# Micro Precision Calibration, Inc.

## Quality Manual

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# Introduction

Executive management of Micro Precision Calibration, Inc. (“Micro Precision”) has issued this Quality Manual as the framework for realizing our company mission, values, objectives and quality commitment to its employees and customers.

This Quality Manual defines and identifies the policies, practices and procedures of Micro Precision’s quality management system.

This quality management system satisfies the requirements of ISO/IEC 17025 and applicable ANSI/NCSL Z540 documents. This quality management system, by virtue of accreditation to ISO/IEC 17025, complies with the requirements of ISO 9001.

# Scope

This quality management system satisfies the requirements of ISO/IEC 17025 and applicable ANSI/NCSL Z540 documents. This quality management system, by virtue of accreditation to ISO/IEC 17025, complies with the requirements of ISO 9001, except requirements of Design and Development of Products and Services. Design and development is not applicable to the scope of Micro Precision’s calibration services. All calibration processes are performed based on established standards or customer-provided specifications.

The fundamental purpose of this Quality Manual is to define the existence of activities and MP interaction necessary for ensuring the effective and consistent operation and control of processes, procedures, and record keeping throughout the company. These include sales and marketing, technical support, purchasing, inspection and testing, packaging and storage, and shipping and delivery. The intent of this Quality Manual is to facilitate the development of effective criteria and methods needed to support and control the processes, to ensure that needed resources and information are available, and that measures and data used to determine satisfactory performance are planned and realized according to plan.

Micro Precision shall relentlessly strive for customer satisfaction, cost competitiveness and continuous improvement in all aspects of our business. Micro Precision shall offer services that meet a well-defined customer or market need, purpose, use, services that are economically supplied and offered at competitive prices that in all respects shall meet customer’s expectations. Micro Precision services shall comply with all applicable standards, specifications, and requirements of society, including an awareness of environmental needs during the service phase. Micro Precision shall demonstrate commitment to achieve the highest level of customer support and satisfaction with integrity and ethics in business transactions while embracing quality in all that we do. These initiatives involve all employees, and by communicating the importance of teamwork, empowerment and accountability we can show them that they Micro Precision’s most valuable asset.

All employees are required to familiarize themselves with the quality management system documentation, understand their roles and responsibilities, and implement the policies and procedures in their work. Personnel shall understand that their work contributes to achieving customer satisfaction and continual improvement.

## 2.0 Quality Policy

Micro Precision is committed to meeting and exceeding customer expectations by providing complete, reliable, reproducible, and accurate calibration and repair services in compliance with ISO/IEC 17025, laboratory accreditation requirements, and ISO 9001 quality management system requirements and in accordance with stated methods and customer requirements, and other applicable requirements.

The quality and reliability of services offered by our company are maintained at levels meeting and exceeding the expectations of our customers and with contractual requirements. The quality management system is designed to achieve the Critical Success Factors.

### *Vision*

To be a global leader in calibration services, test equipment solutions and engineering support services.

### *Mission*

Our mission is to provide our customers with equipment management solutions; to create customer solutions through localized services on a global scale; and to promote growth opportunities and a rewarding work environment for our employees.

### *Core Values*

We define ourselves through the following Core Values:

- Service Value
- Dependability
- Timeliness
- Empowerment
- Innovation
- Teamwork
- Integrity
- Achievement and Discipline

- *Service Value*

Providing the highest level of calibration at the best value for our customers

- *Dependability*

Being dependable in service, support, reporting, and storage of data. Always ensuring data is in compliance with international standards.

- *Timeliness*

Delivering the best turn-around with the most cost-effective service, based on an instrument's specific use, in a courteous and professional manner.

- *Empowerment*

Encourage employees to develop themselves and their careers to their fullest potential, being responsible for their actions, and accountable for the quality of work performed. We recognize that employees have the ability and responsibility to affect in a positive way, our company, other employees and customers.

- *Innovation*

Implementing continuous improvements by being open to new ways to increase the value that we bring to our customers. Proactively pursue new ways of doing business, and "change" for the betterment of the company.

- *Teamwork*

Fostering an environment of enthusiasm and co-operation that enhances customer satisfaction. Maximizing our company's capabilities through cross-organizational support.

- *Integrity*

Being forthright and free from corrupting influence or motive in all of our dealings with our customers and with each other in the company.

- *Achievement and Discipline*

It is through achievement and discipline that we define our company and ourselves by the quality of our work and what we accomplish. We will consistently and conscientiously perform our tasks with the aim of satisfying our customers.

## *Critical Success Factors*

We define our Critical Success Factors as:

- Preferred Supplier
- Financial Growth
- Preferred Employer

- *Preferred Supplier*

We strive to be the supplier that our customers value above all others. We realize growth and market penetration through increased sales and satisfied customers**.** We reduce costs and cycle times through effective use of resources.

- *Financial Growth*

We grow our revenue year over year as we expand our services through repeat business and referral and customer loyalty.

- *Preferred Employer*

We shall improve employee satisfaction, maintain low turnover, recruit top talent, and allowed the creative freedom to pursue new ideas in all areas of our business.

# 3.0 Normative References

The following industry standards and documents form the basis part of Micro Precision's quality management system and are incorporated herein:

- ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*
- ISO 9001, Quality Management Systems – Requirements
- ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

# 4.0 General Requirements

## *4.1 Impartiality*

Micro Precision activities shall be undertaken impartially and structured and managed so as to safeguard impartiality. The laboratory management is committed to apply impartiality in relationship based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (Including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

Micro Precision is responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality. The laboratory shall identify risks to its impartiality on an ongoing basis. This includes those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. If a risk to impartiality is identified, Micro Precision shall demonstrate how it eliminates or minimizes such risk.

## *4.2 Confidentiality*

Micro Precision is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. Micro Precision informs the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer, all other information is considered proprietary information and shall be regarded as confidential.

When Micro Precision is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) is confidential between the customer and Micro Precision. The provider (source) of this information is confidential to Micro Precision and shall not be shared with the customer, unless agreed by the source. Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

# 5.0 Structural Requirements

Micro Precision is legally incorporated as Micro Precision Calibration, Inc., under Articles of Incorporation filed with the State of California. Each laboratory is registered in the state in which it resides.

The corporate and state registration documents are on file in the HR and Admin department at the corporate office with appropriate state operating licenses posted conspicuously in each laboratory, including international facilities.

Micro Precision is a customer-oriented company and is committed to fully understand the needs and expectations of customers, employees, suppliers and partners. Corporate management ensures that an effective system of management tools exist to enable the company to realize these commitments.

The Laboratory Manager and designees is responsible for technical issues to ensure the competency of the laboratory. They oversee technical operations to ensure that needed resources exist. Technical issues encompass development, appropriateness, adequacy and use of selected calibration methods and procedures, alternate calibration methods or procedures, the measurements uncertainties program, the interlaboratory comparisons program, evaluation of calibration and test results and traceability, selection, maintenance and validation of measurement standards and test equipment, and technical competence evaluations and development programs for technical personnel.

Corporate management has appointed the Quality Manager and/or Quality Supervisor at each MP laboratory as the Quality Assurance Administrator with the authority and responsibility, irrespective of other responsibilities, for:

- ensuring the processes of the quality management system are established, implemented and maintained
- compliance to ISO 9001, ISO/IEC 17025, and laboratory accreditation requirements;
- reporting to Corporate management on the performance of the Quality Management System, including needs for improvement;
- promoting awareness of customer requirements throughout the organization; and
- Shall seek positive and negative feedback from its customers. The feedback shall be used and analyzed to improve the quality management system, testing and calibration activities and customer service.

Customer-related processes consider marketing, sales and order handling, processing of changes to existing orders or contracts, and communication relative to product design and development, order status and delivery forecast, requests for concession, customer inspections, audits and feedback, including complaints, and warranties and apply to both internal and external customers.

Requirements not stated by the customer but necessary or implied, statutory and regulatory requirements, including local laws and customs, and organization requirements are determined.

The Quality Director and designees are responsible for coordinating, monitoring and auditing of the quality management system. The Quality Director and designees has the organizational freedom and authority to initiate action to prevent the occurrence of nonconformities, record problems, initiate corrective actions, resolve customer complaints, verify solutions and if necessary, stop those processes until such time as they fully comply.

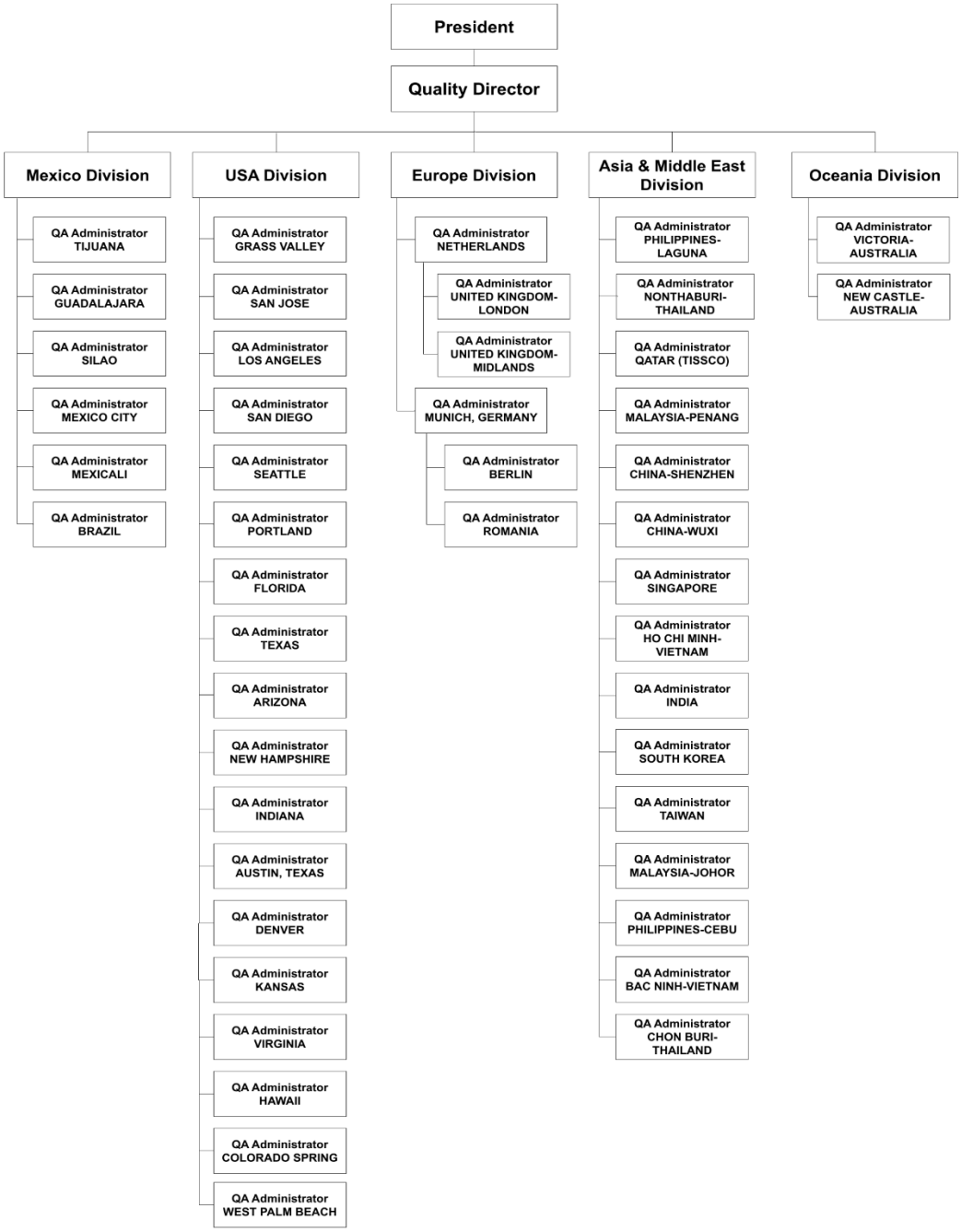
The organizational structure and relationships of laboratories to corporate are defined within the quality management system to ensure that technical operations, administrative and quality management, and support services, including human factors affecting quality are under strict control by management through the Quality Management System.

Specific organizational details are maintained in Micro Precision's procedures locally at all laboratories. International laboratories have the authority and responsibility (where necessary) to translate the quality policies into their native languages and according to local regulations and requirements upon review and approval by Executive Management.

## Micro Precision Quality Management Organization

## Interfaces between Micro Precision Division Organizations

## (Corporate and Quality Management) *R08



# 6.0 Resource Requirement

## *6.1 General*

Corporate management ensures that adequate resources for the implementation and achievement of the organizational policies and objectives are made available. These may include personnel, support services, systems, equipment, facilities, work environment and financial resources. Division management is responsible for ensuring that adequate resources for management, performance of work and verification activities, including internal audits, are identified and communicated to the appropriate level within the organization.

## *6.2 Personnel*

Micro Precision recognizes that personnel are their most valuable asset and strives to make certain that people are properly qualified and trained to perform the tasks required of them and be effective in executing their duties.

Only qualified personnel are hired and trained as needed to successfully complete their assignments. Competent personnel operate measurement and test equipment, perform tests and calibrations, evaluate results, significance of deviations and sign test reports/calibration certificates. In order to manage and develop people effectively, individual education, experience and demonstrated skills are evaluated, monitored and measured through recruitment, ongoing training, and on-the-job performance and advancement opportunities.

Division management formulates goals with respect to education, training and skills of laboratory personnel.

All employees, or personnel under contract to the laboratory, whose work affects quality require appropriate training and/or experience to perform their tasks. No employee, including contracted and additional technical or key support personnel used, performs tasks unassisted until his or her training/competence has been confirmed as being in accordance with the laboratory requirements and quality management system. The overall effectiveness of training is evaluated through appraisals and feedback from internal audits.

Records are maintained on personnel competence, including educational and professional qualifications; training; skills; technical knowledge; and experience of personnel, including contracted personnel, and include the confirmation date and authorization of competence. Current job descriptions of managerial, technical and key support personnel involved in tests and/or calibrations are maintained.

## 6.3 *Facilities and Environmental Conditions*

Micro Precision is committed to providing and maintaining suitable environmental conditions and appropriate laboratory facilities for calibration and testing activities.

A suitable working environment is maintained, including controlled and defined access to and use of all areas affecting the quality of work. Calibration and test area environmental factors that can adversely impact product quality, invalidate the results or adversely affect the required accuracy of measurement are maintained, monitored and controlled, and recorded within specified limits, where practical or applicable, to facilitate proper performance of calibrations or tests.

When Micro Precision performs calibration activities at sites or facilities outside its permanent control, it ensures that the requirements related to facilities and environmental conditions of this document are met.

Micro Precision recognizes that the physical environment in which people work influences their motivation, satisfaction, development and performance and is essential to the accuracy and quality of the products and/or

services they produce. As such, Micro Precision provides a work environment that supports the achievement of organizational policies and objectives leading to overall employee satisfaction.

## *6.4 Equipment*

Micro Precision instruments, measuring and test equipment are used in a manner, which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. Each laboratory will ensure that key quantities or values of instruments where these properties have a significant effect on the results are established.

Instruments, measuring and test equipment including reference materials will be received, handled, stored, packaged, preserved, retained and/or dispositioned and transported in a manner, which will not adversely affect the calibration or condition of the equipment, considering all provisions necessary to protect the integrity of the equipment and the laboratory and the customer. Appropriate precautions will be taken during storage, handling, transportation and preparation to prevent damage to items tested or calibrated on-site.

The appropriate instrument, measuring and test equipment capable of the necessary accuracy and precision are available and selected for the required measurements and accuracy. Equipment and its software will comply with specifications relevant to the calibrations concerned. Appropriate reference materials required for the correct performance of the calibrations or verifications will also be used.

Where the laboratory performs calibrations using equipment that is outside its permanent control, all measures are taken to ensure compliance with the relevant requirements of ISO/IEC 17025, to ensure that the function and status of the equipment are correct and shown to be satisfactory before returning the equipment to service.

Each item of equipment and its software, and reference materials, used for testing and calibration and significant to the result shall, when practicable, be uniquely identified. A suitable indicator or approved identification record will be used to show its calibration status, including the date last calibrated and expiration date or recalibration due date.

A recall system is established and maintained to ensure that standards and equipment are recalled or removed from service when they have exceeded their calibration interval, have broken calibration seals, or are suspected to be malfunctioning because of mishandling, misuse or unusual results, or otherwise judged to be unreliable.

All equipment is properly maintained in accordance with applicable documented maintenance procedures to ensure proper functioning and prevent contamination or deterioration. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, or outside specified limits will be removed from service, clearly identified and segregated to prevent its use until repaired and shown by calibration or verification to perform correctly. The effect or departure from specified limits on previous calibration or tests are examined and non-conforming controls will be implemented.

The extent and frequency of intermediate checks are defined. All instruments, measuring and test equipment are reviewed under the Calibration System Description and any devices identified as not requiring calibration are suitably labeled and may not be used to verify or calibrate products to requirements.

When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

## *6.5 Metrological Traceability*

Micro Precision established metrological traceability to the International System of Units (SI) through an unbroken chain of calibrations or comparisons linking the equipment to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards (e.g. National Institute of Standards and Technology - NIST), international, or intrinsic standards of measurement where available.

## *6.6 Externally Provided Products and Services*

Micro Precision, will use Approved Metrological Traceability Suppliers (including those supplying critical products such as reference materials and laboratory consumables) when subcontracting calibrations or procuring products which impact the quality of the test and/or calibrations. When it is necessary to subcontract work, competent subcontracts will be used. The customer is informed in writing, and customer approval is obtained, preferably in writing, prior to subcontracting. Micro Precision remains responsible to the customer for subcontracted work, except where the customer or regulatory authority specifies the subcontractor to be used.

The method of calibration used by competent outside laboratories and Metrological traceability of measurement and measurement results, including measurement uncertainty, will be known and reviewed.

Micro Precision when using external calibration services, traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The customer is informed in writing, and customer approval is obtained, preferably in writing, prior to subcontracting. Micro Precision remains responsible to the customer for subcontracted work, except where the customer or regulatory authority specifies the subcontractor to be used. Subcontractors will work in accordance with the laboratory's quality management system.

Calibration certificates issued by external calibration laboratories will contain the measurement results, including the measurement uncertainties and/or a statement of compliance with an identified metrological specification.

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

The externally provided products and services requirements to providers contain appropriate information that clearly defines the product needed and applicable characteristics and, as appropriate, the time frame for delivery, services required, governing quality system and compliance standards, and any procedures, equipment or personnel requirements as applicable. Division management is responsible for ensuring that procurement documents are reviewed and approved for technical content prior to issue to the provider.

The Quality Assurance Department is responsible for specifying criteria for supplier selection and defining criteria for supplier evaluations and periodic re-evaluations, including necessary follow-up actions and maintaining the Approved Traceability Provider List and records as described below. Criteria for provider's evaluations include but are not limited to:

- Ability to achieve consistent quality and delivery to specified order requirements
- Cost-competitive pricing
- Provider's competency and records of evidence of compliance to ISO/IEC 17025

Division management is responsible for establishing criteria and conducting the evaluation, re-evaluations and approval of other providers (i.e., providers not used for traceability purposes).

# 7.0 Process Requirements

## *7.1 Review of Requests, Tenders and Contracts*

Micro Precision is implementing an order review process for the review of customer requests, tenders, orders and contracts (including partner arrangements) at the initiation of an order and upon additions and changes to orders or contract occurring during product realization. This review includes ensuring the order or contract (whether written or verbal) is adequately defined, documented and well understood and accepted by both parties and confirmed, differences are resolved prior to commencing work, and that we have the capability and resources to meet the requirements, prior to acceptance.

Division managers, sales managers and designated process owners are responsible for services realization, through delivery of product, and when needed, provide updated reports on the status of orders and contracts. The customer is notified of any deviation from the contract.

Customer orders or contracts, pertinent discussions pertaining to the customer's requirements or the results of the work during the period of execution of the contract and reviews of subcontracted work, and results of the order review, significant changes, and actions arising from the reviews, are recorded and maintained. This enables traceability of customer requirements for the product if needed and facilitates on-going communication and support.

Amendments and changes to customer requirements are reviewed in a similar manner to new orders and, once accepted, are communicated to all parties affected. Customer satisfaction is paramount and is given consideration in all activities.

Micro Precision is closely cooperating with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

## *7.2 Selection, Verification and Validation of Methods*

Documented instructions are maintained on the use and operation of all reference standards used, and major or relevant equipment, in handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.

Appropriate methods and procedures within the laboratory's scope (including, but not limited to, preparation, sampling, and handling, transport and storage, and use of items, evaluate of uncertainty of measurement and analysis of calibration and/or test data), shall be consistent with the accuracy required, which meet the needs of the customer and any standard specifications relevant to the calibrations or tests concerned are used. Deviations from methods will occur only if technically justified, documented, authorized and accepted by the customer.

If the customer does not specify the method to be used, the laboratory will select the appropriate method published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, as specified by the manufacturer of the equipment. The customer will be informed as to the method chosen. The customer will also be informed if the method proposed by the customer is inappropriate or out-of-date.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. Method validation is performed in accordance with planned arrangements, to ensure that the product and product realization process is capable of meeting intended results.

Validation methods are described in the Calibration System Description and are demonstrated through methods such as proficiency testing and interlaboratory comparisons, in-process service checks and measurement validations, and periodic laboratory audits. Records of the results of validations and any actions necessary are maintained.

Quality Control methods intended for control and validation of conformance to planned arrangements are described under *Quality Control* in the Calibration System Description.

## *7.3 Sampling*

Micro Precision does not utilize sampling in its methods, therefore this element has been deemed not applicable.

## *7.4 Handling of Test or Calibration Items*

Micro Precision has established requirements and processes for the effective receipt, handling, storage (including archive and backup mechanisms of records), protection, packaging, preservation, retention and/or disposal, and transport/delivery of test and/or calibration items, product and service to customers to prevent damage, deterioration, and contamination of product during processing and delivery. All provisions necessary is identified and implemented to protect the integrity of the test or calibration item, and to protect the interests of the company and the customer.

Appropriate precautions will be taken during storage, handling, transportation and preparation to prevent damage to items tested or calibrated on-site.

Equipment requiring repairs and maintenance will be identified accordingly and segregated. Items to be calibrated or used to perform calibration will be protected at all times. Unique identification of items is used to prevent confusion between similar items, both physically or when referred to in records or other documents.

## *7.5 Technical Records*

Micro Precision ensures that the technical records for each laboratory activity will contain the results, reports and sufficient information to facilitate identification of factors affecting the measurement results and its associated measurement uncertainty and repeatability.

Technical records include original observations, derived data, calibration records or calibration certificate, staff records and other sufficient information shall be kept in defined retention period. Records include quality and technical records and are held secure and in confidence.

Micro Precision ensures that amendments to technical records are track to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

Amendments shall be clearly marked. The term documents include regulations, standards, other normative documents, test and/or calibration methods, software, specifications, instructions and manuals.

## *7.6 Evaluation of Measurement Uncertainty*

Micro Precision identifies contributions in evaluating measurement uncertainties. All contributions that are significant are taken into account using appropriate methods of analysis. Measurement uncertainties are evaluated for all calibrations including laboratories calibration of their own equipment. Where method precludes

rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

## *7.7 Ensuring the Validity of Results*

Micro Precision has a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

- use of reference materials or quality control materials;
- use of alternative instrumentation that has been calibrated to provide traceable results;
- functional check(s) of measuring and testing equipment;
- use of check or working standards with control charts, where applicable;
- intermediate checks on measuring equipment;
- replicate tests or calibrations using the same or different methods;
- retesting or recalibration of retained items;
- correlation of results for different characteristics of an item;
- review of reported results;
- inter-laboratory comparisons;
- testing of blind sample(s).

Micro Precision monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but not be limited to, either or both of the following:

- participation in proficiency testing;
- participation in inter-laboratory comparisons other than proficiency testing.

Data from monitoring activities is analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate corrective action are taken to prevent incorrect results from being reported.

## *7.8 Reporting of Results*

Micro Precision results are reviewed and approved prior to release.

Results of the calibration (or series of calibrations) documented in the calibration report will be accurate, clear, unambiguous and objective, and in accordance with any specific instructions in the test or calibration methods, or as required by customers or groups of customers. The report includes all information requested by the customer and necessary for the interpretation of the calibration results and all information required by the method used. The certificate of calibration relates to quantities and the results of functional tests. Any statements of compliance to a specification will identify the applicable clause of the specification.

Where the compliance statement to a specification omits the measurement results and associated uncertainties, the technical results will be recorded and maintained for future reference. Retention periods are established and recorded. Statements of compliance will take into account the uncertainty of measurement.

Where the results of subcontractor's calibrations are contained in the report, these results are clearly identified and furnished in electronic form and/or hard copy. Any information listed which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

Calibration results will be recorded in sufficient detail to ensure traceability of all measurements and so that any measurement can be reproduced under conditions close to the original conditions, to facilitate resolution of any anomalies. The information to be recorded on Certificates of Calibration or test reports is described in Micro Precision Internal Procedures, Calibration Report Requirements.

Micro Precision is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer is documented on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

Where opinions or interpretations are included in Certificates of Calibration, the basis upon which the opinions or interpretations are made will be documented and clearly marked as such in the report. A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

To ensure that the probability of incorrect acceptance decisions are made (Probability of False Accept) (PFA) does not exceed 2% Calculation of PFA (Probability of False Accept) is accomplished by using the following formula: *Tolerance Limits +/- Expanded Uncertainty = Acceptance/Guard banded Limits*. Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

Traceability to national, international, or intrinsic standards of measurement and measurement results, associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification, or clauses thereof are stated in certificate of calibration and/or reports, wherever applicable.

Amendments to a report after it has been issued shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number (or other identification)".

When it is necessary to issue a completely new calibration certificate it is uniquely identified and shall contain a reference to the original certificate or report that it replaces.

## 7.9 *Complaints*

Product and service information is available to customers through multiple channels, and customers are able to provide feedback directly to Micro Precision. Proactive communication is achieved through regular communication with customers during sales and marketing, order review processing, customer servicing and customer surveys. The organization uses electronic methods to record feedback, inquiries, contracts or order handling and processing improvements. Our laboratory management is committed to good professional practices and to the quality of its testing and calibration in servicing our customers.

It is our policy to respond to customer or other party complaints courteously and professionally. All complaints are analyzed and appropriate action taken to remedy the complaint in a defined timely manner. Records are maintained of all complaints and of the investigations and corrective actions taken.

## *7.10 Nonconforming Work*

Micro Precision has established requirements for controlling nonconforming products when any aspect of our testing and/or calibration work, or the result of our work, do not conform to our own procedures or the agreed

requirements of the customer. Requirements are implemented in order to prevent the unintended use or delivery of nonconforming products.

Documented procedures address:

- The responsibilities and authorities for the management of nonconforming work, including halting work and withholding test reports and calibration certificates, as necessary;
- Evaluation of the significance of the nonconforming work;
- Taking corrective actions immediately, together with any decision about the acceptability of the nonconforming work;
- Where necessary, customer notification, recall of work and responsibility for authorizing the resumption of work;
- Requirements for the proper identification, documentation, segregation (when practical), and appropriate disposition (e.g., rework, repair or scrapping) of nonconforming work.

When a product, material or information is found to be defective or nonconforming, it is clearly identified and held until appropriate disposition is determined and implemented. Where it is evident that the nonconforming work could recur, or where doubt exists as to compliance with our own policies and procedures, the corrective action procedures and process are followed.

Nonconformance requires that affected parties be notified. Records of the nature of nonconformities and any subsequent action taken, including concessions obtained, are maintained.

## *7.11 Control of Data and Information Management*

Micro Precision has access to the data and information needed to perform laboratory activities. Micro Precision information management system used for the collection, processing, recording, reporting, storage or retrieval of data has been validated for functionality, including the proper functioning of interfaces within the laboratory information management system by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

In this document, Micro Precision information management system includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

Micro Precision information management system is:

- protected from unauthorized access;
- safeguarded against tampering and loss;
- operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- maintained in a manner that ensures the integrity of the data and information;
- Include recording system failures and the appropriate immediate and corrective actions.

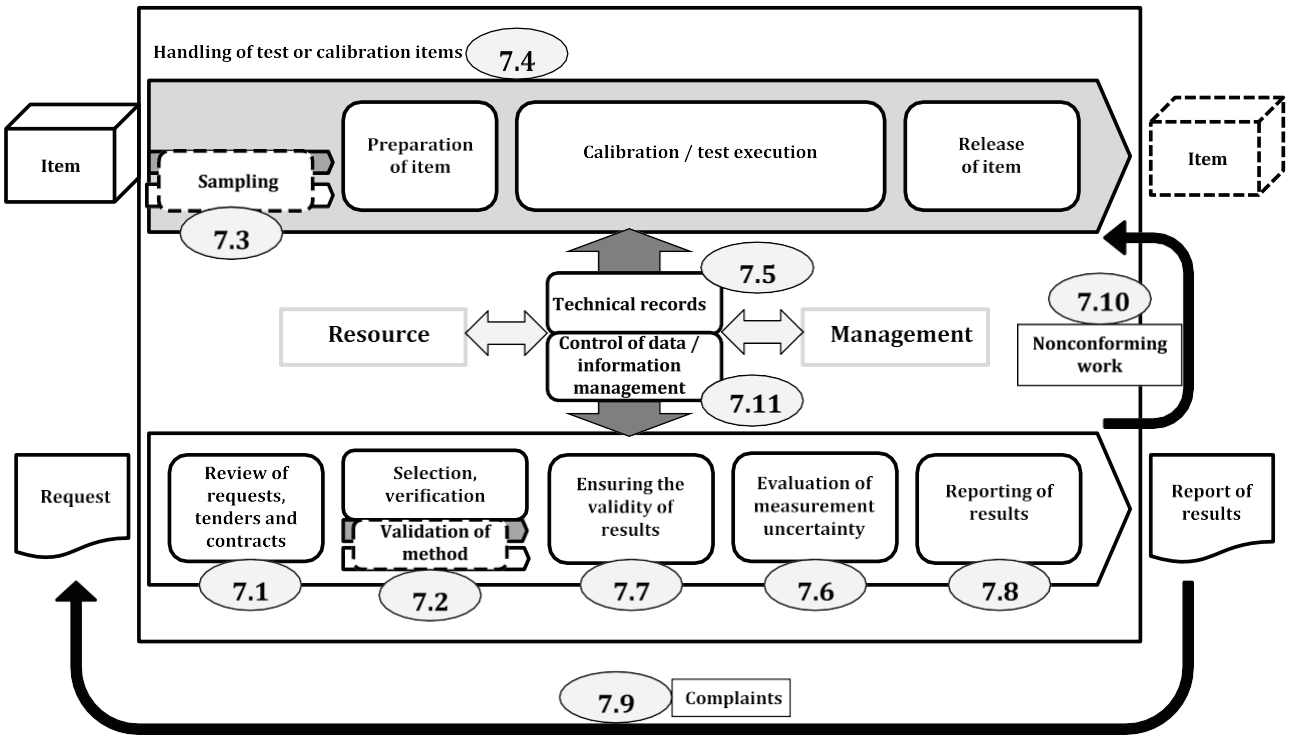
Micro Precision ensure that the operator or external provider of the information management system that managed and maintained off-site shall comply with all applicable requirements of this document.

Micro Precision ensures that instructions, manuals and reference data relevant to the laboratory information management system are made readily available to personnel.

Calculations and data transfers shall be checked in an appropriate and systematic manner.

Computers and automated test equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

**MP operational process that is CURRENTLY APPLIED AND IN PRACTICE**




# 8.0 Management System Requirements

## *8.1 General*

Micro Precision establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of ISO/IEC 17025 International Standard, Micro Precision implements a Management System in accordance with Option A as discussed in the standard.

As a minimum, our management system is addressing the following:

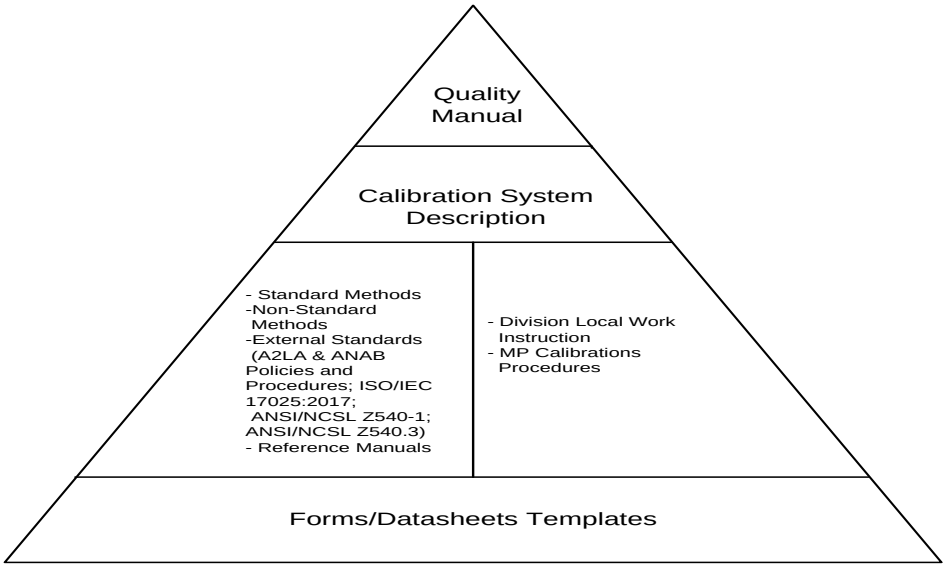
- management system documentation (see 8.2);
- control of management system documents (see 8.3);
- control of records (see 8.4);

- actions to address risks and opportunities (see 8.5);
- improvement (see 8.6);
- corrective actions (see 8.7);
- internal audits (see 8.8);
- management reviews (see 8.9).

## 8.2 *Management System Documentation*

The Quality Management System is defined within this Quality Manual and associated documentation. The Quality Manual includes Quality Policy, is the top tier document. It is supported by the Calibration System Description (operational and administrative procedures), Calibration Procedures (externally and/or internally developed), and division work instructions which are the second tier; and forms and records which are the third tier. The policies and objectives address the competence, impartiality and consistent operation of Micro Precision.

**Micro Precision QMS Document Structure**




Micro Precision management has evidence of development and implementation of the Quality Manual and Calibration System Description.

All documents, data and instructions, required to meet the intent of the Quality Management System are available where and when needed. This includes externally published standards and requirements.

### *8.3 Control of Management System Documents*

Micro Precision has established requirements for documents needed to demonstrate suitability and effective conformance to requirements, operation and control of processes. Documented procedures with internal and external origin address the management system documentation, including authority for and adequacy, revision, review, approval and re-approval, identification, legibility, availability and obsolescence requirements. Unique identification includes issue date and/or revision identification, page numbering, total number of pages and issuing authorities.

Authorized editions of documents are available at all locations where operations essential to the effective functioning of the laboratory are performed. Invalid or obsolete documents are removed from points of issue or use or otherwise assured against unintended use; documents historically preserved are suitably marked.

Documents and work instructions are provided as required by ISO standards listed in Normative References, and where needed to ensure quality of the process, product, or services provided. Responsibility for creating or updating Quality Management System documents is assigned to designated individuals who are best placed in the organization to evaluate the processes and methods used to meet the requirements.

The designated process owners and/or authorized personnel will approve new or changed processes, procedures, instructions, or documents, as applicable, prior to issue. Where practical, revised or new text is identified in the document or appropriate attachments. Reviews, updates and re-approval of documents are performed in the same manner as original documents and reissued as soon as practicable. Documents are not revised by hand notations pending reissue; however, if this should become necessary, documented procedures will identify the method, requirements and authorities. Procedures are established to describe how changes in electronic documents are made and controlled.

Requirements for calculations and data transfers, use of computers and automated test equipment are controlled in accordance with the Calibration System Description.

### *8.4 Control of Records*

Micro Precision has established requirements for quality records in order to demonstrate evidence of conformance to requirements and effective operation of the Quality Management System. Documented procedures address legibility, identification, access, archive, storage, maintenance, protection, retrieval, retention time and disposition, and back-up of electronically stored records, including preventing unauthorized to or amendment of these records.

Records are legible and stored for accessibility in a suitable environment to prevent damage, deterioration or loss. Control of electronic quality records. Retention periods are established and recorded. Records are available to the customer for evaluation in accordance with contract requirements.

Test or calibration records identify the personnel responsible for the performance of the test and/or calibration and checking of results, and contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable repeatability of the test or calibration as close as possible to the original conditions. Quality records include records such as audit reports, management reviews and corrective actions. Specific record requirements are addressed throughout the Quality Manual.

Amendments to records are tracked to previous versions or to original observations. The original and amended data and files shall be retained both for manual records and electronic records.

## *8.5 Actions to Address Risks and Opportunities*

Micro Precision considers the risks and opportunities associated with the laboratory activities in order to:

- give assurance that the management system achieves its intended results;
- enhance opportunities to achieve the purpose and objectives of the laboratory;
- prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
- achieve improvement.

Micro Precision plan actions to address these risks and opportunities; by integrating and implement these actions into its management system; evaluating the effectiveness of these actions. Although this document specifies that the Micro Precision plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Micro Precision decides whether or not to develop a more extensive risk management methodology than is required by this document.

Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results. Micro Precision options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Micro Precision opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

## *8.6 Improvement*

Continual improvement is systematically achieved by implementing the commitments defined in this Quality Manual.

- Corrective actions
- Audit results
- Analysis of data
- Management reviews
- Customer Surveys

## *8.7 Corrective Actions*

Micro Precision has established requirements for corrective action in order to eliminate the cause of nonconformities. Corrective actions are appropriate to the effects of the nonconformities encountered and are taken to prevent recurrence. Documented procedures define responsibilities and requirements for:

- Determining and investigating the root cause(s) of nonconformities and evaluating the need for action to ensure that they do not recur;
- Determining and implementing appropriate action(s) needed, commensurate with the magnitude and risk of the problem;
- If is necessary update risks and opportunities determined during planning,
- Documenting and implementing required changes resulting from the corrective action investigations; including complaints.
- Monitoring the results to ensure the corrective actions taken have been effective;
- Maintaining records of the nature of the nonconformities, causes, subsequent actions and results of actions taken and reviewing corrective action taken.

## *8.8 Internal Audits*

Micro Precision has established requirements for internal audits at planned intervals in order to demonstrate conformance to requirements and planned arrangements, and to determine the effective implementation and maintenance of the Quality Management System. Documented procedures address the responsibilities and requirements for selection, planning, Execution establishing records, reporting results, maintaining records and results and closure of internal audits of processes, to determine compliance to ISO standards, and Laboratory Accreditation requirements.

The audit program is planned and conducted according to a predetermined schedule. The audit program considers the status and importance of each process, operation or areas to be audited, including testing and calibration activities, and considering results from previous audits. Requirements for the audit criteria, scope, frequency, and methods are defined in the audit plan.

Individuals who are independent of the operation or process being audited, and who are qualified and trained in auditing, conduct the audits. The Director of Quality Assurance plans and organizes audits as required by the schedule and requested by management and ensures impartiality and objectivity when selecting auditors and conducting audits.

The area of activity audited, the audit findings and corrective actions that arise from them are recorded. Management responsible for the area audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. When audit findings cast doubt on the effectiveness of operations or on the correctness or validity of test or calibration results, timely corrective action is taken, including notification of customers in writing if investigations show that laboratory results have been affected. The implementation and effectiveness of corrective action taken is verified during follow-up audit activities and verification results are reported.

## *8.9 Management Reviews*

Corporate management conducts a management review of the Quality Management System performance periodically, at least once a year, according to a predetermined schedule. Quality Assurance facilitates the review and records. Division management conducts management reviews periodically at their geographical locations and participates in the annual management review with corporate management. Reviews are conducted to ensure the continuing suitability and effectiveness of the Quality Management System and introduce necessary changes or improvements.

Management review inputs are the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of laboratory activities;

i) customer and personnel feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.

Include audit results, customer feedback and complaints, changes in internal and external issues that are relevant to the laboratory, fulfillment of objectives, status of actions from previous management reviews, corrective actions, follow-up from prior management reviews, suitability of policies and objectives and procedures assessments by external bodies, effectiveness of any implemented improvements, results of risk identification, changes in the volume and type of work, outcomes of the assurance of the validity of results, resources and staff training.

Management review outputs include decisions and actions designed to improve the effectiveness of the Quality Management System and its processes, improvement of the laboratory activities related to the requirements, any need for change and resources. Implementation of management review outputs are carried through management review reports, minutes of the meeting, and/or process and document revisions. Communications to relevant personnel and or external parties are made through emails, meetings, reports and other suitable channels. The Quality Assurance group ensures communication processes are appropriate and records are maintained as needed.

## 9.0 Annex A:

### Cross-Reference: ISO 9001:2015, ISO/IEC 17025:2017 and MPC QMS Documents

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| Scope | 1 | 1 | MP QM – Quality Manual |
| Normative references | 2 | 2 | MP QM – Quality Manual |
| Terms and definitions | 3 | 3 | MP QM – Quality Manual |
| **4. Context of the organization** | | | |
| Understanding the organization and its context | 4.1 | 5.4<br>8.2<br>8.9a | MP-QM – Quality Manual<br>MP-CSD – Calibration System Description<br>Appendix 11- Order Processing<br>Appendix 19- Corrective Action Process |
| Understanding the needs and expectations of interested parties | 4.2 | 4.1.3<br>4.2.1<br>7.9.2<br>5.1<br>7.1<br>7.9<br>8.6<br>8.9.2.i<br>8.9.2.j | MP-QM – Quality Manual<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process -(Table 2 – Quality Policies and Objectives) |
| Determining the scope of the quality management system | 4.3 | 5.3 | MP-QM – Quality Manual (Scope statement)<br>MP-CSD – Calibration System Description<br>Appendix 2 – Accredited Work<br>Appendix 14 – Management Responsibilities and Continual Improvement Process -Quality Policies and Objectives |
| Quality management system and its processes | 4.4 | 5.6<br>8.1.1<br>8.2.4<br>8.2.3 | MP-QM – Quality Manual (8.6 Improvements)<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 13 – Calibration Servicing Process<br>Appendix 15 – Control of Documents<br>Appendix 16 – Control of Records |
| **5. Leadership** | | | |
| Leadership and commitment – general | 5.1 | 8.2.3 | MP-QM – Quality Manual<br>5.0 Structural Requirements 5.1 Organization Structure<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| General leadership responsibilities | 5.1.1 | 4.1<br>5.2<br>5.4<br>8.2.3 | MP-QM – Quality Manual<br>Quality Policy, 5.0 Structural Requirements 5.1 Organization Structure, 7.0 Process Requirement, 8.0 Quality Management System Requirements, 8.5 Actions to address risks and opportunities<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 11- Order Processing<br>Appendix 13- Calibration Servicing Process |
| Customer focus | 5.1.2 | 8.2.3 | MP-QM – Quality Manual<br>Quality Policy, Mission and Vision, Core Values, 5.0 Structural Requirements 5.1 Organization Structure, 8.5 Actions to Address Risks and Opportunities<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 11 – Order Processing |
| Quality Policies and Objectives | 5.2 | 8.9.1 | MP-QM – Quality Manual<br>Quality Policy<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process - Table 2 – Quality Policies and Objectives |
| Establishing the quality policy | 5.2.1 | 8.2.1<br>8.2.2<br>8.9.1 | MP-QM – Quality Manual<br>Quality Policy<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process - Table 2 – Quality Policies and Objectives |
| Communicating the quality policy | 5.2.2 | 8.9.1 | MP-QM – Quality Manual<br>Quality Policy<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process - Table 2 – Quality Policies and Objectives |
| Organizational roles, responsibilities and authorities | 5.3 | 5.2<br>5.5<br>5.6<br>6.2.4<br>6.2.6<br>7.10<br>8.2.5 | MP-QM – Quality Manual<br>Quality Policy, 5.0 Structural Requirements 5.1 Organization Structure, 7.0 Process Requirements, 8.6 Improvement, 7.1 Review of requests, tenders and contracts, 8.6 Improvement<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| **6. Planning** | | | |
| Actions to address risks and opportunities | 6.1 | 4.1.4<br>8.1.2<br>8.5<br>8.7.1e<br>8.9.1m | MP-QM – Quality Manual<br>8.0 Quality Management System, 8.5 Actions to address risks and opportunities, 8.6 Improvements<br>MP-CSD – Calibration System Description<br>Appendix 13 – Calibration Servicing Process<br>Appendix 20 – Risk Management Process-Table 2 – Risk Management Process<br>CQA-WI-002 – MP Risk Management Process |
| Quality objectives and planning to achieve them | 6.2 | 8.2.1<br>8.2.2<br>8.5.1b<br>8.9.1<br>8.9.2 | MP-QM – Quality Manual<br>5.0 Structural Requirement, 6.0 Resource Requirements, 7.0 Process Requirements, 8.2 Quality Management System Documentation, 8.6 Improvement<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Planning of Changes | 6.3 | 5.7a<br>5.7b<br>7.1.8<br>7.11.2<br>8.3.2c<br>8.7.1f<br>8.8.2a<br>8.9.2l<br>8.9.3c | MP-QM – Quality Manual<br>8.9 Management Reviews<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| **7. Support** | | | |
| Resources<br><br>General | 7.1<br><br>7.1.1 | <br><br>5.6<br>6.1<br>7.1.1b<br>7.2.1.6<br>8.9.2c<br>8.9.2l | <br><br>MP-QM – Quality Manual<br>6.0 Resource Requirements, 6.1 General<br>MP-CSD – Calibration System Description<br>Appendix 10-Externally Provided Products and Services,<br>Appendix 14- Management Responsibilities and Continual Improvement Process |
| People | 7.1.2 | 6.2 | MP-QM – Quality Manual<br>6.2 Personnel<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 4 – Authorized Signatories<br>Appendix 6 – Calibration Procedures<br>Appendix 13 – Calibration Servicing Process |
| Infrastructure | 7.1.3 | 6.3<br>6.4 | MP-QM – Quality Manual<br>6.0 Resource Requirements, 6.3 Facilities and environment condition, 6.4 Equipment<br>MP-CSD – Calibration System Description |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| | | | Appendix 5 – Environmental Control Requirements<br>Appendix 10-Externally Provided Products and Services,<br>Appendix 14- Management Responsibilities and Continual Improvement Process |
| Environment for the operation of processes | 7.1.4 | 6.3 | MP-QM – Quality Manual<br>6.0 Resource Requirements, 6.3 Facilities and environment condition<br>MP-CSD – Calibration System Description<br>Appendix 5 – Environmental Control Requirements<br>Appendix 13 – Calibration Servicing Process |
| Monitoring and measuring resources | 7.1.5 | 6.2.5f<br>6.6.2b<br>6.6.2d<br>8.9.2 | MP-QM – Quality Manual<br>6.0 Resource, 6.2 Personnel, 6.6 Externally provided products and services, 8.9 Management Reviews<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 10-Externally Provided Products and Services<br>Appendix 14- Management Responsibilities and Continual Improvement Process |
| General | 7.1.5.1 | 6.4<br>6.5<br>7.7 | MP-QM – Quality Manual<br>6.4 Equipment, 6.5 Metrological Traceability, Ensuring the Validity of results<br>MP-CSD – Calibration System Description<br>Appendix 3 – Field Service<br>Appendix 9 – Handling, Storage, Preservation and Transport<br>Appendix 10-Externally Provided Products and Services<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14- Management Responsibilities and Continual Improvement Process<br>CQA-WI-001 - MP Policy on Inter- Laboratory |
| Measurement traceability | 7.1.5.2 | 6.5 | MP-QM – Quality Manual<br>6.5 Metrological Traceability<br>MP-CSD – Calibration System Description<br>Appendix 9 – Handling, Storage, Preservation and Transport<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process |
| Organizational knowledge | 7.1.6 | 6.2 | MP-QM – Quality Manual<br>5.0 Structural Requirements |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| | | | MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 14- Management Responsibilities and Continual Improvement Process |
| Competence | 7.2 | 6.2<br>6.2.2<br>6.2.3<br>6.2.5 | MP-QM – Quality Manual<br>5.0 Structural 6.2 Personnel<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements |
| Awareness | 7.3 | 8.2.1 | MP-QM – Quality Manual<br>8.6 Improvement<br>MP-CSD – Calibration System Description<br>Appendix 1- Minimum Training Requirements<br>Appendix 14- Management Responsibilities and Continual Improvement Process |
| Communication | 7.4 | 5.7a<br>6.2.4<br>6.6.3<br>7.1<br>7.1.3<br>7.9.6<br>7.9<br>8.6 | MP-QM – Quality Manual<br>5.0 Structural Requirements<br>MP-CSD – Calibration System Description<br>Appendix 10-Externally Provided Products and Services<br>Appendix 11- Order Processing<br>Appendix 14- Management Responsibilities and Continual Improvement Process<br>Appendix 19 – Corrective Action Process |
| Documented information<br><br>General | 7.5<br><br>7.5.1 | 7.5<br>7.11<br>8.2<br>8.2.5<br>8.3<br>8.4 | MP-QM – Quality Manual<br>7.11 Control of Data and information management, 8.2 Quality Management System Documentation<br>MP-CSD – Calibration System Description<br>Appendix 15 – Control of Documents<br>• Table 2 – General Requirements<br>• Table 3 – External Documents<br>• Table 4 – Internal Documents<br>Appendix 16 – Control of Records |
| Creating and updating | 7.5.2 | 5.5.c<br>6.2.2 | MP-QM – Quality Manual<br>8.2 Quality Management System Documentation<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 15 – Control of Documents<br>• Table 2 – General Requirements<br>• Table 4 – Internal Documents<br>Appendix 16 – Control of Records |
| Control of documented information | 7.5.3 | 8.3 | MP-QM – Quality Manual<br>8.3 Control of management system documents<br>MP-CSD – Calibration System Description<br>Appendix 15 – Control of Documents<br>Appendix 16 – Control of Records |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| **8. Operation** | | | |
| Operational planning and control | 8.1 | 5.7.b<br>6.1<br>6.4.3<br>6.6<br>7.1<br>7.2.1.6<br>7.7<br>7.7.1<br>7.7.2<br>8.5.2 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 5 - Environmental Control Requirements<br>Appendix 6 - Calibration Procedures<br>Appendix 10-Externally Provided Products and Services<br>Appendix 11 – Order Processing<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Requirements for products and services | 8.2 | 7.1<br>7.2<br>7.4 | MP-QM – Quality Manual<br>5.0 Structural, 7.1 Review of Request, Tenders and Contracts<br>MP-CSD – Calibration System Description<br>Appendix 6 - Calibration Procedures<br>Appendix 9 - Handling, Storage, Preservation and Transport<br>Appendix 10-Externally Provided Products and Services<br>Appendix 11 – Order Processing<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 16 – Control of Records |
| Customer communication | 8.2.1 | 7.1 | MP-QM – Quality Manual<br>5.0 Structural, 7.1 Review of Request, Tenders and Contracts<br>MP-CSD – Calibration System Description<br>Appendix 11 – Order Processing<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Determining the requirements for products and services | 8.2.2 | 7.1<br>7.8 | MP-QM – Quality Manual<br>5.0 Structural, 7.1 Review of Request, Tenders and Contracts<br>MP-CSD – Calibration System Description<br>Appendix 11 – Order Processing<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 16 – Control of Records |
| Review of the requirements for products and services | 8.2.3 | 7.1<br>7.7 | MP-QM – Quality Manual<br>5.0 Structural, 7.1 Review of Request, Tenders and Contracts |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| | | | MP-CSD – Calibration System Description<br>Appendix 11 – Order Processing<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 16 – Control of Records |
| Changes to requirements for products and services | 8.2.4 | 7.1 | MP-QM – Quality Manual<br>5.0 Structural, 7.1 Review of Request, Tenders and Contracts<br>Appendix 11 – Order Processing<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Design and development of products and services | 8.3 | N/A | (Marked as Not Applicable – Calibration companies may not design products) |
| Control of externally provided processes, products and services<br><br>General | 8.4<br><br>8.4.1 | 6.6<br><br>6.6.1 | MP-QM – Quality Manual<br>6.0 Resource Requirements 6.6 Externally provided products and services<br>MP-CSD – Calibration System Description<br>Appendix 10 – Externally Provided Products and Services |
| Type and extent of control | 8.4.2 | 6.6.2 | MP-QM – Quality Manual<br>6.0 Resource Requirements 6.6 Externally provided products and services<br>MP-CSD – Calibration System Description<br>Appendix 10 – Externally Provided Products and Services<br>Appendix 11 – Order Processing |
| Information for external providers | 8.4.3 | 6.6.3 | MP-QM – Quality Manual<br>6.0 Resource Requirements 6.6 Externally provided products and services<br>MP-CSD – Calibration System Description<br>Appendix 10 – Externally Provided Products and Services |
| Production and service provision | 8.5 | 7.1<br>7.2<br>7.3<br>7.4<br>7.5<br>7.6<br>7.7<br>7.8 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 5 - Environmental Control Requirements<br>Appendix 6 - Calibration Procedures<br>Appendix 9 - Handling, Storage, Preservation and Transport<br>Appendix 11 – Order Processing<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 16 – Control of Records |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| Control of production and service provision | 8.5.1 | 4.1<br>5.5.c<br>5.6<br>6.2<br>6.3<br>6.4<br>7.2<br>7.3<br>7.4<br>7.5<br>7.6<br>7.7<br>7.8<br>8.5 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Page 8 – Impartiality<br>Appendix 1 – Minimum Training Requirements<br>Appendix 5 - Environmental Control Requirements<br>Appendix 6 - Calibration Procedures<br>Appendix 9 - Handling, Storage, Preservation and Transport<br>Appendix 11 – Order Processing<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 16 – Control of Records<br>Appendix 20 – Risk Management Process |
| Identification and traceability | 8.5.2 | 6.5<br>7.4 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 12 – Control of Instruments and Equipment<br>Table 5 (Status Labeling)<br>Table 6 (Traceability<br>Appendix 13 – Calibration Servicing Process |
| Property belonging to customers or external providers | 8.5.3 | 6.3<br>6.4<br>6.6<br>7.4 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 5 - Environmental Control Requirements<br>Appendix 9 - Handling, Storage, Preservation and Transport<br>Appendix 10 – Externally Provided Products and Services<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process |
| Preservation | 8.5.4 | 6.3<br>7.4<br>7.7 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 5 - Environmental Control Requirements<br>Appendix 9 - Handling, Storage, Preservation and Transport<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process |
| Post-delivery activities | 8.5.5 | 7.1.8<br>7.8 | MP-QM – Quality Manual<br>7.0 Process Requirements, 8.7 Corrective Action<br>MP-CSD – Calibration System Description |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| | | | Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 19 – Corrective Action Process |
| Control of changes | 8.5.6 | 5.7.b<br>7.1.8 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 11 – Order Processing<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Release of products and services | 8.6 | 7.7<br>7.8 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 9 - Handling, Storage, Preservation and Transport<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 16 – Control of Records |
| Control of nonconforming outputs | 8.7 | 8.7<br>7.7.3<br>7.10 | MP-QM – Quality Manual<br>7.0 Process Requirements<br>MP-CSD – Calibration System Description<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 18 – Control of Nonconforming Product<br>Appendix 19 – Corrective Action Process |
| **9. Performance evaluation** | | | |
| Monitoring, measurement, analysis and evaluation<br><br>General | 9.1<br><br>9.1.1 | 6.2.3<br>6.2.5<br><br>7.6<br>7.7 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements,<br>MP-CSD – Calibration System Description<br>Appendix 1 – Minimum Training Requirements<br>Appendix 6 - Calibration Procedures<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 17 – Internal Audit Process<br>Appendix 19 – Corrective Action Process<br>Appendix 20 – Risk Management Process |
| Customer satisfaction | 9.1.2 | 8.6<br>8.6.1<br>8.6.2 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 11 – Order Processing<br>Appendix 13 – Calibration Servicing Process |

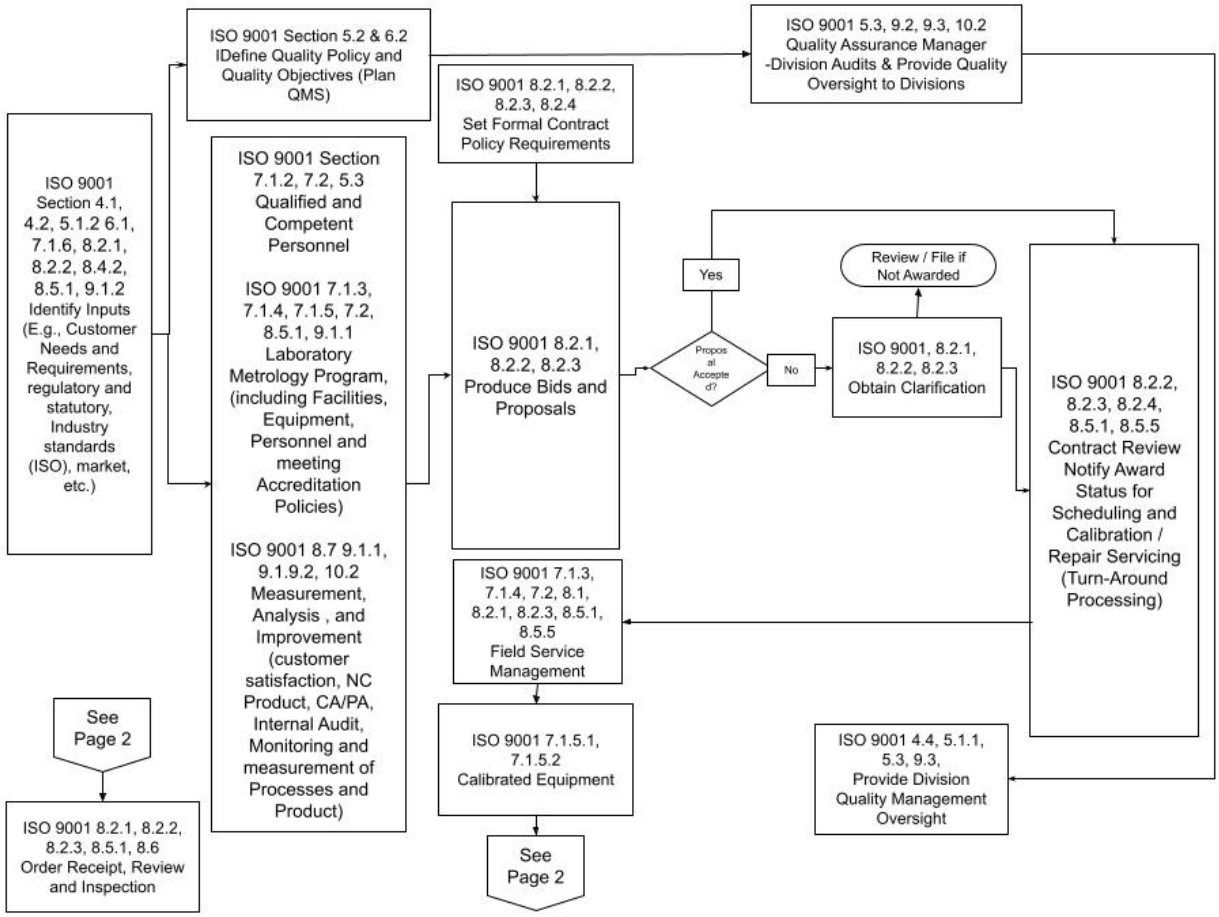
| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| | | | Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 19 – Corrective Action Process |
| Analysis and evaluation | 9.1.3 | 7.6<br>7.7<br>8.6.2 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 12 – Control of Instruments and Equipment<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Internal audit | 9.2 | 8.8 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 15 – Control of Documents<br>Appendix 16 – Control of Records<br>Appendix 17 – Internal Audit Process<br>Appendix 19 – Corrective Action Process<br>Appendix 20 – Risk Management Process |
| Management review<br><br>General | 9.3<br><br>9.3.1 | 8.9 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 10-Externally Provided Products and Services<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Management review inputs | 9.3.2 | 8.9 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 10-Externally Provided Products and Services<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 15 – Control of Documents<br>Appendix 16 – Control of Records<br>Appendix 19 – Corrective Action Process |
| Management review outputs | 9.3.3 | 8.9 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 10-Externally Provided Products and Services<br>Appendix 13 – Calibration Servicing Process<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 15 – Control of Documents<br>Appendix 16 – Control of Records<br>Appendix 19 – Corrective Action Process |

| Clause Title of ISO 9001:2015 | Clause of ISO 9001:2015 | Clause of ISO/IEC 17025:2017 | Supporting MPC Quality System Documents |
|---|---|---|---|
| **10. Improvement** | | | |
| General | 10.1 | 8.6<br>8.6.1 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process |
| Nonconformity and corrective action | 10.2 | 7.9<br>7.10<br>8.7 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 16 – Control of Records<br>Appendix 17 – Internal Audit Process<br>Appendix 18 – Control of Nonconforming Product<br>Appendix 19 – Corrective Action Process |
| Continual improvement | 10.3 | 8.2.3<br>8.6<br>8.6.1<br>8.9.1 | MP-QM – Quality Manual<br>8.0 Quality Management System Requirements<br>MP-CSD – Calibration System Description<br>Appendix 10 – Externally Provided Products and Services<br>Appendix 14 – Management Responsibilities and Continual Improvement Process<br>Appendix 15 – Control of Documents<br>Appendix 16 – Control of Records<br>Appendix 17 – Internal Audit Process<br>Appendix 19 – Corrective Action Process |

## 10.0 Annex B:

### Documented Business Process Flow: Calibration and Repair Process

### (Based on ISO 9001)

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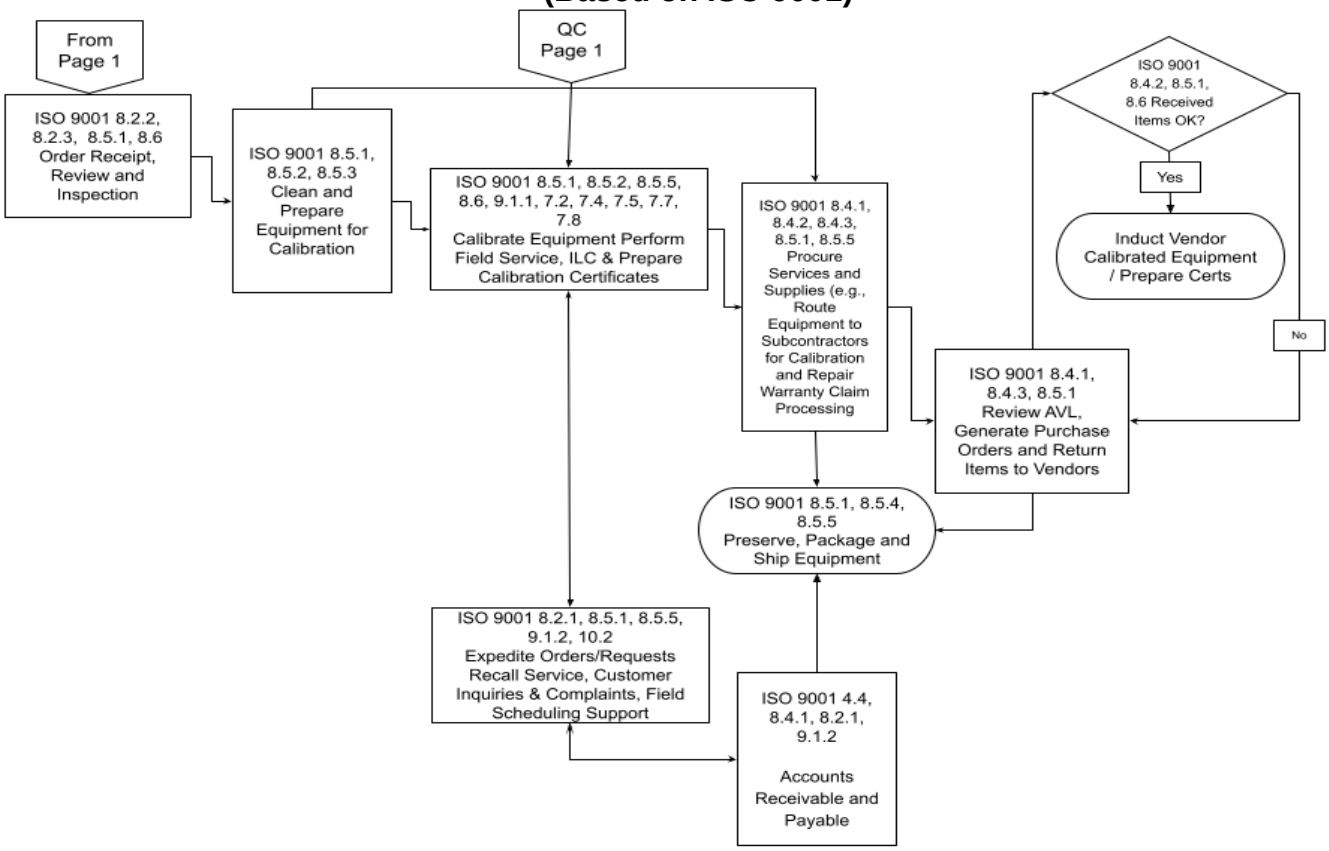
## 10.0 Annex B:

### Documented Business Process Flow: Calibration and Repair Process

### (Based on ISO 9001)



## 11.0 Document Revision Control History

| Rev | Issue Date | Revision By | Revision Description |
|---|---|---|---|
| 00 | 06/27/18 | Jarrod Trammell | Replace the Quality Manual MPC-QM R11a 04-23-18, due to ISO/IEC 17025:2017 latest revision released by ISO/IEC International Standard. |
| 01 | 01/24/19 | Jarrod Trammell | Update list of MP Laboratories |
| 02 | 03/15/19 | Enrique Hernandez | Change Director of Quality Assurance to Quality Director and Quality Management Representative to Quality Administrator Change name of signatory |
| 02a | 11/29/19 | Enrique Hernandez | Update list of MP Laboratories<br>Added statement in Scope Page 3 |
| 03 | 12/02/20 | Enrique Hernandez | Update list of MP Laboratories (Replace MP-Massachusetts with MP New Hampshire). |
| 04 | 01/05/21 | Enrique Hernandez | Update list of MP Laboratories (Add MP-Munich Germany) |
| 05 | 06/06/22 | Sarah Charmak | Update list of MP Laboratories (Add MP-Brazil)<br>Update manual's authorized signatory |
| 06 | 01/19/24 | Sarah Charmak | Update list of MP Laboratories (Add MP-Kansas, MP-United Kingdom(UK), MP-Berlin, & MP-Romania) |
| 06a | 02/22/24 | Sarah Charmak | Update list of MP Laboratories (Add MP-Virginia) |
| 07 | 01/07/25 | Sarah Charmak | Update list of MP Laboratories (Add MP-Hawaii, MP-United Kingdom-Midlands, & MP-Chon Buri, Thailand) |
| 07a | 30-Jul-25 | Sarah Charmak | Update list of MP Laboratories, Add Oceania Divisions (MP-Victoria & MP-New Castle)<br>Revised Quality Policy Statement<br>Revised Scope Statement<br>Revised 8.9 Management Review<br>Additional Annex A: Cross-Reference: ISO 9001:2015, ISO/IEC 17025:2017 and MPC QMS Documents,<br>Additional Annex B: Documented Business Process Flow: Calibration and Repair Process (Based on ISO 9001) |
| 08 | 24-Aug-26 | Sarah Tolley | Update list of MP Laboratories, (MP-Colorado Spring & MP-West Palm Beach) |

**Micro Precision Calibration, Inc.**

Approved By:
Jarrod Owen Trammell, President - Quality Director Date: 24-Aug-26

Issued By:
Sarah Tolley, Corporate QA Date: 24-Aug-26