service.
- 5.5.10** The TECH MGR is responsible for defining the equipment that require confidence checks. Form #CONF is used to document the procedure, results, and schedule for performing the required checks.
- 5.5.10.1** The TECH MGR is responsible for defining equipment transported to the customer site that require appropriate checks made on-site to confirm the calibration status and fitness for use of equipment before testing or calibration begins.
- 5.5.10.2** Where such checks cannot be made on-site (for equipment whose performance is not sensitive to movement), calibration status and fitness for use shall be checked in the permanent laboratory before and after site testing or calibration. Checks will be documented on form# CONF. If equipment is found to

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be unfit for use and/or out of calibration, it shall not be used and shall be immediately withdrawn from service.

**5.5.10.3** When onsite and after appropriate warmup, the technician will perform available “self test” or “AutoCal” functions on the equipment to assure the equipment is functioning within the parameters of the “self test” or “AutoCal”.

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

**5.5.12** Calibration equipment, including both hardware and software is safeguarded from adjustments which would invalidate the calibration results.

## **5.6 Measurement Traceability**

### **5.6.1 General**

**5.6.1.1** All equipment used for calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the calibration or sampling is calibrated before being put into service. The laboratory has an established program for the calibration of its equipment.

### **5.6.2 Specific Requirements**

#### **5.6.2.1 Calibration**

**5.6.2.1.1** The laboratory’s program for calibration of its 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).

**5.6.2.1.2** Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability to SI units.

### **5.6.3 Reference Standards and Reference Materials**

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**5.6.3.1** Reference standards are calibrated by a body that can provide traceability as described in 5.6.2.1. Reference standards of measurement are 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.

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

**5.6.3.3** 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.

**5.6.3.4** The laboratory has procedures for 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, where the absence of such could jeopardize the quality in calibration results.

## **5.7 Sampling**

**5.7.1** In the event that sampling becomes part of the services provided by Midwest Metrology, LLC, a procedure would be established for sampling of substances, matrices, materials, or products for subsequent calibration, as applicable. The sampling plan as well as the procedure would be made available at the location where sampling is undertaken. Sampling plans are, whenever reasonable, based on appropriate statistical methods. The sampling process addresses the factors to be controlled to ensure the validity of the test results.

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

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**5.7.3** Prior to performing sampling, the laboratory develops 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 the diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedure is based upon.

## **5.8 Handling of Calibration Items**

### **5.8.1 Procedure**

The requirements of this management system are met pertaining to the transportation, receipt, handling, protection, retention, and/or disposal of calibration items. It includes provisions necessary to protect the integrity of the calibration item.

### **5.8.2 Identification of Items**

Midwest Metrology, LLC uses a database of all calibration items, which includes all reference standards and all items calibrated by MM. This database uses one or more unique identifiers such as serial number and owner.

### **5.8.3 Condition of Received Items**

Upon receipt of an item for calibration, either in lab or in field, an inspection is performed identifying any abnormalities or departures from normal or specified conditions, as may be described in the relevant calibration method and is recorded. When there is any 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 conclusion of the discussion on the shipper or other document maintained in the applicable customers file.

### **5.8.4 Handling, Storage and Transportation of Calibration Items**

Calibration item(s) prepared, handled, stored and/or transported by MM are dealt with in an appropriate manner that ensures the avoidance of deterioration, loss, or damage. These instructions

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are provided as necessary either in writing or verbally, this includes any instructions provided with the item. When item(s) are to be stored under specified environmental conditions, these conditions are maintained, monitored and recorded. Where calibration item(s) or portion of an item is to be held secure (e.g. for reasons of record, safety or value, or to enable complimentary calibrations to be performed later), the laboratory provides storage and security that protect the condition and integrity of the secured item(s) or portions concerned.

Delivery of calibrated item(s) to the customer is done with care to ensure that the item(s) are not subjected to stress that could corrupt the item's integrity.

Measurement standards transported for in field calibration of customers equipment is transported with care to prevent stress response error.

## **5.9 Assuring the Quality of Calibration Results**

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

The quality of calibration is ensured by monitoring the results. This monitoring is planned and reviewed and may include, but not limited to, the following:

- a) Regular use of certified reference materials and/or internal quality control using secondary reference materials.
- b) Participation in interlaboratory comparisons or proficiency testing.
- c) Replication of calibrations using the same or different methods.
- d) Re-calibration of retained items.
- e) Correlation of results for different characteristics of an item.

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**5.9.2** 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**

### **5.10.1 General**

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

The results are usually reported in a calibration report and include all information requested by the customer and necessary for the interpretation of the calibration results and all information required by the method used.

Any information listed in 5.10.2 and 5.10.4 and not reported to the customer is readily available in the laboratory.

### **5.10.2 Calibration Certificates**

**5.10.2.1** See also 5.10.4.

Unless there exists exceptional reasons for not doing so, each calibration certificate includes at least the following information:

- a) a title (e.g. Calibration Certificate);
- b) name and address of laboratory, and location where the calibrations were carried out if different from the address of the laboratory;
- c) unique identification of the calibration certificate and on each page an identification in order to ensure that the page is recognized as a part of the calibration certificate. A clear identification of the end of the calibration certificate;
- d) name and address of the customer placing the order;
- e) identification of the methods used;
- f) a description of, the condition of, and unambiguous identification of the item(s) calibrated;

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- g) the date of receipt of the calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the calibration;
- h) reference to sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- i) the calibration results with, where appropriate, the units of measurement;
- j) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the calibration certificate;
- k) where relevant, a statement to the effect that the results relate only to the items calibrated.

### 5.10.3 Test Reports

Not applicable at this time.

### 5.10.4 Calibration Certificates

**5.10.4.1** In addition to the requirements listed in 5.10.2, calibration certificates include the following, where necessary for the interpretation of calibration results:

- a) the environmental conditions under which the calibration was made that have an influence on the measurement results;
- b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof. Uncertainty Statements will contain an explanation of the uncertainty statement (for example, "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of  $k=2$ );
- c) evidence that the measurements are traceable by a statement of traceability on the calibration certificate;

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- d) any other details relevant to the calibration such as the location of the calibration item.

**5.10.4.2** The calibration certificate relates only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this statement identifies which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results, the laboratory records those results and maintains them for possible future reference.

When statements of compliance are made, the uncertainty of measurement is taken into account.

**5.10.4.3** When an instrument for calibration has been adjusted or repaired, the calibration results before adjustment or repair, if available, is reported.

**5.10.4.4** The calibration certificate does not contain any recommendation on the recalibration interval except where this has been agreed upon with the customer. This requirement may be superseded by legal regulations.

### **5.10.5 Opinions and Interpretations**

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

### **5.10.6 Calibration Results Obtained from Subcontractors**

In the event that a calibration is subcontracted, the customer must approve the subcontracting either in writing or verbally, this approval is documented either on the shipper or other document maintained in the customers file. The subcontracted laboratory performing the work issues the calibration certificate to the contractor. The contractor (MM) may issue a certificate as the contractor clearly identifying the subcontractor and includes the certificate provided by the subcontractor to the customer.

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### **5.10.7 Electronic Transmission of Results**

In the event that calibration results are transmitted by telephone, fax, e-mail, or other electronic or electromagnetic means, the customer must approve the process prior to occurrence. (See also 5.4.7)

### **5.10.8 Format of Certificate**

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

Attention is given to the layout of the calibration certificate, especially with regard to the presentation of the calibration data and ease of assimilation by the reader.

Headings are standardized as far as possible.

### **5.10.9 Amendments to Calibration Certificates**

Material amendments to a calibration certificate after issue is made in the form of a further document, or data transfer, which includes the statement "Supplement to Calibration Certificate, serial number...(or as otherwise identified)", or an equivalent form of wording. Such amendments must meet the requirements of International Standards referenced by Midwest Metrology, LLC as being in compliance to.

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

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## A2LA Supplemental Requirements

**POLICY:** It is the policy of Midwest Metrology to comply with all supplemental requirements set forth by A2LA. Due to possible additions, deletions, and/or revisions, it is the responsibility of the QUAL MGR to assure that current copies are in the control of this Quality System and that appropriate personnel are made aware of changes.

### 6.1 A2LA Calibration Program Requirements

6.1.1 Calibration Intervals for each measuring instrument or standard is established to control the probability of calibrations being out-of-tolerance at the end of the calibration interval. The method used to establish and adjust intervals is documented in [5-5SOP01](#) section 5.5.13 and based upon a determination of the standard's performance.

Equipment records include the measured value for each parameter to be found out of tolerance during calibration or verification.

6.1.2 The laboratory maintains an up-to-date list of primary laboratory standards and the names of the calibration services that calibrates the standards. The Primary standards list is a controlled document maintained in accordance with the laboratory Standard Operating Procedures.

6.1.3 Where an intrinsic standard or system is used as a standard, the following requirements apply;

- a) *direct intrinsic standard or system-to-intrinsic standard or system comparison with NIST or an accredited laboratory shall be conducted at appropriate intervals to ensure the correct realization of the measurand;*
- b) *documented calibration history of the device used to measure differences between intrinsic standard or system and unknown values shall be maintained;*
- c) *documented calibration history of the intrinsic standard or system components (e.g. the time base of the reference*

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*frequency counter in a Josephson voltage array system) shall be maintained.*

- d) *documented evidence of periodic checks on system precision and stability (e.g. leakage currents, ground loops, thermal emf's, step integrity, trapped magnetic flux, noise and microwave power impinging on a Josephson array) shall be maintained.*

6.1.4 *When necessary, the laboratory shall have at least two distinct work areas;*

- a) *A receiving and cleaning area where items to be calibrated can be cleaned and prepared to enter the laboratory without contaminating the calibration area with dirt, dust, solvents or solvent fumes, etc.*
- b) *A dedicated calibration area where the items are calibrated*
- c) *Since the mission of the laboratory is to mostly support on -site calibrations, the cleaning of items to be calibrated is done – site at the test station. Other cleaning/preparation of items to be calibrated is of a minor nature, and can be accomplished at the calibration/repair bench.*

**6.1.5 Calibration Certificates and Reports  
(Additional A2LA Requirements Midwest Metrology, LLC is committed to comply with.)**

- a) *The uncertainty of reported measurements shall be stated as the actual uncertainty of measurement, not as the accredited best uncertainty unless that best uncertainty actually applies. An indiscriminate use of the best uncertainty listed on the A2LA scope of accreditation as the uncertainty of an actual calibration is not justified.*
- b) *If a recommended recalibration interval is included on a certificate, this recommendation shall be qualified with a statement to the effect that any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired.*
- c) *Laboratories are permitted to issue certificates with a statement of compliance (i.e. conformance to a specification)*

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*relating to the metrological aspects of specifications. In such cases the laboratory shall ensure that”*

- 1) *the specification is a national or international standard or one that has been agreed to or defined by the customer.*
- 2) *the measurements needed to determine conformance are within the accredited scope of the laboratory.*
- 3) *when parameters are certified to be within specified tolerance, the associated uncertainty of the measurement result is properly taken into account with respect to the tolerance by a documented procedure or policy established and implemented by the laboratory that defines the decision rules used by the laboratory for declaring in or out of tolerance conditions.*
- 4) *the certificate relates only to metrological quantities and states which clauses of the specification are certified to have been met.*

#### **6.1.6 ANSI/NCSL Z-540-1-1994 Additional Requirements**

6.1.6.1 *The quality manual and related quality documentation shall contain the laboratory’s scope of calibrations.*

6.1.6.2 *The quality system adopted to satisfy the requirements of this Standard shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.*

6.1.6.3 *Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy*

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*required, and with any standard specifications relevant to the calibrations/verifications concerned.*

6.1.6.4. *Where it is necessary to employ methods that have not been well-established, these shall be subject to agreement with the customer, be fully documented and validated, and be available to the customer and other recipients of the relevant reports.*

6.1.6.5 *Tamper-resistant seals shall be affixed to operator accessible controls or adjustments on measurement standards or measuring and calibration equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.*

6.1.6.6 *Each certificate or report shall include at least the following information:*

- a) *a title, e.g. "Calibration Report", or "Calibration Certificate";*
- b) *name and address of laboratory, and location where the calibration was carried out if different from the address of the laboratory;*
- c) *unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;*
- d) *name and address of customer, where appropriate;*
- e) *description and unambiguous identification of the item calibrated;*
- f) *characterization and condition of the calibration item;*
- g) *date(s) of performance of calibration where appropriate;*

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*h) identification of the calibration procedure used, or unambiguous description of any non-standard method used;*

*i) reference to sampling procedure, where relevant;*

*j) any deviations from, additions to or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions;*

*k) measurements (including where applicable "as found" data), examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;*

*l) a statement of the estimated uncertainty of the calibration results (where relevant);*

*m) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;*

*n) where relevant, a statement to the effect that the results relate only to the items calibrated;*

*o) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.*

*p) special limitations of use; and*

*q) traceability statement.*

*6.1.6.7 The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out-of-tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.*

*6.1.6.8 Where a laboratory sub-contracts any part of the calibration, this work shall be placed with a laboratory complying with the requirements of this Standard [ANSI/NCSL Z540-1-1994]. The laboratory shall ensure*

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*and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory with respect of the work being sub -contracted.*

6.1.6.9 *Where a complaint, or any other circumstance, raises a concern regarding the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations, the laboratory shall ensure that complaints in those areas of activity and responsibility involved are promptly resolved.*

## **6.2 A2LA Advertising Policy Requirements**

### 6.2.0.1

6.2.0.2 The procedure for controlling the use of the A2LA **symbol** is that when any party produces a document with the A2LA **symbol**, the document meets the following requirements

### **6.2.1.0 General Requirements**

6.2.1.1 **Policy:** *It is the laboratory policy to ensure that the A2LA Advertising policy is understood and complied with by all applicable employees, and that all documents produced comply to the most recent version of the A2LA*

#### **Advertising**

*policy. Failure to comply with A2LA's Advertising Policy requirements may result in suspension or revocation of the laboratory's accreditation.*

*Procedure 4.16SOP01 defines the requirements and usage of the "A2LA" and "A2LA Accredited" symbols.*

6.2.1.2 *The "A2LA Accredited" **symbol** shall not be used by a laboratory that is not A2LA accredited*

6.2.1.3 *The "A2LA Accredited" **symbol** shall not be used by applicants for A2LA accreditation.*

6.2.1.4 *The "A2LA Accredited" **symbol** shall be used by an A2LA accredited laboratory only under the name in which it holds A2LA accreditation.*

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6.2.1.5 *When promoting or providing proof of accreditation, accredited laboratories shall use the scope(s) of accreditation, as this document details the specific tests or calibrations which are accredited. The certificate shall be used for display purposes and may also accompany the scope.*

6.2.1.6 *It is the responsibility of the QUAL MGR to communicate this Advertising Policy and its requirements to the necessary corporate/marketing representatives to ensure that all requirements are met.*

### **6.2.2.0 Symbol Reproduction**

6.2.2.1 *“A2LA Accredited” symbol sheets are sent to all accredited laboratories and an electronic version is available upon request.*

6.2.2.2 *Where the A2LA name and/or symbol is used by accredited laboratories it shall always be accompanied by at least the word “accredited.”*

6.2.2.3 *While there are no restrictions on the size and color of the “A2LA Accredited” symbol reproduction, the symbol must maintain its form.*

6.2.2.4 *The “A2LA Accredited” symbol may be generated electronically provided that the prescribed formats and forms are retained.*

6.2.3.0 *Use of the “A2LA Accredited” symbol on Test/Calibration Reports*

6.2.3.1 *Where the “A2LA Accredited” symbol is used to endorse test or calibration results, it shall always be accompanied by the A2LA certificate number(s).*

6.2.3.2 *The “A2LA Accredited” symbol may be displayed on all certificates and reports that contain exclusively results from calibrations and tests that have been carried out within the laboratory’s official A2LA Scope of Accreditation.*

6.2.3.3 *The “A2LA Accredited” symbol shall not be used on certificates and reports if none of the results presented are*

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*from tests or calibrations included on the A2LA Scope(s) of accreditation*

6.2.3.4 *Where both accredited and non-accredited tests/calibrations are included on an endorsed report or certificate, non-accredited results shall be clearly and unambiguously identified as such. This can be done by placing an asterisk after each such result along with a footnote stating: “The test/calibration results are not covered by our current A2LA accreditation”.*

6.2.3.5 *On reports where results are reported within the field where accreditation exists but in a technology that is not included in the scope, they must be so indicated. (For example, if a laboratory is accredited in the Environmental Field for only wet chemistry and metals, any gas chromatographic data reported would need to be identified as non-accredited.)*

6.2.3.6 *If the intent is to ensure that the customer meets the requirements of the A2LA Traceability Policy, the calibrations performed by an A2LA accredited calibration laboratory must be included on the calibration laboratory’s A2LA Scope of Accreditation, and the calibration certificate issued must contain the “A2LA Accredited” symbol (or a reference to A2LA accreditation) and the A2LA certificate number.*

6.2.3.7 *There shall be nothing in the reports, certificates or in any attachments or other materials which implies or may lead any user of the results or any interested party to believe that the work is accredited when it is not.*

#### **6.2.4.0 Subcontracted Tests and Calibrations**

6.2.4.1 *An A2LA accredited laboratory may include the results of subcontracted tests or calibrations in its endorsed reports or certificates only if:*

6.2.4.1.1 *The accredited laboratory has informed the customer in writing of the proposed subcontracting and has obtained prior approval; and*

6.2.4.1.2 *The subcontractor is itself accredited by A2LA or an A2LA recognized MRA partner for the specific test or calibrations concerned and the results have been*

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*included in the subcontracting laboratory's endorsed calibration or test report(s) submitted to the accredited laboratory. Any non-accredited subcontracted calibrations or tests shall be specified as noted in section 6.2.3.4.*

**6.2.4.1.3** *The subcontracted calibration or test results shall be clearly and unambiguously identified on the certificate or report.*

## **6.2.5 Opinions and Interpretations**

**6.2.5.1** *Where statements of opinions and interpretations are outside the Scope of Accreditation, the laboratory is required to include a disclaimer such as the following in the certificate or report* "The opinions/interpretations expressed in this report are outside the scope of this laboratory's A2LA accreditation."

**6.2.5.2** *It is preferable, however to express opinions and interpretations that are outside the Scope of Accreditation on separate letter which is not part of the endorsed certificate or report that does not carry the "A2LA Accredited" symbol or other reference to A2LA Accreditation.*

### **6.2.6.0 Calibration Labels**

**6.2.6.1** *Calibration labels containing the "A2LA Accredited" symbol may be affixed only to equipment that has been calibrated by the accredited calibration laboratory.*

**6.2.6.2** *Calibrations labels containing the "A2LA Accredited" symbol shall include at least the following information:*

**6.2.6.2.1** *The name of the accredited calibration laboratory or its A2LA certificate number*

**6.2.6.2.2** *The instrument identification*

**6.2.6.2.3** *The date of the current calibration*

**6.2.6.2.4** *Cross reference to the calibration certificate issued with respect to this calibration.*

### **6.2.7.0 Advertising, Publicity, and Business Solicitation**

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- 6.2.7.1 *Accredited laboratories may incorporate statements concerning their accreditation in publicity and/or advertising materials, including brochures and organization publications, technical literature, business reports, web sites and quotations or proposals for work.*
- 6.2.7.2 *The use of the “A2LA Accredited” **symbol** or other reference to A2LA used to promote accreditation enhances the reputation and value of accreditation for all stakeholders. It is the responsibility of the accredited laboratories to ensure that there is no misrepresentation of the accreditation status and that the accreditation process is not brought into disrepute.*
- 6.2.7.3 *The accreditation claim shall be related only to the testing or calibration that is covered under the A2LA Scope of Accreditation, and not with any other activities in which the laboratory or its parent organization are involved.*
- 6.2.7.4 *A2LA accreditation is site specific. The accreditation claim shall be related only to the specific laboratory location that is covered under the A2LA Scope of Accreditation, and not with any other non-accredited locations.*
- 6.2.7.5 *In proposals or quotations, the accredited laboratory shall distinguish tests or calibrations that are covered under the A2LA Scope of Accreditation from those that are not covered.*
- 6.2.7.6 *Where the “A2LA Accredited” **symbol** is printed on letterhead or other corporate stationery, such stationery shall not be used for work proposals, quotes, reporting of test or calibration results exclusively outside the A2LA Scope of Accreditation, or certifying a product or other item.*
- 6.2.7.7 *The “A2LA Accredited” **symbol** or accreditation claim shall not be affixed to a material, item or product (or related part, including packaging), or used to imply that an item or product has been certified.*
- 6.2.7.8 *If the “A2LA Accredited” **symbol** is included in the literature relating to a product, the **symbol** must appear directly adjacent to the reference to the accredited calibration or testing laboratory and it must be clearly stated that inclusion*

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of the **symbol** does not imply certification/approval of the products calibrated or tested.

6.2.7.9 The “A2LA Accredited” **symbol** shall not be displayed on business cards in a manner that might imply personnel certification.

6.2.8.0 Misuse of the “A2LA Accredited” **symbol** or Accreditation Status

6.2.8.1 Every circumstance where the principle of accurate representation applies cannot be anticipated and dealt with in this document. Therefore, it is the responsibility of the accredited and applicant laboratory representatives not to misrepresent their accredited status under any circumstances.

6.2.8.2 If there are questions, the laboratory should submit intended uses of the **symbol**, draft advertisements, and/or any other accreditation claims to A2LA headquarters for advance review.

6.2.8.3 Upon suspension or termination of accreditation, a laboratory must immediately cease to issue calibration certificates, test reports, and test certificates displaying the **symbol** and shall cease publishing documents containing the **symbol**.

#### **6.2.9.0 Policy on Measurement Traceability**

**Policy:** It is Midwest Metrology’s policy to ensure that the A2LA Measurement Traceability policy is understood and complied with by all applicable employees, and that all calibrations performed and certificates produced comply to the most recent revision of the A2LA Measurement Traceability policy.

6.2.9.1 All calibrations and verifications of measuring and test equipment, reference standards, and reference materials be are to be conducted by one of the following:

- A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body.

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- *A reference material producer accredited to ISO/IEC Guide 34 by a mutually recognized Accreditation Body .*
- *A recognized National Metrology Institute (NMI, i.e. one in which supports the measurement comparison activities of the CIPM, Comité International des Poids et Mesures)*
- *A mechanical testing laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the A2LA Calibration Program Requirements (as indicated on their Scope of Accreditation*
- *In-house calibrations must be supported by the elements found in section 6.2.9.9 of this document.*

*6.2.9.2 For those external calibrations and verifications, these must be documented in a calibration certificate or report endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status or endorsed by the National Metrology Institute (NMI). For those internal calibrations and verifications, those requirements outlined in requirement T9 of this document apply.*

*6.2.9.3 All A2LA-Accredited and enrolled organizations shall define their policy for achieving measurement traceability. This policy shall be in compliance with this policy document.*

*6.2.9.4 Where measurement uncertainty analysis is applicable, A2LA requires laboratories to calculate measurement uncertainty in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement." These uncertainties, when reported, shall be reported as the expanded uncertainty with a defined coverage factor,  $k$  (typically  $k = 2$ ) and the confidence interval (typically to approximate the 95% confidence level).*

*6.2.9.5 If a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement shall be accompanied by an explanation of the meaning of the*

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*uncertainty statement. (For example, "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of  $k=2$ .)*

*6.2.9.6 TURs shall be calculated using the expanded un certainty of the measurement, not the "collective uncertainty of the measurement standards".*

*6.2.9.7 Implicit uncertainty statements must be accompanied by words to the effect that the uncertainty ratio was calculated using the expanded measurement uncertainty. In addition the coverage factor and confidence level must be stated.*

*6.2.9.8 Calibration reports and certificates issued by A2LA - accredited calibration laboratories shall contain a traceability statement.*

*6.2.9.9 All in-house calibrations shall be supported by the following minimal set of elements:*

- a) Midwest Metrology must maintain documented procedures for the in-house calibrations and the in-house calibrations must be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records must be retained for an appropriate, prescribed time.*
- b) Midwest Metrology must maintain training records for calibration personnel and these records must demonstrate the technical competence of the personnel performing the calibrations: evidence of competence includes, for example, documented training and the results of measurement audits.*
- c) Midwest Metrology must be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration labs or a national metrology institute.*
- d) Midwest Metrology must have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be calculated for each type of calibration and records of these calculations shall be maintained. (Note: Records of these*

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*calculations must be maintained for calibrations done as of 8/1/06.) Measurement uncertainty must be taken into account when statements of compliance with specifications are made.*

- e) Reference standards must be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals must be based on the historical behavior of the reference standard.*

END

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### Revision History

Rev	Date	Responsible Person	Description of Change
A	8/1/00	Bill Sierschula	Initial Release
B	8/26/00	Bill Sierschula	Address change
C	12/10/04	Bill Sierschula	Addressed on-site and A2LA supplemental requirements
D	8/1/06	Bill Sierschula	Revised system for compliance to ISO/IEC 17025:2005
E	9/5/06	Bill Sierschula	Revised system in various locations, see highlighted areas.
F	12/28/06	Bill Sierschula	Revised 4.2.6, 4.8, 4.9, and 4.11

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