

# Micro Precision Calibration, Inc.

## Calibration System Description

Rev. 02, 03-05-20

# Calibration System

## Description

MP CSD

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*This document is integral to the Micro Precision Calibration Quality Manual and includes Appendices incorporating requirements of ISO/IEC 17025 pertaining to the operation and maintenance of a Calibration Laboratory, including minimum operations procedures and personnel requirements. When approved, this document has the support of top management for implementation by each Division. Together, this Calibration System Description, referenced appendices, and the Micro Precision Calibration Quality Manual comprise the Quality Management System.*

## Personnel

### ***Authority and Competency***

Only authorized and qualified personnel will perform tests/calibrations, operate specific equipment, sign and/or issue calibration reports, evaluate results, and give opinions and interpretations. The Lab Manager has authority and responsibility for the competency of personnel and associated records.

- Competency will be based on appropriate education, training, experience and/or demonstrated skills, as required;
- Goals with respect to the education, training and skills of laboratory personnel will be formulated;
- Evidence of competency of staff performing specific on-site tests/calibrations will be readily available.
  - Evidence includes training records for all technical personnel, including any contracted personnel, appropriate analysis of blind proficiency samples (where available) and other demonstrations of method proficiency.
- On-site personnel who are not employed or sub-contracted by Micro Precision Calibration are not permitted to assist in the performance of accredited tests or calibrations, unless adequately supervised by trained staff that are employed or subcontracted by Micro Precision Calibration.
- A record of Approved Signatories criteria (see Appendix 4) for signatory approval and limits of signatory authority will be maintained and readily retrievable. The Approved Signatories Lists will be signed by the President and the Quality Director. Quality Inspectors will be controlled and assigned to authorized personnel only (see Appendix 4).
- Current Job Descriptions for managerial, technical and key support include personnel involved in calibrations. As applicable, the following are considered in defining job descriptions:
  - Responsibilities with respect to performing tests and/or calibrations;
  - Responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
  - Responsibilities for reporting opinions and interpretations;
  - Responsibilities with respect to method modification and development and validation of new methods;
  - Expertise and experience required;
  - Qualifications and training programs;
  - Managerial

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- Tech 1 through 5 refers to Calibration Technician levels of rank.
- Receiving Inspectors – Individuals who have a high degree of skill in the induction of customer requirements into the system database and performing initial inspection of customer orders.
- Final Inspectors – Individuals who have competency in the requirements of calibration services and the impact of necessary service documentation. Final Inspectors are responsible for performing quality checks on completed documentation and status labels.

### ***Training and Records***

All personnel will undergo initial and periodic indoctrination and training. Training will address the Quality Management System and technical requirements of the laboratory.

The Lab Manager has responsibility for the training of personnel and associated records. The Quality Director or delegate (or President, as appropriate) has responsibility for the training and associated records of Quality personnel.

- Training programs will be designed so as to provide opportunity for progressive advancement for technical personnel;
- Training programs that are relevant to the present and anticipated tasks of the Laboratory will be developed and maintained, including statistical techniques, where appropriate.
- Training programs will be commensurate with years of direct metrological experience and satisfactory demonstration of capabilities in calibration, calibration procedures, processes, and traceability and documentation requirements.
- Personnel training requirements are described in Appendix 1.
- Technicians performing accredited tests/calibrations will be trained in accordance with Appendix 2.
- Field Service personnel will be trained and will implement their work in accordance with Appendix 3.
- Training records for each employee will be maintained current.
- Training records will identify the relevant authorizations, competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel, will be readily available and will include the date of authorization (see Appendix 1, Minimum Training Requirements and Appendix 16, Control of Records).
- Personnel undergoing training will be appropriately supervised.

### References:

Quality Manual (Section 6.2 Personnel)  
Appendix 1, Minimum Training Requirements  
Appendix 2, Accredited Work  
Appendix 3, Field Service Guidelines  
Appendix 4, Authorized Signatories  
Process Map (F6), Training Process

### Impartiality

Micro Precision activities shall be undertaken impartiality 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.

#### References:

Quality Manual, (Section 4.1 –Impartiality)

ISO/IEC 17025:2017, par. 4.1

### 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.

#### References:

Quality Manual, (Section 4.2 –Impartiality)

ISO/IEC 17025:2017, par 4.2

## Accommodation and Environment

### **General Requirements**

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 (Appendix 5), where practical or applicable, to facilitate proper performance of calibrations or tests.

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The following are considered where applicable and practical (where required by the relevant specifications, methods and procedures, or where conditions influence the quality of the results):

- Line voltage limits;
- Temperature and rate of change of temperature;
- Electromagnetic interference;
- Maintaining effective separation between neighboring areas with incompatible activities, and implementing measures to prevent cross-contaminations;
- Biological sterility requirements;
- Dust particle count limits/dust control
- Static controls;
- Humidity, sound and vibration
- Designated calibration and storage areas
- Energy sources;
- Lighting;
- Heating and ventilation;
- Cleanliness and good housekeeping practices, and
- Utilities (e.g., water, compressed air, electric power and chemicals) used during servicing to ensure uniformity of effect on servicing processes, and radiation.

The environment criteria established in Appendix 5 are designed to ensure valid results while not adversely affecting the required uncertainty of measurement. The extent of control and any needed modifications to or deviations from established specifications at any Division will be based upon the laboratory's particular scope of measurements being performed and local environmental constraints.

Reference standards are maintained in a suitable environment at all times, such that handling, transport and storage do not invalidate their calibration status. Provisions for restricting access to the field service calibration and test areas when unrestricted access could invalidate the test or calibration results will be taken.

Temperature and humidity conditions are continuously monitored, controlled and recorded and, when necessary, correcting compensations are applied to measurement results.

Calibration activities are stopped when environmental conditions jeopardize calibration results.

### **Field Services**

For on-site facility or mobile unit calibrations, where the environment may affect the instrumentation or the required accuracy and precision of measurement, the data is qualified per these criteria.

Where field service calibrations are undertaken in a hostile or unsuitable environment or in an environment that may affect the test or calibration results, these conditions and the effect of the environment on the performance of the test/calibration will be monitored (see Appendix 3 and Appendix 5).

#### References:

Quality Manual, (Section 6.3 – *Facilities and Environmental condition*)

Appendix 3, Field Service Guidelines

Appendix 5, Environmental Control Requirements

### Test and Calibration Methods

Up-to-date calibration procedures (Appendix 6) (whether standard methods or internal procedures/amplifications/modifications), work instructions, workmanship standards, drawings, specifications and procedures are made available to all staff, including on-site personnel, for use during the servicing process.

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

Deviations (Appendix 7) from methods will occur only if technically justified, documented, authorized and accepted by the client.

Appropriate methods and procedures within the laboratory's scope (including, but not limited to, preparation (Appendix 8), sampling, and handling, transport and storage (Appendix 9), and use of items, estimation of uncertainty of measurement and analysis of calibration and/or test data), 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.

Where methods are not specified, the latest valid edition of such methods, which have been published in international or national standards, published by reputable technical organizations or in relevant scientific texts or journals, will be used, wherever possible. When necessary, the standard will be supplemented with additional details to ensure consistent application.

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.

Procedures are adequate for their purpose and contain sufficient information to ensure their proper implementation, to ensure consistency of application from one application to another and to ensure valid measurement results.

Customer approval is obtained where it is necessary to employ methods that have not been established as standard and shall include a clear specification of the customer's requirements. Such methods will be fully documented and validated, and will be available to the customer and other recipients of the relevant reports.

The laboratory will confirm that it can properly operate standard methods before introducing the test/calibration. The confirmation will be repeated if the method changes.

#### References:

Quality Manual (Section 7.0 – Process Requirement)

Appendix 6, Calibration Procedures

Appendix 7, Permitting Departures

Appendix 8, Cleaning and Prep

Appendix 9, Handling, Storage, Preservation and Transport

Process Map (F4), Calibration Methods Process

## **Measurement Assurance**

Measuring processes incorporating measurement assurance methods using statistical process controls and methods are incorporated to ensure compliance to desired goals. The use of measurement assurance procedures to ensure stated measurement uncertainty or reliability goals are met by ensuring there is review of the measurement process, control criteria, and methodology.

Measurement Assurance Process used:

Statistical process: Calculation of Probability of False Accept, Estimation of Measurement Uncertainty (Process defined in CSD)

Calibration Process: Inter-laboratory Comparisons (Process defined in CSD)

Control: Equipment Control/environmental Control (Process defined in CSD)

The controls shall be adjusted when the results of the previous measurements indicate that such action is appropriate to maintain acceptable measurement uncertainty or reliability. The control of measurement process shall be maintained, any process, which exceeds control, must be corrected or adjusted to in calibration process and statistical calculation.

## **Calculation of Probability of False Accept**

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:  $1.25-1/TUR$

When the TUR is less than 4, the test limit is set to 1.25 times the specification limit minus the uncertainty of the standard. This strategy, NCSL's Recommended Practice RP-10. This is continuous at a 4:1 TUR and does not require near the producer risk penalty, especially for the higher TURs. K ranges from 92% to 100% of the specification limit for TURs from 3 to 4 and a 2 confidence interval.

Calculation of TUR (Test Uncertainty Ratio) when PFA (Probability of False Accept) calculation is not practicable is determined by documented measurement assurance techniques which will be employed to verify the adequacy of higher echelon measurement processes.

1. When these techniques are not used, then the collective uncertainty of the M&TE and standards shall not exceed 25% of the acceptable tolerance (manufacturers' specifications) for each characteristic of the item being calibrated. This process ensures a 4:1 calibration ratio.

Comparison of the uncertainty is calculated using the terms of the measurement units being calibrated, not percentages. Calibration Standards listed in a calibration procedure may be substituted with other standards as long as the required characteristic being utilized for the calibration meets the minimum use requirements listed in the procedure.

### References:

NCSL's Recommended Practice RP-10

### Estimation of Measurement Uncertainty

Uncertainty calculations will follow the Guide to the Expression of Uncertainty in Measurement” (GUM)\* All uncertainty budgets identify important contributors, evaluation type of contributors, (either type A or type B), probability distribution type of each contributor and the combined total uncertainty. The Measurement Uncertainty process is illustrated in the Measurement Uncertainty Process Map in Appendix 12.

- In all cases, the relevant uncertainty component due to the unit under test is included.
- For measurements, which are mainly impacted by the unit under test, such as for some hand tools, the major contributor reported will be resolution of the instrument under test.
- For measurements comprising both reference and transfer standards, both the uncertainty of the reference standard including its long term reproducibility between calibration intervals, and accuracy of the transfer standard will be incorporated into the budget. In all cases, repeatability data will be available and the relevant statistic will be incorporated into the budget.
- Other factors such as environmental conditions, cabling effects, operator biases, etc. will be incorporated as applicable.
- The Total Uncertainty Reported will be equal to: 2 standard deviations (K=2) approximating 95% confidence level.

#### References:

Quality Manual, (Section 7.6 – *Evaluation of measuring uncertainty*)

ISO/IEC 17025:2017, par. 7.6

Guide to the Expression of Uncertainty in Measurement (GUM)

Appendix 12, Control of Instruments and Equipment

Process Map (F8), Measurement Uncertainty Process

### Inter-laboratory Comparisons

As required by Micro Precision and accreditation body policies, Division labs will participate in proficiency testing.

#### **Proficiency Testing Requirements (ISO/IEC 17025 Accredited Laboratory)**

- MP shall conduct proficiency tests in accordance with their normal/testing calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider.
- MP Division laboratories shall also ensure that proficiency testing samples are equally distributed among personnel trained and qualified for the relevant tests.
- Proficiency Testing participation is required for all MP Division labs for at least two proficiency testing activities per year, every year.
- MP Division labs must all participate in relevant and available proficiency testing at a frequency sufficient to ensure that all major sub-disciplines and materials/matrices/product types (as defined on each section) on the scope(s) of accreditation are covered over a four year period.

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- MP Corporate QA will design a 4-year Proficiency Testing Plan to cover applicable program requirements of each Division Lab's scope of accreditation over a four-year period.
- The Proficiency Testing Plan shall also cover any available participation and any inter-laboratory organized studies, as applicable.
- Testing results will be submitted promptly upon completion of testing and as specified by the accrediting body. MP Corporate QA will consolidate the collected proficiency testing results from participating divisions and submit consolidated testing results to the accrediting body within 30 days.
- Detailed corrective action responses for any outlying or unacceptable results related to calibration on their Scope of Accreditation will be submitted as well to the accrediting body within 30 days upon receipt of final PT results. Corrective Action Reports (discussed in Appendix 19) will be used to document and resolve unsatisfactory measurement results.

Complete and accurate records (see Appendix 16) are kept to facilitate traceability and assignable cause(s) in the event of unsatisfactory results. Proficiency testing activity must be demonstrated successful prior to receiving accreditation. This requirement is particularly applicable when performing testing using artifacts supplied by the accrediting body that are subject to extensive travel, or due to the nature of the artifact itself.

The lab will cooperate in disposition actions recommended by the accrediting body and approved by the Quality Director. The Division Manager of MP's accredited labs will notify the Quality Director promptly upon receipt of any changes or updates to the accrediting body's Proficiency Testing requirements or policies. Programs and artifacts will be chosen which will provide the most meaningful data for the lab's capabilities. Inter-laboratory tests will be administrated by third party agencies that are acceptable by the lab's certification or accreditation body.

### References:

Quality Manual (7.7 Ensuring the validity of results)

ISO/IEC 17025:2017 par. 7.7

AR2250 Guidance on Proficiency Testing/Inter-Laboratory Comparison

AR2251 ISO/IEC 17025 Calibration Process

A2LA R103-General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories.

ISO/IEC 17043 Conformity assessment — General requirements for proficiency testing

ANAB Guidance on Proficiency Testing / Inter-laboratory Comparisons

Appendix 12, Control of Instruments and Equipment

Appendix 16, Control of Records

Appendix 19, Corrective Action Process

Process Map (F5) ILC Process

MP PT Policy: CQA-WI-001

### Control of Technical Data

#### ***Calculations and Data Transfers***

Calculations and data transfers are subject to appropriate checks in a systematic manner. Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task. Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the following are ensured:

#### ***Computers and Automated Equipment***

Computer software is documented in sufficient detail and suitably validated as being adequate for use and procedures established and implemented to protect data integrity include, (but are not limited to) integrity and confidentiality of data entry or capture, data storage, data transmission and data processing (Appendix 15, Control of Documents). 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 and test data.

Appropriate procedures are implemented for the maintenance of security of data, including the prevention of unauthorized access to and unauthorized amendment of computer records (Appendix 16, Control of Records). Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.

The laboratory might have an information management system applicable to electronic and conventional information. The system has to be validated and protected.

- The requirements for information management systems are not restricted only to computerized systems (LIMS) but to any kind of system handling information.
- Test the system in place to check integrity, potential unauthorized access, protection against tampering and test backups
- The system has to be maintained in a correct manner and kept in a suitable environment.
- Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated
- Employee shall have access to instructions to the LIMS
- Calculations and data transfers shall be checked

#### References:

Quality Manual (Section 7.11 – Control of data and information management)

ISO/IEC 17025:2017 par. 7.11

Appendix 15, Control of Documents

Appendix 16, Control of Records

Process Map (F2) QMS Documentation Development Process Map

Process Map (F15) Records Control Process

### Equipment

Inspection, 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 in accordance with this Calibration System Description.

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Where test software or comparative references such as test hardware are used for inspections, prior to release for use they are checked to prove that they are capable of verifying the acceptability of the product, they comply with relevant standard specifications, and they are checked at prescribed intervals.

All inspection, measuring and test equipment, (both in the permanent laboratory and at the customer's facilities or in on-site mobile units.) are controlled, calibrated and maintained in accordance with this Calibration System Description (also see details in Appendix 12). Up-to-date instruction on equipment use and maintenance (including relevant manufacturing manuals) will be readily available for use by appropriate laboratory personnel. Authorized personnel will operate equipment.

The appropriate inspection, 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 (ref. Appendix 12, Control of Instruments and Equipment).

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

Reference standards of measurement held by Micro Precision are used for calibration or verification only and for no other purpose, unless it can be demonstrated that their performance as reference standards have not been invalidated.

Where needed to maintain confidence in the calibration status of the equipment, reference standards, reference materials, and measuring and test equipment are subject to in-service checks between calibrations and verifications according to defined procedures (ref. Appendix 12) and schedules.

Reference standards will be calibrated before and after any adjustment by a body that can provide traceability as described under Measurement Traceability of this document. A certificate of calibration, or test report will be maintained as a quality record for each item of equipment calibrated (ref. Appendix 12, Table 2, MP Major Instrumentation) and as described in Certificates of Calibration and Data.

### ***Intervals***

Equipment, including measuring standards, which can affect product quality, is identified, calibrated, adjusted and maintained at prescribed intervals (recall system), or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. (Refer to Measurement Traceability and Appendix 12, Table 3, MP Instrument Control). The bases used for calibration are documented where no such standards exist.

To assure acceptable reliability that the equipment will remain in-tolerance throughout the interval, decisions affecting the choice of calibration intervals are established for all equipment requiring calibration in accordance with specific objective criteria set forth in Appendix 12, Table 3, MP Instrument Control).

Subsequent calibrations are performed prior to any probable change in accuracy significant in the use of the equipment. Calibration intervals are shortened, if necessary, to ensure continued accuracy, depending on the results of preceding calibrations. Calibration intervals are not lengthened unless the preceding calibration results provide definite indications that such action will not adversely affect confidence in the accuracy of the measuring equipment.

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Relevant data, including those available from any statistical process control system operated by or for Micro Precision, will be considered when determining whether the changes in the intervals of calibration are appropriate.

Service and calibration records provide historical data for evaluating and adjusting the calibration intervals, and confirm that equipment has been calibrated on or before its designated date or removed from service, and will be maintained in accordance with Appendix 16, Control of Records.

### ***Check Standards***

Where intervals are not employed, check standards may be used to regularly monitor equipment. If check standards are implemented, their use is in accordance with a documented measurement assurance process.

### ***Calibration Process***

Calibration process requirements (Appendix 13, Calibration Servicing Process) include receiving inspection, details of equipment type, acceptance criteria, unique identification and status labeling (Appendix 12, Table 5, Status Labeling), location, frequency of checks, check method (Appendix 6, Calibration Procedures) and the action to be taken when results are unsatisfactory (Appendix 19, Corrective Action Process)

### ***Labeling***

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, (Appendix 12, Table 5, Status Labeling) including the date last calibrated and expiration date or recalibration due date.

The laboratory (or mobile units) facilities (including any test hardware or software) will be safeguarded from adjustments which would invalidate the calibration settings or results. Labeling and tamper-resistant seals in the field and laboratory are addressed in Appendix 3, Field Service Guidelines and Appendix 12, Table 5, Status Labeling, respectively.

### ***Maintenance***

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 implemented.

### ***Accredited Work***

Equipment maintenance and calibration records include the location, date and operator for all maintenance and calibration as well as details of storage between uses.

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 (also see Appendix 18, Control of Nonconforming Product).

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A temporary extension of the calibration due date for a limited period of time may be specified under conditions that do not unreasonably impair the satisfaction of the customer's requirements.

When it is necessary to utilize reference standards on-site, adequate measures are taken to ensure that the necessary calibration status is maintained during transportation and while on-site.

The response of such reference standards to environmental changes or other relevant parameters are known and documented. The calibration interval for customer equipment will not be recommended in the calibration certificate except where this has been previously agreed with the customer (ref. Appendix 3, Table 2, Field Service Calibrations).

Appropriate checks are made on-site to confirm the calibration status and fitness for use of equipment before testing or calibration begins. Where such checks cannot be made on-site (equipment whose performance is not sensitive to movement), calibration status and fitness for use are checked in the permanent laboratory before and after site testing or calibration. Equipment whose performance is sensitive to movement is verified /calibrated on-site. If equipment is found to be unfit for use and/or out of calibration, it shall not be used and is immediately withdrawn from service. The effects of such equipment on previous tests or calibrations are examined (ref. Appendix 3, Table 2, Field Service Calibrations).

### References:

Quality Manual (Section 6.4 – Equipment)  
ISO/IEC 17025:2017 par. 6.4  
Appendix 3, Field Service Guidelines  
Appendix 6, Calibration Procedures  
Appendix 12, Control of Instruments and Equipment  
Appendix 13, Calibration Service Processing  
Appendix 16, Control of Records  
Appendix 18, Control of Nonconforming Product  
Appendix 19, Corrective Action Process  
Process Map (F3) MP Standards Process  
Process Map (F4) Calibration Methods Process  
Process Map (F9) Corrective Action Process  
Process Map (F10) Overview of Calibration Servicing Process  
Process Map (F10-R) Receiving Inspection Process  
Process Map (F10-A) In-Process Inspection Servicing MP Instruments  
Process Map (F10-B) In-Process Inspection Servicing Customer Equipment  
Process Map (F10-F) Final Inspection Process  
Process Map (F11) Control of Non-conformances Process  
Process Map (F15) Control of Records Process

## Measurement Traceability

Test equipment and equipment used for subsidizing measurements (e.g., environmental conditions) having a significant effect on the accuracy or validity of calibration results will be calibrated before placing into service. Traceability to the International System of Units (SI) (Système International d'unités) will be established 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. National measurement standards that are consistent with the recommendations of the General Conference on Weights and Measures (CGPM) may be used. The Policy on Traceability is described in Appendix 12, Table 6 - Traceability.

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### ***Externally provided products and services***

When using external calibration services, traceability of measurement are assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. Externally Provider will work in accordance with the laboratory's management system.

Procurement requirements are described in Appendix 10, Externally provided products and services.

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.

#### References:

Quality Manual, (Section 6.5 Metrological Traceability)

ISO/IEC 17025:2017 par. 6.5

Appendix 2, Accredited Work

Appendix 10, Externally provided products and services

Process Map (F7-A) Subcontractor Process

Process Map (F7) Procurement Process

## Handling of Test and Calibration Items

Instruments, measuring and test equipment including reference materials will be received (Appendix 13, Table 3, Receiving Inspection), handled, stored, packaged, preserved (Appendix 9), retained and/or dispositioned and transported (Appendix 9) 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.

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 and steps taken, including unique identification of items, to prevent confusion between similar items, both physically or when referred to in records or other documents. Methods implemented will accommodate subdivision of groups of items and the transfer of items within and from the laboratory. Steps taken are documented, in accordance with written procedures (Appendix 13, Table 3, Receiving Inspection).

Requirements and appropriate facilities (Appendix 12, Control of Instruments and Equipment, and Appendix 5, Environmental Control, respectively) will be provided for equipment and reference standards and reference materials, to ensure proper functioning and to avoid contamination, deterioration or damage during storage, handling, transport (Appendix 9), planned maintenance, preparation (Appendix 8) and use during calibration and to protect their integrity.

Any relevant instructions provided with instruments, measuring and test equipment is followed. Calibration equipment, including hardware and software, will be safeguarded from adjustments that invalidate the calibration results.

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## References:

Quality Manual (Section 7.4 –Handling of Test or calibration items)

ISO/IEC 17025:2017 par. 7.4

Appendix 5, Environmental Control

Appendix 8, Cleaning and Prep

Appendix 9, Handling, Storage, Preservation and Transport

Appendix 13, Calibration Servicing Process

Process Map (F3) MP Standards Process

Process Map (F10) Overview of Calibration Servicing Process

Process Map (F10-R) Receiving Inspection Process

## Quality Control

The quality of results provided to customers will be ensured by implementing checks, in addition to periodic audits, which will be reviewed and include, as appropriate, but not be limited to: Internal Quality Control to monitor the validity of calibrations undertaken, recording data in a manner to detect trends and, whenever practical, using statistical techniques to review results. Monitoring will be planned and reviewed. Quality control is implemented throughout stages of processing --- from receiving inspection to in-process calibration servicing and until final inspection activities (Reference: Appendix 13).

These measurement assurance techniques in controlling the measurement process to consistently produce the highest quality measurements may include but will not be limited to participation in proficiency testing and other inter-laboratory comparisons (Appendix 12); regular use of certified reference materials and/or in-house Quality Control using secondary reference materials; replicate test or calibration measurements using the same or different methods and correlation of results for different characteristics of an item. Quality in the permanent laboratory and at field services will be assured through measurement, monitoring and analysis (ref. QMS/CSD Continual Improvement and Administration).

## References:

Quality Manual (Section 8.0 –Quality Management System Requirement)

ISO/IEC 17025:2017 par. 8.0

Appendix 13, Calibration Servicing Process

## Calibration Certificates and Data

Certificate of Calibration or reports will conform to requirements of ISO/IEC 17025.

### ***Accredited Work (On-Site Facilities and/or Mobile Units)***

Results obtained from site tests/calibrations are identified as such on issued Certificates / Reports, whether they form part or all of the information presented. Certificates / Reports shall contain any details relevant to the calibration/test such as location of calibration/test item and Accredited Lab Number (Ref. Appendix 13, Table 7, Calibration Report Requirements and Appendix 3, Field Service Guidelines).

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### ***Reporting the Results***

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 Appendix 13, Table 7, Calibration Report Requirements.

Opinions and interpretations will be clearly identified. Records will document those established schedules and procedures are followed to maintain the adequacy of all Measuring and Test Equipment.

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 results will be recorded and maintained for future reference. Statements of compliance will take into account the uncertainty of measurement.

Where the results of externally provider calibrations are contained in the report, these results are clearly identified and furnished in electronic form. 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.

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.

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.

### ***Externally Provider Reports***

Externally providers will issue certificates to Micro Precision for review. Micro Precision retains responsibility for issuing Externally Provider certificates to its customers. The presentation of the calibration data and ease of assimilation by the reader are considered at all times in the arrangement of the report. The calibration report is standardized as far as possible.

### ***Reports for Other Divisions***

Certificate of calibration prepared for other MP Divisions (or where agreed in writing by the customer) may be reported in a simplified way.

### ***Errors in Reports***

Any errors in records will be corrected by drawing a line through the mistake and entering the correct value alongside. Alterations will be signed or initialed by the individual making the correction. Mistakes will not be erased, made illegible or deleted. Similar measures such as assigned passwords, archival and limited and controlled access, etc. will be taken for records stored electronically to ensure the integrity of original data against change or loss.

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## ***Amended Reports***

Material amendments to the calibration report after it has been issued are made only in the form of a further document or data transfer statement suitably identified with a statement (e.g., "Supplement to Calibration Report or Certificate of Calibration" or equivalent), serial number (or other identification). When it is necessary to issue a complete new calibration certificate it is uniquely identified and shall contain a reference to the original certificate or report that it replaces. When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

## ***Transmitting Reports***

Transmission of calibration results by telephone, telex, facsimile or other electronic or electromagnetic means are carried out in accordance with Appendix 15, Table 3, Documents of External Origin, to ensure that confidentiality is preserved.

### References

Quality Manual (Section 8.4 – Control of Record)

ISO/IEC17025:2017 8.4

Appendix 3, Field Service Guidelines

Appendix 7, Permitting Departures

Appendix 13, Calibration Servicing Process

Appendix 15, Control of Documents

Process Map (F2) QMS Documentation Development Process

Cross-Functional Process Map (System Relationship Map)

## **QMS/CSD Continual Improvement and Administration**

### ***Management Responsibilities and Continual Improvement***

The effectiveness of the Quality Management System and Calibration System Description will be continually improved through the use of the Quality Policy, Quality Objectives, Audit Results, Analysis of Data, Corrective Actions, Preventive Actions, and Management Review. The referenced appendices describe the process requirements.

Division managers will define and implement continual improvement within the Division to realize and support operations, and ensure the effectiveness and efficiency of processes, considering:

- Effectiveness (e.g., results meet customer requirements);
- Efficiency (e.g., turn-around time, resources in terms of time and money);
- External effects (e.g., regulatory requirements);
- Potential weaknesses (e.g., lack of capability, inconsistencies in operations or potential non-conformances);
- Employing better methods (e.g., needed improvements such as better calibration methods or work instructions);

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- Controlling change (e.g., planned and unplanned);
- Measuring the planned benefits (e.g., attainment of goals and objectives).

Division Managers will support improvements in operations, personnel proficiency and customer satisfaction through incremental, ongoing inputs, integral to existing processes such as:

- Validation of data;
- Production yield data;
- Calibration and service delivery data;
- Self-assessments and internal audit data;
- Customer requirements, complaints and feedback (both positive and negative);
- Experience of employees;
- Financial data

Goals and objectives are used to drive the business towards profitability and continual improvement. They are established during the Corporate-wide and Division Management Review meetings and are monitored and measured through metrics. Links to current goals and objectives are provided in the MP-QM.

### References:

Quality Manual (Section 8.6 Improvement and 8.9 Management Review)

ISO/IEC17025:2017 par. 8.6,8.9

Appendix 14, Management Responsibilities and Continual Improvement

Process Map (F1) Quality Management System Process

Process Map (F18) Management Responsibility Process

Process Map (F19) Customer Satisfaction Process

Process Map (F20) Management Review Process

## **Administration**

Documents and records will be controlled and will provide evidence of the implementation of required operations and effectiveness of implementation.

### **Control of Documents**

The purpose of document control is to ensure that everyone who 'needs to know' is informed and those who do not need to know are excluded. Records (Appendix 16) are a special type of document and are discussed in the next section. Documents include the following and requirements are described in Appendix 15:

- Quality Manual and Calibration System Description
- Quality policy and objectives
- Specifications
- Guidelines
- Calibration Procedures

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- Division Procedures, Work Instructions and Drawings
- Process maps (Process Maps of processes) and their interactions
- Amendments or changes to documents

Quality will review and approve documents prior to release for use. Documents approved for use will be made readily available to concerned personnel through either the on-line computer system or in hard copy format. Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported. Documents displayed on the on-line computer system will be controlled through password access granted to designated quality and management personnel to ensure that changes to documents are legible, maintained current, readily identifiable, distribution is controlled, to prevent use of obsolete documents, and that documents are available at points of use.

### References:

Quality Manual (Section 4.0 – Quality Management System - Documentation Requirements)

ISO/IEC17025, par. 4.3

Appendix 15, Control of Documents

Process Map (F2) QMS Documentation Development Process

### ***Control of Records***

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. Requirements for records are described in Appendix 16 and examples of records include:

- Corrective Action Reports
- Preventive Action Proposals
- Training Records
- Equipment History Records
- Chart Recorder Records
- Audit Reports
- Calibration Reports
- Procurements Records
- Externally Provider Records
- Customer Records

### References

Quality Manual (8.4 Control of Record)

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ISO/IEC17025:2017, par. 8.4  
Appendix 16, Control of Records  
Process Map (F15) Control of Records Process

### ***Internal Audit***

Assessments are conducted of the QMS and the laboratory activities to verify compliance with requirements. The assessments are intended to determine the implementation and effectiveness of the overall QMS and CSD and provide a means to monitor continual improvement. The MP-CSD document contains the policies, and specific responsibilities and requirements are described in Appendix 17.

#### References:

Quality Manual (Section 8.8 Internal Audit)  
ISO/IEC17025:2017, par. 8.8  
Appendix 17, Internal Audit Process  
Process Map (F14) Internal Audit Process

### ***Control of Nonconforming Products***

Nonconforming products are prevented from being used through labeling and segregation, until evaluated and determined to meet requirements. Policies are provided in the MP-QM document and specific requirements are described in Appendix 18. The process flow is illustrated in the Control of Non-conformances Process Map.

#### References:

Quality Manual (Section 7.10 Nonconforming Work)  
ISO/IEC17025, par. 7.10  
Appendix 18, Control of Nonconforming Product  
Process Map (F11) Control of Non-conformances Process

### ***Corrective Action***

Corrective action is used as a tool for improvement. Trends are examined, and the significance of problems is evaluated in terms of the potential impact on operating costs, product performance, and customer satisfaction, etc. Actions taken are evaluated as to their effectiveness and efficiency. Corrective actions are monitored to ensure goals are met and are considered in Management Reviews. Customers shall be notified in writing if investigations show that laboratory results may have been affected. Policies are described in the MP-QM document. Process requirements and responsibilities are described in Appendix 19.

#### References:

Quality Manual (Section 8.7 Corrective Action and 8.6 Improvement)  
ISO/IEC17025, par. 8.7 ,8.6  
Appendix 19, Corrective Action Process  
Process Map (F9) Corrective Action Process

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## ***Preventive Action***

Preventive action is used as a tool to prevent loss or mitigate the effects of loss in order to maintain performance goals and customer satisfaction. Preventive action includes evaluation of historical trends and internal and external inputs (e.g., employee suggestions for improvement, customer satisfaction measurements, management review output, etc.). Preventive Action Proposals are used to record preventive actions desired or needed, and are reviewed during management reviews. Policies are described in the MP-QMS document. Process requirements and responsibilities are described in Appendix 20.

### References:

Quality Manual (Section 8.7 Corrective Action and 8.6 Improvement)

ISO/IEC17025, par. 8.7 ,8.6

Appendix 20, Preventive Action Process

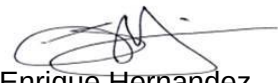
Process Map (F13) Preventive Action Process

## **Micro Precision Calibration, Inc.**

Approved

By:  Jarrod Trammell Date: 03/05/20  
President

Issued

By:  Enrique Hernandez Date: 03/05/20  
Quality Director

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## *Document Revision Control History*

| Rev | Issue Date | Revision By           | Revision Description                                                                                                                                  |
|-----|------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| 00  | 07/27/18   | Jarrold Trammell      | Replace the Calibration System Description MP-CSD R10a 07-31-16, due to ISO/IEC 17025:2017 latest revision released by ISO/IEC International Standard |
| 01  | 11/29/19   | Enrique Hernandez Jr. | Align requirements of Appendix 16 – Control of Records.                                                                                               |
| 02  | 03/05/20   | Enrique Hernandez Jr. | Revised the Statement on Appendix 18 – Control of Nonconforming Product, Table 2 Page 2 of 5.                                                         |

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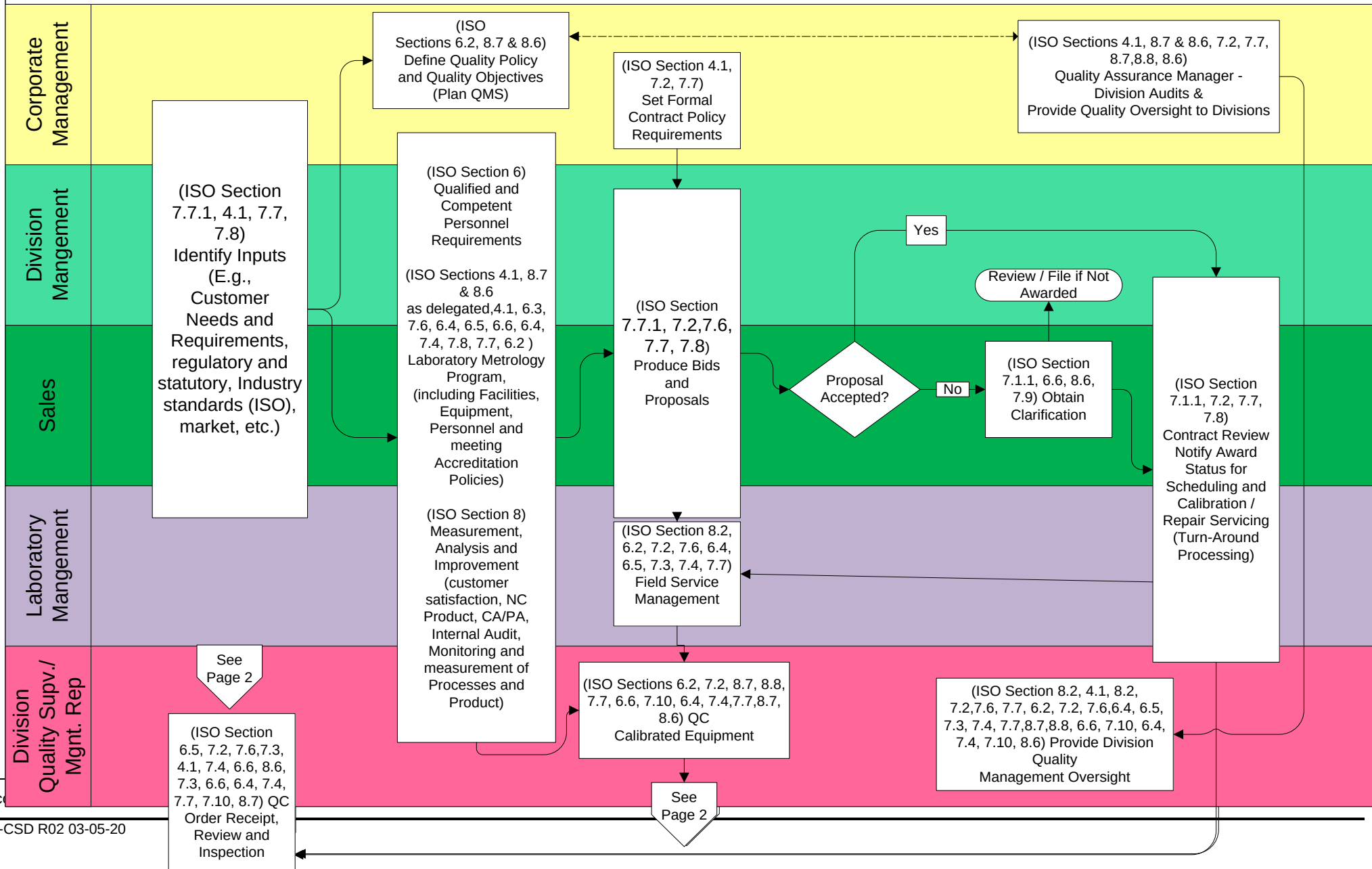
## Description

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6-01/02 R1

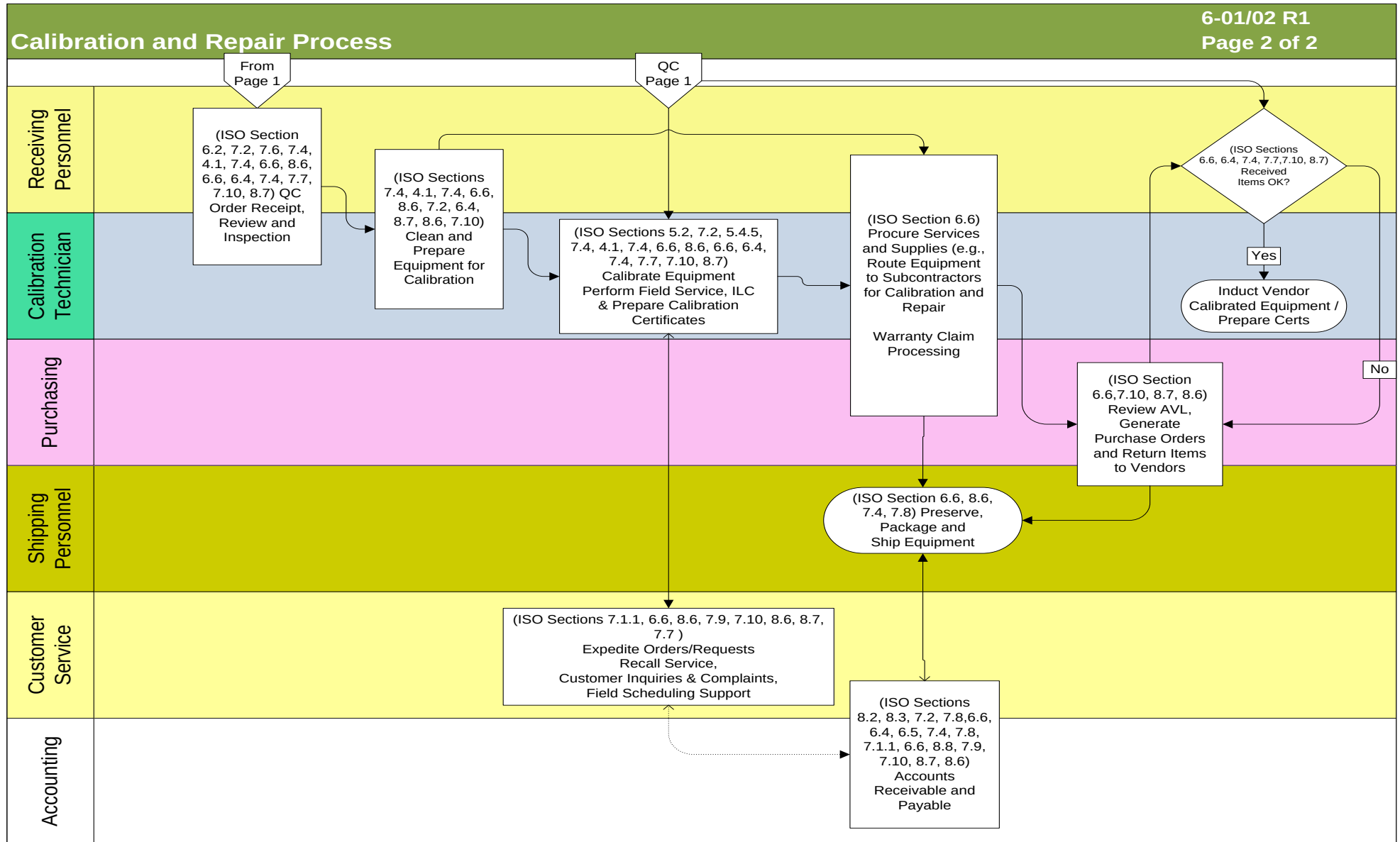
Page 1 of 2

### Calibration and Repair Process



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## Appendix 1 – Minimum Training Requirements

Management will indoctrinate all personnel as to the requirements of the Quality System, including the Calibration System Description, identifying specific processes and/or procedures applicable to each individual's duties and communicate corporate policies to all personnel. All specified requirements on Appendix 1 will be utilized for the selection of personnel.

**Table 1 – Responsibilities**

| Responsibility                                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Remarks                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| President                                                                           | Issues and/or updates certification for Quality Director.<br>Develop a certification form for Quality Director                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Initial certification good until revoked.<br>See training requirements for Quality Director                                                                                               |
| Quality Director                                                                    | Issues and/or updates certifications and maintains records on-line at MP-Teamsite, for Lead Auditors, Internal Auditors, QA Manager, QC Supervisors, Lab Managers and Division Managers, including Lab Managers, QA Manager and QC Supervisors who have authority to perform final inspection on calibration work performed.<br><br>Forwards certificate copies to QA Manager, Lead Auditors of respective divisions, and Corporate Human Resource Office and retains soft copies on-line at MP-Teamsite.<br><br>Develop testing materials for continuous knowledge upgrade and ensure competency.<br><br>Trains, indoctrinates, tests and certifies Division QC Supervisors to assure their competency for QA management at the Division.<br>Conducts annual review of QC Supervisor in concert with Division Manager. | See training requirements for Lead Auditor and Internal Auditor.<br><br>See training requirements for QC Supervisors                                                                      |
| QA Manager or QC Supervisor (or Division Manager in the absence of a QC Supervisor) | Signs <u>Training Evaluation Form</u> for Receiving Inspector and Final Inspector.<br><br>Promptly forwards copies of these certifications to the Quality Assurance Manager, retains soft copies on-line at MP –Teamsite.<br><br>Develop testing materials for receiving and final inspectors.<br><br>Trains, indoctrinates, tests and certifies Division QC Inspectors (Final Inspectors and Receiving Inspectors) on QA criteria.<br><br>Assures that a personnel training is implemented at the Division; interfaces As needed with the Corporate Quality Department for needed improvements to training programs or other training implementation issues. Updated training information shall be made available at all times and monitored on-line on a regular basis.                                               | See training requirements Final Inspectors and Receiving Inspectors. Training and indoctrination when hired and as needed during the year (e.g., revised procedures, ISO standards, etc.) |

# Calibration System Description

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**Table 1 – Responsibilities**

| <b>Responsibility</b>                                                 | <b>Requirements</b>                                                                                                                                                                                                                                          | <b>Remarks</b>                                                                  |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Division Manager                                                      | Develop training matrix for on-going training needs of the local staff.                                                                                                                                                                                      |                                                                                 |
| Department Leads, Supervisors and Managers                            | Assure that all personnel, including trainees and personnel under contract, are qualified and meet Minimum Requirement Levels.<br>Holds workshops to assure compliance with requirements; files training records to document training provided to employees. |                                                                                 |
| Global Sales Director                                                 | Conducts annual review of the Sales Associate (see training requirements in Table 4 below).                                                                                                                                                                  |                                                                                 |
| Calibration Supervisors, Lab Managers, QA Manager, and QC Supervisors | <ul style="list-style-type: none"> <li>Do not allow any Calibration Technician or QC Inspector to perform duties outside their scope of certification.</li> <li>Report on performance &amp; needed improvement</li> </ul>                                    | On-going                                                                        |
| Department Managers                                                   | Provide training necessary to allow department personnel to accomplish their assigned tasks while complying with the Quality System and Calibration System Description requirements                                                                          | When hired and as necessary during the year; refresher in QS at least annually. |
| Lab Manager (or Division Manager in the absence of a Lab Manager)     | Issues Technician Certifications for new technicians or whenever a technician changes levels                                                                                                                                                                 |                                                                                 |

**Table 2 – Training Applicable to All Employees**

| <b>Requirements</b>                                                                 | <b>New Employee</b>                              | <b>On-Going Maintenance</b> | <b>Remarks</b>          |
|-------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------------|-------------------------|
| Access Teamsite and completes the Quality Management System Training course online. | Starting with first day of employment.           | x                           | Notes 1 and 2           |
| Study specific processes and/or procedures applicable to employee's job.            | On first day of employment and on goings needed. | x                           | Notes 2 and 4           |
| Annual quality updates to be administered by the quality department                 |                                                  | X                           | Document on Certificate |

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**Table 2 – Training Applicable to All Employees**

| Requirements                                                                                                                                                                                                                                                                                        | New Employee                                            | On-Going Maintenance | Remarks                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|----------------------|------------------------------------|
| Co-operation – the laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers. |                                                         | <b>X</b>             |                                    |
| ESDC – All service or technician personnel who handle or repair electronic instruments and/or electronic components will receive initial rudimentary ESDC training                                                                                                                                  | To be completed within 3 days of commencing Employment. | <b>X</b>             | Also see Appendix 5, Table 2, ESDC |
| Workshops will be held, as necessary, to ensure employees have a proficient grasp on Quality criteria, as it pertains to their specific tasks and to the Quality System.                                                                                                                            | <b>X</b>                                                | <b>X</b>             | Note 3                             |
| A Certificate will be issued and maintained current for each employee that has satisfactorily met training, skills, experience and education requirements (e.g., Internal or Lead Auditor, QC Inspector, Technician 1, 2, 3, etc.)                                                                  | <b>X</b>                                                | <b>X</b>             | Note 5                             |
| All employee must act with impartiality by being able to give a fair opinion for decision related to his job function activities or from its relationships. Employee must notify immediately to his superior or HR manager if any unfair act is identified.                                         | <b>X</b>                                                | <b>X</b>             |                                    |

**Notes:**

Note 1: All personnel are required to read, understand and implement the Quality System, and communicate to management when it is not possible to follow a Quality, operation or calibration procedure. QMS Online training course are to be completed:

Note 2: Every two years when there are no revisions to both Quality Manual and CSD; 2.) Whenever a revision of the Quality Manual and CSD is released to which QA Corporates mandates to release an automated training record indicating such revision change in details.

Note 3: Training Evaluation Form is used to identify any initial training requirements, including Quality, operations, calibration procedures or supplemental training required.

Note 4: Training records for all technical personnel, including contracted personnel will identify competence, educational and professional qualifications, training, skills and experience, relevant authorizations and date of authorization. CQA-FM-002 MP Training Record Form is used to document on-going training or supplemental training. Additional training and certification requirements for personnel performing accredited work are described in Appendix 2.

Note 5: The Evaluation Report may serve as validation for Quality Personnel. Also see specific training and record requirements under: Quality Personnel (Table 3), Electronic Technicians (Table 6), Dimensional Technicians (Table 7), Senior Technical Management (Table 8), Sales (Table 4) and Shipping/Receiving personnel (Table 5).

# Calibration System Description

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**Table 3 - Quality Personnel**

| <b>Requirements</b><br>Table 2 contains additional training requirements applicable to all employees                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>QA Manager</b> | <b>Lead Auditor</b> | <b>Internal Auditor</b> | <b>QC Supv.</b> | <b>Receiving Inspector</b> | <b>QC/FI Inspector</b> | <b>TQD</b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------------|-------------------------|-----------------|----------------------------|------------------------|------------|
| Factors considered in selecting candidates for QC/FI inspection include aptitude, awareness and comprehension of quality principles, education and/or experience in QC/FI.                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                   |                     |                         | X               | X                          | X                      | X          |
| Initial and periodic training is required to assure capability in Receiving Inspection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                   |                     |                         |                 | X                          |                        |            |
| Initial and periodic training is required – to assure their capability in Quality Checking and Final Inspection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                   |                     |                         |                 |                            | X                      | X          |
| Minimum of 8 hours quality training conducted by an outside body or training can also be done internally if a qualified personnel is available to spearhead a particular topic or subject to ensure the following QA management objective:<br><br>Knowledge and understanding of quality and calibration industry standards;<br><br>Awareness and commitment to quality management principles (i.e., continuing improvement, process improvement, cycle time reduction, customer satisfaction, communication to employees, quality policy, quality objectives, audit results, analysis of data, preventative and corrective actions. Management Review | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Understanding basic processes of all functions and their importance to the quality of work and customer satisfaction.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Attend Internal Audit Training pertinent to requirements guide by ISO/IEC 17025:2017 and ISO 9001:2015 Standards appropriate for the work performed or future policies and objectives of Executive Management                                                                                                                                                                                                                                                                                                                                                                                                                                          | X                 | X                   | X                       | X               |                            |                        |            |

# Calibration System

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**Table 3 - Quality Personnel**

| <b>Requirements</b><br>Table 2 contains additional training requirements applicable to all employees     | <b>QA Manager</b> | <b>Lead Auditor</b> | <b>Internal Auditor</b> | <b>QC Supv.</b> | <b>Receiving Inspector</b> | <b>QC/FI Inspector</b> | <b>TQD</b> |
|----------------------------------------------------------------------------------------------------------|-------------------|---------------------|-------------------------|-----------------|----------------------------|------------------------|------------|
| Read and understand the current issue of ISO/IEC 17025:2017 and standards                                | X                 | X                   | X                       | X               |                            |                        | X          |
| Read and understand the current issue Of ANSI/NCSL Z540-1-1994 (R2002) and ANSI/NCSL Z540.3-2006 (R2013) | X                 | X                   | X                       | X               |                            |                        | X          |
| Completion of QMS Training Course; 70% min. score on Exam 101                                            | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Completion of QMS Training Course; 70% min. score on Exam 102                                            | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Completion of QMS Training Course; 70% min. score on Exam 103                                            | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Completion of QMS Training Course; 70% min. score on Exam 104                                            | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Completion of QMS Training Course; 70% min. score on Exam 201                                            | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Completion of QMS Training Course; 70% min. score on Exam 401                                            | X                 | X                   | X                       | X               | X                          | X                      | X          |
| Qualification and Certification                                                                          | Note 1 below      | Note 2 below        | Note 3 below            | Note 4 below    | Note 5 below               | Note 6 below           | Note 7     |

Note 1: Written appointment of qualification signed by the Quality Director.

Note 2: Completion of the internal auditor qualification form, , CQA-FM-003 MP Auditor Qualification and Certificate, signed by the Quality Director, scoring 35 out of 55 possible points.

Note 3: Completion of CQA-FM-003 MP Auditor Qualification and Certificate, signed by the Quality Director, scoring a minimum of 25 of the 55 points available.

Note 4: Annual review by the Division Manager and Quality Director to evaluate and document the QC Supervisor's ability in quality control methods and past performance in handling quality issues. CQA-FM-005 MP Quality Control Qualification Certificate Form is signed by the Quality Director when all QC Supervisor requirements have been satisfactorily met.

Note 5: Training Evaluation Form signed by QC Supervisor to document that the individual has competent verbal and written skills. Issue Form CQA-FM-004 MP Initial and Final Inspector Qualification Certificate Form Certificate signed by QA Manager or QC Supervisor.

# Calibration System Description

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Note 6: Training Evaluation Form signed by QC Supervisor to document that the individual has competent verbal and written skills and is qualified to inspect work against documented procedures and/or processes and to detect non-conformances in calibration processes. Issue CQA-FM-004 MP Initial and Final Inspector Qualification Certificate Form signed by QA Manager or QC Supervisor.

Note 7: TQD Qualification Certificate CQA-FM-024 MP TQD Qualification Certificate signed by Regional Technical Manager to document that the individual has competent verbal and written skills and is qualified to inspect work against documented procedures and/or processes and to detect non-conformances in calibration processes. Document that the requirements have been satisfactorily met as well as the specific scope discipline that they are capable of performing. This certification will be reviewed and renewed annually.

**Table 4 - Sales Personnel**

| <b>Requirements</b><br>Table 2 contains additional training requirements applicable to all employees                                                                                                                                          | <b>Sales Manager</b> | <b>Sales Associate</b> | <b>Remarks</b>                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------|---------------------------------------------------------------------------|
| Annual review of the Sales Manager's knowledge of customer requirements and to verify that customer requirements are being documented and met.                                                                                                | <b>X</b>             |                        | General – Table 1, Responsibilities, Division Manager<br>Table 4 - Note 1 |
| Completion of QMS Training Course;<br>Annual review of the Sales Associates knowledge of calibration service as it relates to sales and customer service. Acute awareness concerning the induction and documentation of customer requirements |                      | <b>X</b>               | General – Table 1, Responsibilities, Sales Manager<br>Table 4 - Note 1    |
| Completion of QMS Training Course; 70% min. score on Exam 101                                                                                                                                                                                 | <b>X</b>             | <b>X</b>               |                                                                           |
| Completion of QMS Training Course; 70% min. score on Exam 102                                                                                                                                                                                 | <b>X</b>             | <b>X</b>               |                                                                           |
| Completion of QMS Training Course; 70% min. score on Exam 104                                                                                                                                                                                 | <b>X</b>             | <b>X</b>               |                                                                           |
| Completion of QMS Training Course; 70% min. score on Exam 105                                                                                                                                                                                 | <b>X</b>             | <b>X</b>               |                                                                           |
| Completion of QMS Training Course; 70% min. score on Exam 201                                                                                                                                                                                 | <b>X</b>             | <b>X</b>               |                                                                           |
| Completion of QMS Training Course; 70% min. score on Exam 401                                                                                                                                                                                 | <b>X</b>             | <b>X</b>               |                                                                           |
| Qualification and Certification                                                                                                                                                                                                               | <b>X</b>             | <b>X</b>               | Table 4 - Note 2                                                          |

Notes:

1. It is suggested that Sales personnel acquire 8 hours external training in sales.
2. Qualification and certification will be documented as evidence of annual review and satisfactory achievement of Requirements.

# Calibration System Description

**MP CSD**

**Table 5 – Shipping and Receiving Personnel**

| Requirements                                                                                                                                          | Shipping | Receiving | Remarks             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-----------|---------------------|
| Table 2 contains additional training requirements applicable to all employees                                                                         |          |           |                     |
| Sufficient training in handling sensitive instrumentation and identification of non-conformances and the proper method of reporting non-conformances. | X        | X         | Table 5 – Note 1    |
| ESDC – All service personnel who handle electronic instruments and/or electronic components will receive initial rudimentary ESDC training.           | X        | X         | Appendix 5, Table 2 |
| Completion of QMS Training Course; 70% min. score on Exam 101                                                                                         | X        | X         |                     |
| Completion of QMS Training Course; 70% min. score on Exam 102                                                                                         | X        | X         |                     |
| Completion of QMS Training Course; 70% min. score on Exam 103                                                                                         | X        | X         |                     |
| Completion of QMS Training Course; 70% min. score on Exam 104                                                                                         | X        | X         |                     |
| Completion of QMS Training Course; 70% min. score on Exam 105                                                                                         | X        | X         |                     |
| Completion of QMS Training Course; 70% min. score on Exam 201                                                                                         | X        | X         |                     |
| Completion of QMS Training Course; 70% min. score on Exam 401                                                                                         | X        | X         |                     |
| Qualification and Certification                                                                                                                       | X        | X         | Table 5 – Note 2    |

**Notes:**

1. Managers will also receive 8 hours of Internal Software Training.
2. Qualification and certification will be documented as evidence of annual review and satisfactory achievement of requirements.

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**Table 6 – Electronic Technician Personnel**

| <b>Requirements</b>                                                                                                                                                                                             | <b>Tech 1<br/>Elect.</b> | <b>Tech 2<br/>Elect.</b> | <b>Tech 3-5<br/>Elect.</b> | <b>Supv.<br/>Elect.</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|----------------------------|-------------------------|
| Table 2 contains additional training requirements applicable to all employees.                                                                                                                                  |                          |                          |                            |                         |
| AAE Degree or Equal.                                                                                                                                                                                            | X                        | X                        | X                          | X                       |
| Experience in basic instrumentation                                                                                                                                                                             | X                        | X                        | X                          | X                       |
| Experience in most instrumentation                                                                                                                                                                              |                          | X                        | X                          | X                       |
| Specified minimum number of years of experience (electronic for electronic tech)                                                                                                                                | 1                        | 3                        | 5                          | 7                       |
| Minimum number of years' experience in metrology.                                                                                                                                                               |                          |                          | 1                          | 1                       |
| Basic Trouble Shooting Techniques                                                                                                                                                                               | X                        | X                        | X                          | X                       |
| Experience in advanced instrumentation                                                                                                                                                                          |                          |                          | X                          | X                       |
| Demonstrates good verbal communication, good written skills                                                                                                                                                     | X                        | X                        | X                          | X                       |
| Ability to write procedures, train personnel, capable in managing company instrumentation and day-to-day turnaround, good housekeeping skills, capable in computer database management for company instruments. |                          |                          | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 101                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 102                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 103                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 104                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 105                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 201                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Completion of QMS Training Course; 70% min. Score on Exam 401                                                                                                                                                   | X                        | X                        | X                          | X                       |
| Qualification and Certification                                                                                                                                                                                 | Note 1<br>Below          | Note 1<br>Below          | Note 1<br>Below            | Note 1<br>Below         |

**Notes:**

CQA-FM-014 MP Technician Qualification Certificate signed by Lab Manager to document that the specific Technician Level requirements have been satisfactorily met as well as the specific scope discipline that they are capable of performing. This certification will be reviewed and renewed annually.

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**Table 7 - Dimensional/Mechanical Technician Personnel**

| <b>Requirements</b>                                                                                                                                                                                             | <b>Tech 1<br/>Dim/Mech.</b> | <b>Tech 2<br/>Dim/Mech.</b> | <b>Tech 3-5<br/>Dim/Mech.</b> | <b>Supv.<br/>Dim/Mech.</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------|-------------------------------|----------------------------|
| Table 2 contains additional training requirements applicable to all employees.                                                                                                                                  |                             |                             |                               |                            |
| Experience in basic hand tools                                                                                                                                                                                  | X                           | X                           | X                             | X                          |
| Experience in most instrumentation                                                                                                                                                                              |                             | X                           | X                             | X                          |
| Specified minimum number of years of experience in dimensional/mechanical calibration:                                                                                                                          | 1                           | 2                           | 3                             | 5                          |
| Basic Trouble Shooting and Repair Techniques                                                                                                                                                                    |                             | X                           | X                             | X                          |
| Experience in advanced instrumentation                                                                                                                                                                          |                             |                             | X                             | X                          |
| Demonstrates good verbal communication, good written skills                                                                                                                                                     | X                           | X                           | X                             | X                          |
| Ability to provide verbal report on findings.                                                                                                                                                                   |                             | X                           | X                             | X                          |
| Ability to write procedures, train personnel, capable in managing company instrumentation and day-to-day turnaround, good housekeeping skills, capable in computer database management for company instruments. |                             |                             | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 101                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 102                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 103                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 104                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 105                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 201                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Completion of QMS Training Course; 70% min. Score on Exam 401                                                                                                                                                   | X                           | X                           | X                             | X                          |
| Qualification and Certification                                                                                                                                                                                 | Note 1<br>Below             | Note 1<br>Below             | Note 1<br>Below               | Note 1<br>below            |

**Notes:**

CQA-FM-014 MP Technician Qualification Certificate signed by Lab Manager to document that the specific Technician Level requirements have been satisfactorily met as well as the specific scope discipline that they are capable of performing. This certification will be reviewed and renewed annually.

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**Table 8 - Senior Technical Management**  
***(Quality Director, Division Manager and Lab Manager)***

| <b>Requirements</b>                                                                                                                            | <b>Quality Director</b> | <b>Division Manager</b> | <b>Lab Manager</b> | <b>Remarks.</b>       |
|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------|--------------------|-----------------------|
| Table 2 contains additional training requirements applicable to all employees.                                                                 |                         |                         |                    |                       |
| Years of metrology experience and/or years of audit/ quality experience.                                                                       | 7                       | 7                       | 7                  | Note s 1 and 4 and 5. |
| Capable in developing formal plans for facilities and equipment, personnel training and certification, measurement standards and traceability. | X                       | X                       | X                  | Note 5 below.         |
| Ability to recognize and address non-conformances and file Corrective Action Reports.                                                          | X                       | X                       | X                  |                       |
| Provide administration in all areas of service to facilitate both quality and quick turnaround                                                 | X                       | X                       | X                  |                       |
| Capable in conducting workshops and classes for personnel / technician training.                                                               | X                       | X                       | X                  |                       |
| Meets all requirements of either an Electronic or Dimensional Supervisor.                                                                      |                         |                         | X                  | Notes 2 and 3 below.  |
| Capable in developing formal plans for facilities and equipment, personnel training and certification, measurement standards and traceability. |                         |                         | X                  |                       |
| Qualification and Certification                                                                                                                | X                       | X                       | X                  |                       |

**Notes:**

Note 1: A Division Manager who does not have sufficient metrology experience may be appointed, if the Lab Manager at his facility works closely with the Division Manager concerning technical issues.

Note 2: If the Lab Manager does not meet Tech 3 Electronic requirements, then there must be another technician at Tech 3 Electronic level that can report to the Lab Manager.

Note 3: If the Lab Manager does not meet Tech 3 Dimensional requirements, then there must be another technician at a Tech 3 Dimensional level that can report to the Lab Manager.

Note 4: The Division Manager may appoint a Lab Manager with 5 to 10 years' experience if the Division Manager has at least 10 years' experience and can work closely with the Lab Manager.

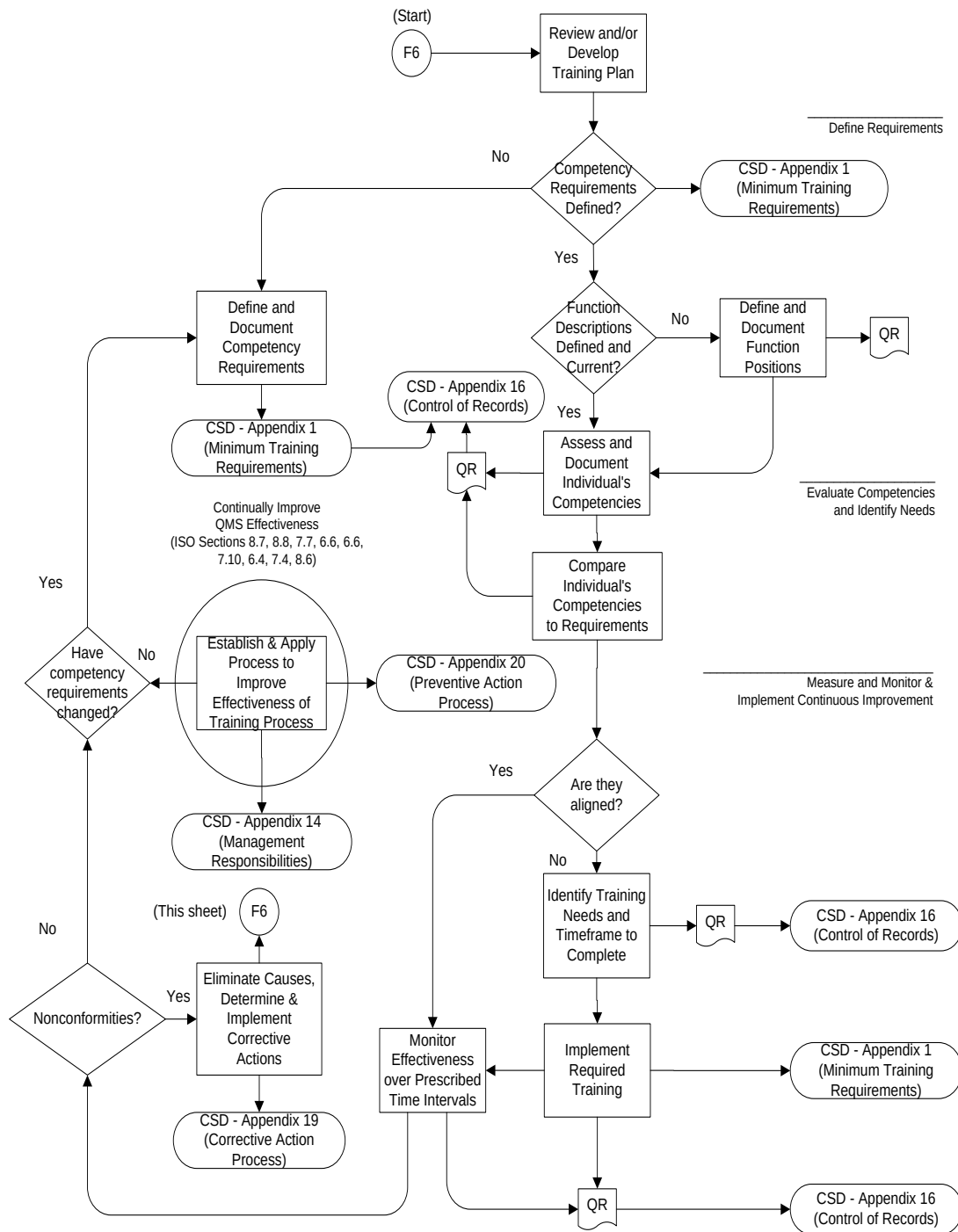
Note 5: In the event the designated Quality Director becomes unable to perform his/her duties, the alternate Quality Director appointed by the President will assume the role and responsibilities of the designated Quality Director.

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## Training Process

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.5,  
8.7,8.6, 8.9, 6.2)  
Doc. F6 R2 6-09-03



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## Appendix 2 - Accredited Work

### ***Training Requirements***

Personnel performing lab accredited work, including site work, will be appropriately trained in accreditation policies and requirements (e.g., inter-laboratory comparisons, proficiency testing, traceability requirements, use of accredited etc.).

Requirements in this section are in addition to training and qualification requirements described in Appendix 1 – Minimum Training Requirements.

Only qualified personnel will be allowed to perform lab accredited work.

If a Registrar specifies technicians for specific disciplines, then only those technicians will issue calibration certificates that use accredited logo.

Lab accredited personnel will participate in Registrar surveillance and in on-going Proficiency.

The corporate signatory (also see Appendix 4 – Authorized Signatories) will specify the individuals and their authorized limits of authority within Micro Precision's scope of accreditation, when dictated by the accreditation agency.

Personnel performing lab accredited work must score 70% minimum on the following exams: 101 through 105, 201 and 401.

### ***MP Policy on the Use of Accredited Symbol***

- The “accredited symbol” issued to MP Organization will be used only by Accredited MP Laboratories and not those still in the process of accreditation. Accredited MP Laboratories may make a narrative reference to their approved accreditation, but shall not use accrediting body's logo.
- The “accredited symbol” shall be used by an accredited MP Labs only under the name by which it hold the accreditation.
- Accredited MP division will only use the “accredited symbol” within the scopes of its accreditation. For non-accredited results which are included with accredited results on the accredited certificate or report, those non-accredited tests or calibration will be clearly and unambiguously defined on the report that is issued. A footnote or asterisk on the report or certificate will be placed to identify and acknowledges that the report includes non-accredited work.
- All accredited MP laboratories are required to use the appropriate accredited symbol on all accredited calibration certificates and test reports which demonstrate measurement traceability to national/international standards of measurement in accordance with the Policy on Measurement Traceability
- While accredited MP laboratories agreed to use accredited symbol or claim accreditation, they shall

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avoid instances which give impression that accrediting body accepts responsibility for any results, or for any opinions or interpretations derived from those results, or that accrediting body approves any product or item tested, calibrated, inspected, certified or produced.

- All accredited MP divisions shall or may use the accreditation symbol on the following:
  - Letterhead
  - Websites
  - Marketing documentation
  - All accredited calibration reports
- When in doubt, the accredited MP Lab should submit intended uses of the symbol, draft advertisements, and/or any other claims to accrediting body office for advance review thru MP Corporate Quality.
- MP shall NOT use accredited symbol on the following condition:
  - Applicants for accreditation
  - Externally Provider which is not accredited by Accreditation Bodies
  - Work proposals where Accredited symbol is printed in the letter head or corporate stationary
  - Quotes where Accredited symbol is printed in the letter head or corporate stationary
  - Reporting of results exclusively outside the Scope of Accreditation
  - For certifying a product or other item
  - Displayed on business cards in a manner that might imply personnel certification
- Only upon receipt of advanced, written approval from Accrediting Body, MP shall use the accredited symbol on clothing (e.g., lab coats, uniforms, etc.) accompanied by an indication of the type of entity where it is accredited (Calibration and Testing).

### Reference:

ANAB MA 2100, Accreditation Manual for Laboratory-Related Activities

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### Appendix 3 – Field Service Guidelines

**Table 1 – Responsibilities**

| Responsibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Lab Mgr. | Technician |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|------------|
| <ul style="list-style-type: none"> <li>Assures that all needed standards, tools, equipment and supplies are provided to field service team, and ensures that all operational requirements, as applicable, are followed by field service technicians.</li> <li>Assures that technicians are qualified to perform the work and that appropriate supervision is provided for field service team.</li> <li>Assures that account information, worksheets, calibration procedures, equipment calibration reports, and operations manual are kept up-to-date on all technicians' laptop and computers used in the field service work.</li> </ul>                                                                                                                                                                                                                                                                   | X        |            |
| <ul style="list-style-type: none"> <li>Implements all applicable customer requirements, Quality Manual and Calibration System Description requirements.</li> <li>Ensure safe handling, use and transport of customer and MP equipment at all times during field service work.</li> <li>Seek customer supervision and/or assistance in operating and/or calibrating customer equipment that is installed, mounted, and/or set-up in the operation line.</li> <li>Study the equipment set up, operation process, and safety features of the unit prior calibration whenever it is part of a machine assembly and or production line.</li> <li>Protects and completes necessary documentation pertaining to field service work, including documentation on the worksheets, Field Service Order form, abuse, misuse and/or mishandling of instruments and equipment, as well as laptop and computers</li> </ul> |          | X          |

**Table 2 – Field Service Calibrations**

| Applicable Operations Procedures | Hierarchical Requirements                                                                                                                                                                                                                                                                                                                                                                                                               | Notes                                                                                                                                                 |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Environmental Control</b>     | <ul style="list-style-type: none"> <li>Per Customer Contract/Order Requirements</li> <li>Use Portable Temp / Humidity Recorders</li> <li>Use Ambient Temp / Humidity</li> <li>Be aware of and document as needed, any environmental conditions that might affect calibration accuracy.</li> </ul>                                                                                                                                       | See Appendix 5, Environmental Controls including access / safeguarding requirements                                                                   |
| <b>Training</b>                  | <ul style="list-style-type: none"> <li>Qualified Technicians perform calibration according to disciplines identified in their Technician Qualification Certificate (COA-FM-014).</li> <li>A current <u>Technician Qualification and Certificate</u> will be on file.</li> <li>Supplemental qualification is required for Accredited Lab Work</li> <li>Safety training and/or orientation at the customer field service site.</li> </ul> | <p>Appendix 1, Minimum Training Requirements</p> <p>Appendix 2, Accredited Work Requirements</p> <p>Required and provided by customer at the site</p> |

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**Table 2 – Field Service Calibrations**

| Applicable Operations Procedures       | Hierarchical Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Notes                                                                                                      |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| <b>Handling, Storage and Transport</b> | <ul style="list-style-type: none"> <li>Never, at any time, dismantle or remove an instrument from a customer's instrument set up, such as control panel or instrument group package. Never turn off or disconnected equipment from customer facility production lines without the customer authorization.</li> <li>Read and study instrument/ equipment set-up, its operational and safety features in the production line to come up with the best calibration set-up and approach on servicing the unit.</li> <li>Work closely with the customer representative in operating the customer equipment while performing calibration.</li> <li>Never remove instrumentation from the customer's facility without the customer's authorization. Complete and obtain the customer's signature on the Shipping Memorandum for any instruments to be brought back to the MP lab for calibration.</li> <li>Document any evidence of instrument use or abuse or if instrument was subject to any occurrence which would detract from the instruments' net worth or accuracy.</li> <li>MP and customer instruments and equipment will be protected at all times during handling, transport and use</li> <li>Check for visual signs of damage, broken parts and missing parts. Document visual damages on Field Service Order Form and notify customer.</li> </ul> | <p>See Appendix 9, Handling, Storage, Preservation and Transport</p> <p>See, Table 1, Responsibilities</p> |
| <b>Receiving Inspection</b>            | <ul style="list-style-type: none"> <li>Use Customer list and document add-ons (same requirements apply for both field and in-house). See Appendix 13, Table 3 for Receiving Inspection.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                            |
| <b>Documentation</b>                   | <ul style="list-style-type: none"> <li><u>Field Service Order Form</u> (mandatory for all jobs; include attachments with special customer instructions);</li> <li><u>Customer Add-On List</u> (for additional equipment) <ul style="list-style-type: none"> <li>New instruments may be added as per customer protocol.</li> </ul> </li> <li>Customer contact must be defined for this purpose.</li> <li><u>Deviating from established requirements</u> – see Appendix 7, Table 2.</li> <li>Protect field service paperwork from deterioration so that readability is not detracted from and input Worksheet data into the main computer system within 24-72 hours of returning to the main lab, unless longer reporting is allowed by the customer.</li> <li>Data written on worksheets are to be entered into database, upon returning to the main lab (includes Calibration Report Data and Instrument History Data).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>See Appendix 3, Table 1, Responsibilities</p>                                                           |

## MP CSD

| Applicable Operations Procedures                                                                                           | Hierarchical Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Notes                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>Cleaning and Prep</b><br><i>Electronic Instruments</i><br><i>Both Electronic and Dimensional / Mechanical Equipment</i> | <ul style="list-style-type: none"> <li>Wipe surface dust.</li> <li>Open and blow out dust as necessary.</li> <li>Remove labels and clean residue</li> <li>Implement Appendix 8, Table 2 requirements to the extent applicable for the field service customer requirements</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | All requirements listed in Appendix 8, Table 2 may not be practical or possible during field services |
| <b>Status Labeling</b>                                                                                                     | Implement Appendix 12, Table 5 requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                       |
| <b>Control of Calibration Equipment Accuracy</b><br><i>Supervision</i>                                                     | <p>Technicians will never perform work in the field that is outside their scope of qualification.</p> <ul style="list-style-type: none"> <li>A Tech 3 will oversee electronic mobile or field service lab jobs, and a Tech 2 will oversee dimensional mobile or field service lab jobs, whenever possible <ul style="list-style-type: none"> <li>When not possible, the Lab Manager will review instrument lists for the work to be performed and assure the technician(s) assigned to the job have the capability to perform the work.</li> <li>If the Lab Manager determines there are any instruments on the list that the technician(s) are not qualified to service, then the specified instrument(s) will be brought back to the main lab for servicing.</li> </ul> </li> </ul>                                                                                                                    | See Appendix 3, Table 1, Responsibilities                                                             |
| <i>Security and Safeguarding</i><br><br><i>Instrument Information</i><br><br><i>Recording Information</i>                  | <ul style="list-style-type: none"> <li>As practical, safeguard and secure from unauthorized access, the mobile unit or site facility where calibration is performed to: <ul style="list-style-type: none"> <li>Ensure that no adjustments can be made to instruments, consumables and supplies that would invalidate calibration settings or results.</li> </ul> </li> <li>Verify the following instrument information on the MP Calibration Report with the customer: <ul style="list-style-type: none"> <li>Recall cycles;</li> <li>Model Number;</li> <li>Serial Number;</li> <li>Instrument locations (as required by customer);</li> <li>Instrument departments (as required by customer);</li> <li>Customer control numbers (as required by customer);</li> <li>Log "N/A" for blank items.</li> </ul> </li> <li>Collect all data for any instrument not listed on the MP Recall Report.</li> </ul> |                                                                                                       |

# Calibration System

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**Table 2 – Field Service Calibrations**

| Applicable Operations Procedures                                                                                     | Hierarchical Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Notes                                                  |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <p><i>New Instruments</i></p> <p><i>Verify Information</i></p>                                                       | <ul style="list-style-type: none"> <li>○ Use a worksheet;</li> <li>○ Use a laptop computer, or</li> <li>○ If the instrument will not be calibrated in the field, use a Shipping Memorandum, as appropriate.</li> <li>• If the customer wants an instrument calibrated which is not on the Capability/Price Listing: <ul style="list-style-type: none"> <li>○ Obtain either the Division Manager's approval to perform the work <u>except</u>: <ul style="list-style-type: none"> <li>- If the customer's protocol allows, adding instruments may be done without MP approval.</li> </ul> </li> </ul> </li> <li>• Verify and/or update missing or incorrect data when found, for any instrument that is listed on the MP Recall Report using the appropriate form / method (as above). <ul style="list-style-type: none"> <li>○ Record all instrument descriptive information if it cannot be verified against the MP Recall Report or in the CMS database.</li> <li>○ Log the Work Order number, technician name and date on each Worksheet or compute</li> </ul> </li> <li>• Verify measurement scale (i.e., Fahrenheit, Celsius, PSI or In HG.)</li> <li>• Verify and calibrate using the instrument's full measurement range (or as defined by customer) and check its current calibration label status (i.e., in calibration),</li> </ul> |                                                        |
| <p><i>Measurement Point Certification</i></p> <p><i>Field Service Work Order</i></p> <p><i>Customer Approval</i></p> | <ul style="list-style-type: none"> <li>• Certification at measurement points, which are not included in the Calibration Procedure being used, can only be performed if authorized by the customer. <ul style="list-style-type: none"> <li>○ Refer to and verify customer calibration specifications or procedures for special instructions.</li> </ul> </li> <li>• When all calibration has been completed, log the number and type of instruments calibrated on the Field Service Work Order</li> <li>• Obtain customer's approval by having the customer's authorized representative sign the Field Service Form.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                        |
| <b>Calibration Procedure Control</b>                                                                                 | See Appendix 6, Table 2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                        |
| <b>Final Inspection</b>                                                                                              | A current Quality Control Qualification and Certificate will be on file for individuals performing QC Final Inspection.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | See Appendix 1, Minimum Training Requirements, Table 3 |
| <b>Completing Calibration Certificates</b>                                                                           | Complete and mail no later than one (1) week after work is done. Normally within 24-72 hours of returning to the main lab.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                        |

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## Appendix 4 – Authorized Signatories

Approved signatories and limits of authority are maintained by the President at Corporate with assessment criteria based on the following:

Qualifications and experience;

Position in the overall staff structure;

Familiarity with the calibration or test procedures and awareness of any limitations of these procedures;

Knowledge of the procedures for recording, reporting and checking results;

Awareness of the needs for periodic re-calibration of equipment;

Awareness of the requirements and conditions of ISO/IEC 17025 standard requirements, particularly those related to calibration or test reports.

### Quality System Manual and Calibration System Description Manual Control

The content and MP Teamsite publication of the Quality System Manual and Calibration System Description manual are controlled and maintained by the Quality Director. The on-line files at MP Teamsite are the current controlled editions. In addition, the on-line files of manuals at MP Teamsite are protected against alteration, deletions or additions through controlled and restricted access by the Corporate Quality Department (e.g., protected server location, adobe file limitations such as read only) (Also refer to Control of Documents, Appendix 15, Table 2.)

**Table 1 – Responsibilities**

| Requirements                                                                                                                                                             | QA Director | QA Mgr. | Div. Mgr. | Lab Mgr. | Tech. |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------|-----------|----------|-------|
| Maintained and control Division Authorized Signatory List that identifies all company calibration and quality personnel and their limits of authorities across division. | X           | X       |           |          |       |
| Notify Corporate Quality Department for any addition and/or deletion of Quality Inspector in the signatory list.                                                         |             | X       | X         |          | X     |
| Notify Corporate Quality Department for any addition and/or deletion of calibration Technicians and their levels in the signatory list.                                  |             |         |           | X        |       |
| Reporting of Results: The results are reviewed and authorized prior to release.                                                                                          |             |         | X         | X        | X     |

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### Appendix 5 - Environmental Control Requirements

**Table 1 – Responsibilities**

| Requirements                                                                                                                                                                                                                                                          | QC Supv. | Div. Mgr. | Lab Mgr. | Techs |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-----------|----------|-------|
| <ul style="list-style-type: none"> <li>Ensure that laboratory facility and environmental requirements are provided and maintained.</li> </ul>                                                                                                                         | X        | X         | X        |       |
| <ul style="list-style-type: none"> <li>Interface as necessary with the QA Manager concerning environment requirements and obtaining approved departures (see Appendix 7) from established requirements.</li> </ul>                                                    | X        |           |          |       |
| <ul style="list-style-type: none"> <li>Sensitive to environmental conditions at all times and accurate in recording pertinent values in Calibration Certificates.</li> </ul>                                                                                          |          |           | X        | X     |
| <ul style="list-style-type: none"> <li>Sensitive to interactivity between neighboring calibration areas</li> </ul>                                                                                                                                                    |          |           | X        |       |
| <ul style="list-style-type: none"> <li>Initiate sufficient controls to assure that only qualified personnel are allowed access to the calibration areas and/or use lab instrumentation.</li> </ul>                                                                    |          |           | X        |       |
| <ul style="list-style-type: none"> <li>Has authority to grant access to customers / visitors to the lab.</li> </ul>                                                                                                                                                   |          | X         | X        |       |
| <ul style="list-style-type: none"> <li>Make the customer aware of environmental conditions and how the accuracy of the calibration may be affected if environmental parameters of field service area(s) are not within limits established in Table 2 below</li> </ul> |          |           | X        | X     |

**Table 2 – Minimum Requirements**

| Category                                    | Perm. Lab                        |                                    | Field Services                     |                                    | Criteria / Remarks                                                                                                                  |
|---------------------------------------------|----------------------------------|------------------------------------|------------------------------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
|                                             | Elect.                           | Dim Mech                           | Elect.                             | Dim Mech                           |                                                                                                                                     |
| Temperature<br>Min<br>Max<br><br>Min<br>Max | 65°F<br>75°F<br><br>18°C<br>24°C | 64 °F<br>72 °F<br><br>18°C<br>22°C | 65 °F<br>75 °F<br><br>18°C<br>24°C | 64 °F<br>72 °F<br><br>18°C<br>22°C | Gage Block Measurement<br>66.2 °F<br>69.8 °F<br><br>19°C<br>21°C<br><br>Notes 1 and 2 below.<br>See Appendix 16, Control of Records |
| Temperature Stability                       | +/- 4 °F/hr<br>+/- 2°C/hr        | +/- 2°F/hr<br>+/- 2°C/hr           | +/- 4 °F/hr<br>+/- 2°C/hr          | +/- 2 °F/hr<br>+/- 2°C/hr          | Gage Block Measurement<br>+/- 1.8°F/hr<br>+/- 1.0°C/hr<br>Notes 1 and 2 below                                                       |

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**Table 2 – Minimum Requirements**

| Category                                                           | Perm. Lab                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |          | Field Services |          | Criteria / Remarks                                          |
|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------------|----------|-------------------------------------------------------------|
|                                                                    | Elect.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Dim Mech | Elect.         | Dim Mech |                                                             |
| Humidity                                                           | 20 – 80%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 20 – 80% | 20 – 80%       | 20 – 80% | Notes 1 and 2 below.<br>See Appendix 16, Control of Records |
| Air Borne Particles<br>(Applicable only for Clean Room Laboratory) | <u>No signs of visible contamination.</u> <ul style="list-style-type: none"> <li>Check particle count and dust control weekly;</li> <li>Monitor by physically checking larger surfaces for dust and contamination (avoid cross-contamination).</li> <li>If needed, implement environment improvements such as:                             <ul style="list-style-type: none"> <li>Upgrading the air condition filters;</li> <li>Shortening cleaning cycles.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                             |          |                |          |                                                             |
| Ventilation                                                        | Sufficient circulation to eliminate stagnant air and to maximize temperature stability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |          |                |          |                                                             |
| Ambient Noise                                                      | No intrusive noise that would inhibit normal communication or concentration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |          |                |          |                                                             |
| Luminance                                                          | Sufficient illumination to prevent optical strain.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |          |                |          |                                                             |
| Electrical Supply                                                  | Phase 1 – 100 to 120 Volts<br>Phase 3 – 210 to 230 Volts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |          |                |          |                                                             |
| Vibration @ 8 – 100 Hz                                             | No detectable vibration on the most sensitive instrument in the lab.<br><br>Sufficiently isolate vibration sensitive devices such as analytical balances and precision comparators from other activities.<br><br>No change should be detectable in the device's most sensitive resolution, while at rest.<br><br>Whether in the field or lab, any environmental factor that may affect calibration should be considered and must be noted on the Calibration Report.                                                                                                                                                                                                                                                                                                           |          |                |          |                                                             |
| ESDC                                                               | Repairs will only be performed at static controlled workstations by personnel wearing a skin contact wrist strap connected to the workstation grounding system.<br><br>ESDC workstations will have a static dissipate surface between 10(5) and 10(9) ohms.<br><br>The static surface or mat will be connected to ground through a grounding strap.<br><br>The ESDC workstation and the wrist strap will be designed so as to eliminate possible personnel injury from electrical leakage.<br><br>See ESDC training requirements, Appendix 1, Table 2, Training Applicable to All Employees.<br><br>ESDC Repair areas must be certified each year, evidenced by issuing the ESD bench a calibration control number and testing the bench and wrist strap for ground resistance |          |                |          |                                                             |

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**Table 2 – Minimum Requirements**

|                                                | Perm. Lab                                                                                                                                                                                                                                                                                                                                                                                                                                                       |          | Field Services |          |                    |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------------|----------|--------------------|
| Category                                       | Elect.                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Dim Mech | Elect.         | Dim Mech | Criteria / Remarks |
| Environmental Control Validation Requirements: | Initially to document compliance with this Appendix 5, Table 2, Minimum Requirements; Periodically when changes are made to the facility (e.g., structure, electrical, lighting, ventilation, air conditioning or others that might affect the original environmental conditions.) Field technicians must be aware of environmental conditions and adjust the uncertainty values accordingly when environmental conditions do not meet procedural specification |          |                |          |                    |
| Documentation Requirements                     | Document out-of-range environmental conditions on the Calibration Certificate.<br><br>Document the occurrence and activity on the Chart Recorder record when limits are exceeded.                                                                                                                                                                                                                                                                               |          |                |          |                    |

**Notes:**

Record temperature and humidity 24 hours a day at the permanent lab.

Cease calibrations if stated limits are exceeded; Lab Manager to note the occurrence and activity on the record when limits are exceeded.

**Table 3 – Lab Access Controls**

| Item                        | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Access to calibration Areas | <ul style="list-style-type: none"> <li>Only qualified personnel are permitted to access calibration areas and/or use lab instrumentation</li> </ul>                                                                                                                                                                                                                                                                                                                         |
| Supervision                 | <ul style="list-style-type: none"> <li>Technician in training for a specific lab area or instrumentation usage will be supervised by a technician on-hand, who is qualified for the lab area or instrumentation.</li> </ul>                                                                                                                                                                                                                                                 |
| Customers / Visitors        | <ul style="list-style-type: none"> <li>Controlled access will be required for visits to the lab areas by customers and/or unauthorized visitors. No unauthorized visits will be allowed. (See Table 1 – Responsibilities, in this Appendix 5).</li> </ul>                                                                                                                                                                                                                   |
| Field Services              | <ul style="list-style-type: none"> <li>Mobile units will be locked and safeguarded to eliminate the possibility of unauthorized access.</li> <li>All reasonable steps will be taken at customer facilities to control and eliminate unauthorized access to Micro Precision calibration areas and/or instrumentation.</li> <li>Above requirements pertaining to access, supervision, customers/visitors above requirements are also applicable to Field Services.</li> </ul> |

# Calibration System Description

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## Appendix 6 - Calibration Procedures

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                           | Div. Mgr. | Lab Mgr. | Techs. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------|--------|
| <ul style="list-style-type: none"> <li>Ensures that any technician who uses a particular procedure is well acquainted with it and can perform accurate calibrations using the procedure</li> </ul> |           | X        |        |
| <ul style="list-style-type: none"> <li>Performs annual testing of proficiency in calibration procedure use.</li> </ul>                                                                             |           | X        |        |
| <ul style="list-style-type: none"> <li>Assures the newest revision level of a Procedure is used for the instrument under test.</li> </ul>                                                          |           |          | X      |
| <ul style="list-style-type: none"> <li>Development and validation (e.g., uncertainties, repeatability, robustness, etc.) of Micro Precision calibration procedures (see Table 2 below).</li> </ul> | X         | X        |        |
| <ul style="list-style-type: none"> <li>Uploads latest validated procedure into CMS Database to insure only current validated procedures are used.</li> </ul>                                       | X         | X        |        |
| <ul style="list-style-type: none"> <li>Monitor and update Master List of all calibration procedures used in the division.</li> </ul>                                                               | X         | X        |        |
| <ul style="list-style-type: none"> <li>Conduct technical trainings on technicians regarding the newly issued or newly revised calibration procedures.</li> </ul>                                   |           | X        |        |

**Table 2 – Calibration Procedure Requirements**

| Item                          | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                                                                                                                                 |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Calibration Procedures</b> | <ul style="list-style-type: none"> <li>Customer procedure, Manufacturer procedure, procedure published or approved by recognized governing bodies, or Micro Precision procedure.</li> <li>The <u>Calibration Procedure</u> Includes: <ul style="list-style-type: none"> <li>Unique procedure number;</li> <li>Equipment needed for calibration;</li> <li>Functions to be tested;</li> <li>Range and points that data is to be recorded, as a minimum;</li> <li>Tolerance / accuracy of each function.</li> </ul> </li> </ul> | The Calibration Data Format is a unique computer record file which contains all necessary Calibration Procedure information to perform the calibration. |

# Calibration System Description

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**Table 2 – Calibration Procedure Requirements**

| Item                                                                                                                                                                                                                                                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Remarks                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Hierarchy And Currency of calibration procedures / method</b>                                                                                                                                                                                     | <ul style="list-style-type: none"> <li>• <u>Use latest edition:</u> <ul style="list-style-type: none"> <li>○ published in international or national standards;</li> <li>○ by reputable technical organizations; or</li> <li>○ by relevant scientific texts / journals, or</li> <li>○ as specified by manufacturer of equipment</li> <li>○ Developed by the lab (if appropriate and validated).</li> </ul> </li> <li>• Procedures will be available where calibration is Performed</li> <li>• Hierarchy for instrument calibration procedures: <ul style="list-style-type: none"> <li>○ Customer-specified methods (governs if established in order review).</li> <li>○ Manufacturer Procedure (if it exists);</li> <li>○ Procedure published or approved by recognized governing bodies.</li> <li>○ Micro Precision Calibration Procedure must be written if neither Manufacturer procedure nor the procedure published or approved by recognized governing bodies are available</li> </ul> </li> </ul> | Supplement the calibration procedure / method with additional details to ensure consistent application, when necessary.                                                                                                                                                                                     |
| <b>Selection and Use of Calibration Standards.</b>                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Reference standards used for calibration shall be as specified in the calibration procedures. However, alternate standards can be used provided they meet or exceed specification of the instruments identified by calibration procedures.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                             |
| <b>Developing calibration method / procedure</b><br>(includes): <ul style="list-style-type: none"> <li>• non-standard methods;</li> <li>• standard methods used outside their intended scope;</li> <li>• Modification of standard methods</li> </ul> | <ul style="list-style-type: none"> <li>• Validate to confirm methods are fit for their intended use;</li> <li>• Validation will be as extensive as necessary to meet the needs of the given application or field of application;</li> <li>• Record the validation procedure, results obtained and conclusion as the method being fit for intended use;</li> <li>• Assure that range and accuracy of the values obtained from validation methods as assessed for the intended use, are relevant to customer requirements;</li> <li>• Plan and update plans during development of calibration methods;</li> <li>• Calibration instructions will be written clearly;</li> <li>• Qualified personnel with adequate resources will develop calibration methods.</li> <li>• When changes are made to a validate method, the influence of such changes is determined and where they are found to affect the original validation, a new method validation is performed.</li> </ul>                              | Values obtained from validated methods will include: uncertainty of results detection limit selectivity of the method linearity limit of repeatability and/or reproducibility robustness against external influences and/or cross-sensitivity against interference from the matrix of the calibration, Etc. |
| <b>Customer Notification and Approval</b>                                                                                                                                                                                                            | <ul style="list-style-type: none"> <li>• Required where necessary to employ methods <u>not established as standards</u>. Such methods will be: <ul style="list-style-type: none"> <li>○ Fully documented and validated, and these will be</li> <li>○ Available to customer and other recipients of relevant reports.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                             |

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**Table 2 – Calibration Procedure Requirements**

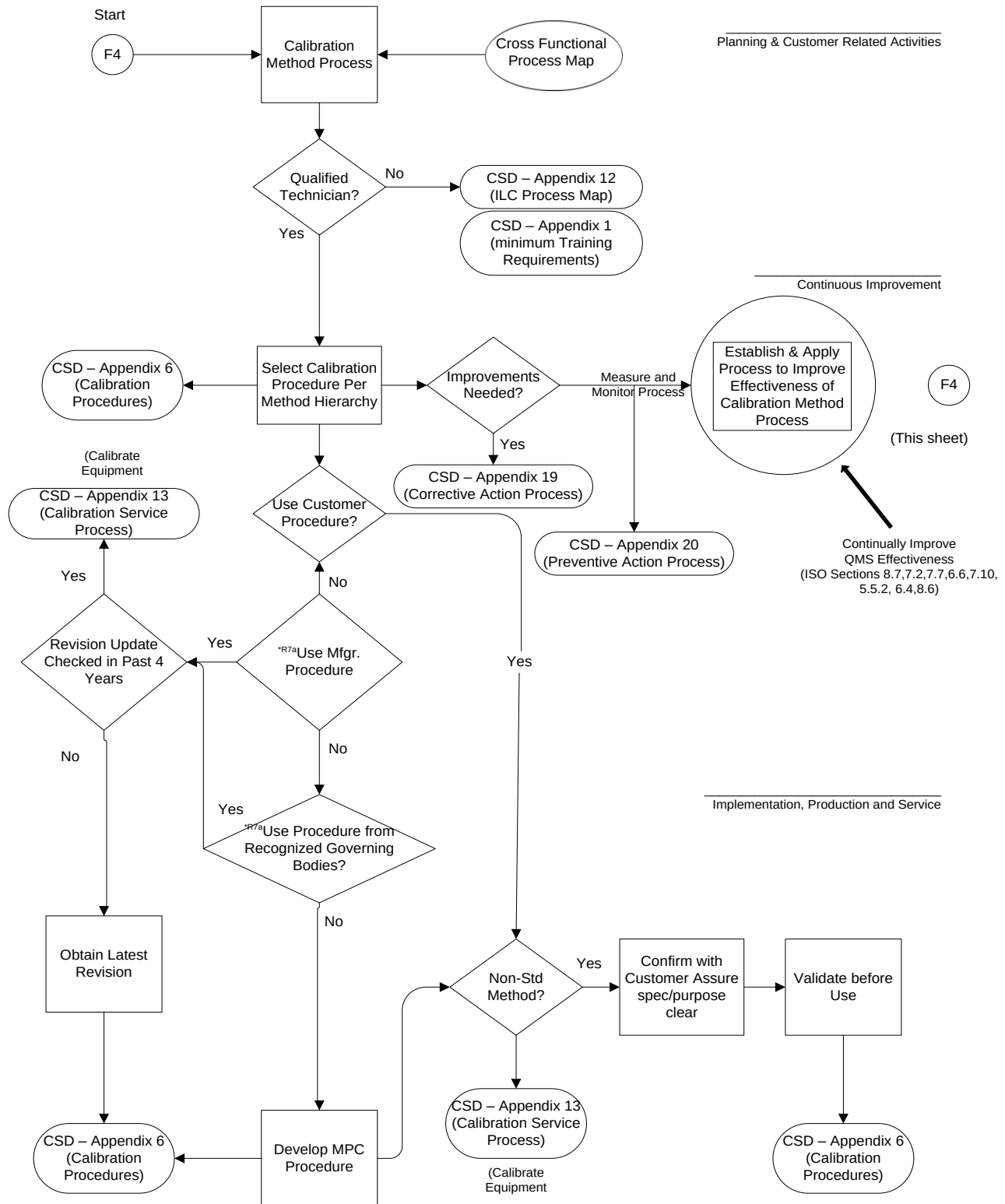
| Item                                    | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Remarks                                  |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
|                                         | <ul style="list-style-type: none"> <li>Required if <u>customer specified method is inappropriate or out-of-date.</u></li> <li>Inform customer of all methods used;</li> <li>Record discussion and customer disposition.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                          |
| <b>Customer Specified Method</b>        | May use customer's calibration procedure if this is a customer requirement;<br>Lab will select the appropriate method (see Currency of Procedures / Methods, above in this table) if method is not specified by customer.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                          |
| <b>Worksheet Or Straight Data Entry</b> | <p><u>Record all work</u> using either straight data entry or Micro Precision Worksheets (applies to lab or field).</p> <p>If using Worksheets, record the Tech number, job number, date and environmental state in the Worksheet header;</p> <p>A Worksheet (or equivalent) must be used if the technician does not have sole access to a computer throughout the calibration process of each individual instrument.</p> <p><u>Calibration in the lab:</u><br/>Check Work Order Note Tab for pertinent service information.</p> <p><u>Calibration in the field:</u><br/>Record all instrument descriptive information (unless an instrument listing or a computer with instrument listing information is available and can be used to verify current instrument information).</p> <p><u>Record the following:</u><br/>Actual points tested (when appropriate);<br/>Adjustments made and parts replaced (i.e., battery, fuse, etc.);<br/>Before and after condition;<br/>Calibration procedure;<br/>Instrument standards used;<br/>Location where calibrated;</p> <p><u>Verify current instrument information:</u><br/>Record the correct information on the Worksheet or in the computer if an error or omission is found.</p> | See Appendix 16, Control of Records      |
| <b>Data Attachments</b>                 | <ul style="list-style-type: none"> <li>Note data attachments in the main body of the Calibration Certificate (if data attachments are required).</li> <li>Include the Calibration Control Number of the instrument and the calibration date in the Data Attachment</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Also see Appendix 16, Control of Records |

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Ref. ISO/IEC 17025:2017 (Sections 6.6, 6.3,  
7.2, 8.7, 8.6)  
Doc. F4 R3 02-03-12

## Calibration Method Process



# Calibration System Description

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## Appendix 7 – Permitting Departures

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                              | QA Mgr.<br>/ QC Supv. | Pres<br>. | Quality<br>Director | Customer |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------|---------------------|----------|
| <ul style="list-style-type: none"> <li>Reviews and approves departures from established procedures prior to submittal to the Quality Assurance Manager for release approval</li> </ul>                                                                                                                                                                                                                                | x                     |           |                     |          |
| <ul style="list-style-type: none"> <li>Reviews and releases for issue departures from established procedures.</li> </ul>                                                                                                                                                                                                                                                                                              |                       |           | x                   |          |
| <ul style="list-style-type: none"> <li>Ensures that approved and released departures are implemented according to the approved departure process.</li> </ul>                                                                                                                                                                                                                                                          | x                     |           |                     |          |
| <ul style="list-style-type: none"> <li>Approves departure from Quality Policy</li> </ul>                                                                                                                                                                                                                                                                                                                              |                       | x         |                     |          |
| <ul style="list-style-type: none"> <li>Approval required if any departure from approved Quality Policy:                             <ul style="list-style-type: none"> <li>Also impacts customer requirements,</li> <li>Or prior to calibrating if a limited calibration will be performed, or</li> <li>When using the customer's instruments to perform the customer's equipment calibration.</li> </ul> </li> </ul> |                       |           |                     | x        |

**Table 2 – Departures Process**

| Item                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Applicability</b> | <ul style="list-style-type: none"> <li>Obtain formal approval for departing (i.e., operating outside of) documented requirements of:                             <ul style="list-style-type: none"> <li>Customer-supplied, Manufacturer's, calibration procedures published or approved by recognized governing bodies, or Micro Precision Calibration procedure;</li> <li>Deviating from calibration methods must be technically justified, documented, authorized and (where applicable) accepted by the customer.</li> <li>Established CSD requirements (e.g., established environmental controls, etc.);</li> <li>Established Quality Policy</li> <li>Deviating from customer requirements (e.g., purchase order, etc.) Also see Documentation requirements below.</li> </ul> </li> <li>Document both temporary and permanent departures.</li> </ul> |         |

# Calibration System Description

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**Table 2 – Departures Process**

| Item                                | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks                                                                                                                                   |
|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Not Applicable</b>               | <p>The following are not considered departures from established procedures:</p> <ul style="list-style-type: none"> <li>• <u>A limited calibration</u> <ul style="list-style-type: none"> <li>○ It is sufficient to document the limitation on the completed Calibration Report (e.g., Bore micrometer calibrated to 50% of range only).</li> </ul> </li> <li>• <u>Substitution or inclusion of a customer's reference standard</u> in the calibration of the customer's instruments, when: <ul style="list-style-type: none"> <li>○ The reference standard or instrument to be used for calibration has a current Micro Precision Calibration Report on file;</li> <li>○ The instrument to be used for calibration and the instrument under test belong to the same customer; and</li> <li>○ The customer's approval has been received</li> </ul> </li> </ul> | Also see Responsibilities in Table 1 above.                                                                                               |
| <b>Customer Notice and Approval</b> | <ul style="list-style-type: none"> <li>• Document any customer approval of departures prior to implementing the departure. <ul style="list-style-type: none"> <li>○ <u>Before</u> the limited Calibration Report is issued, when economical;</li> <li>○ Acquiring customer approval when dealing with inexpensive hand tools <u>may not be</u> considered cost effective in certain circumstances.</li> <li>○ Also see Documentation (below).</li> </ul> </li> <li>• When departure adversely impacts compliance to ISO/IEC 17025.</li> <li>• When departure adversely impacts the quality of service provided to the customer</li> </ul>                                                                                                                                                                                                                     | <p>See Table 1 above for Responsibilities</p> <p>Notify the customer of the negative impact.</p>                                          |
| <b>Global Impact</b>                | <ul style="list-style-type: none"> <li>• Revise the impacted procedure (e.g., QPM, CSD, calibration method, work instructions, etc.) as soon as practical.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | See Table 1 for Responsibilities                                                                                                          |
| <b>Documentation</b>                | <ul style="list-style-type: none"> <li>• Document the following: <ul style="list-style-type: none"> <li>○ Specific impacted procedure;</li> <li>○ Reason for departure;</li> <li>○ Extent of departure;</li> <li>○ Applicable period of time for the departure (e.g., departing from customer requirements and the applicable duration);</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | If a departure involves a customer purchase order, the customer should issue an addendum to the order, identifying the departure allowed. |

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## Appendix 8 - Cleaning and Prep

**Table 1 – Responsibilities**

| Responsibility | Requirements                                                                                                                                                                                                                                              | Remarks                                        |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Lab Manager    | <ul style="list-style-type: none"> <li>Determines extent of cleaning and prep required for all work.</li> <li>Determines condition and degree of cleanliness of received instruments and if instrument needs to be routed to Cleaning and Prep</li> </ul> | Consider customer requirements and facilities. |

**Table 2 – Instrument Preparation**

| Requirements<br>Also see Appendix 9 – Handling, Storage, and Transport Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Electronic Instruments | Mechanical Instruments |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|
| <ul style="list-style-type: none"> <li>Instruments that are dirty will not be brought into the Cal Lab until they have been cleaned (see Lab Manager Responsibilities in Table 1 above).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                            | X                      | X                      |
| Check for missing exterior hardware (e.g., feet, knobs, handles) <ul style="list-style-type: none"> <li>If hardware is in stock, replace and notate on Worksheet or in computer;</li> <li>If hardware not in stock, initiate parts order (see Appendix 10, Table 2).               <ul style="list-style-type: none"> <li>Complete and affix red reject status label (Appendix 12, Table 5).</li> <li>As appropriate, route instrument for temporary storage awaiting receipt of parts, or if instrument will not be repaired, route instrument for return to customer.</li> </ul> </li> </ul> | X                      | X                      |
| <b><u>Cleaning</u></b> – (See clarifications for Field Service, Appendix 3, Table 2) <ul style="list-style-type: none"> <li>Clean exterior using applicable cleaning solutions</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                      | X                      |                        |
| <ul style="list-style-type: none"> <li>Use a soft brush to clean front panel and switches.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | X                      |                        |
| <ul style="list-style-type: none"> <li>If instrument has an exterior filter on back panel, then remove and clean.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | X                      |                        |
| <ul style="list-style-type: none"> <li>Wash all power cords and control cables as necessary</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | X                      |                        |
| <ul style="list-style-type: none"> <li>Use precaution to prevent water / liquids from traveling inside the unit or case.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                            | X                      | X                      |
| <ul style="list-style-type: none"> <li>Use mineral spirits, alcohol or other suitable solvent and soft cloth when necessary to remove old labels and adhesives. If a razor blade is used to peel off old stickers, be sure to not scratch the instrument or case.</li> </ul>                                                                                                                                                                                                                                                                                                                   | X                      | X                      |
| <ul style="list-style-type: none"> <li>Use gage cleaning fluid, mineral spirits or other suitable solvent to clean instrument (never use alcohol as a cleaning agent as this may promote rust on metal surfaces).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                   | X                      |                        |
| <ul style="list-style-type: none"> <li>Use a nylon brush and soft cloth for basic cleaning.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | X                      |                        |
| <ul style="list-style-type: none"> <li>If necessary, use a brass brush to remove embedded chips from instrument gears and racks.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                    | X                      |                        |
| <ul style="list-style-type: none"> <li>Use precaution to prevent fluids.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | X                      |                        |
| <ul style="list-style-type: none"> <li>Submerge and soak all thread gages in gage cleaning fluid; allow soaking long enough so that all debris can be removed from threads with nylon brush.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                        | X                      |                        |

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**Table 2 – Instrument Preparation**

| <b>Requirements</b><br>Also see Appendix 9 – Handling, Storage, and Transport Requirements                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Electronic<br/>Instruments</b> | <b>Mechanical<br/>Instruments</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------------------|
| <ul style="list-style-type: none"> <li>Use gage cleaning fluid or Naphtha on wood cases; brush out interior of case and wipe as necessary.</li> </ul>                                                                                                                                                                                                                                                                                                                                                   | X                                 |                                   |
| <p><b><u>Traveler</u></b></p> <p>Check Traveler to assure that all items are accounted for.</p> <ul style="list-style-type: none"> <li>If discrepancies are found or Receiving Inspection has not signed off Traveler, move job back to Receiving for correction.</li> <li>Initial, Cleaning/Prep completion date and time on Traveler.</li> <li>Move cleaned instruments to Waiting Service area.</li> <li>Also see sign-off responsibilities in Table 1 of this Appendix 8 for exceptions.</li> </ul> | X                                 | X                                 |

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## Appendix 9 - Handling, Storage, Preservation and Transport

**Table 1 – Responsibilities**

| Responsibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Lab Mgr. | Techs. | All |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|--------|-----|
| <ul style="list-style-type: none"> <li>Handling all equipment (customer equipment and Micro Precision reference standards, reference materials and software) in such a way that does not adversely affect the instrument's accuracy or degrade the instrument's net worth, including:                             <ul style="list-style-type: none"> <li>protection from contamination during transport, maintenance or use,</li> <li>so as to not affect the before calibration or after calibration condition;</li> </ul> </li> </ul> |          |        | X   |
| <ul style="list-style-type: none"> <li>Notifying departments whenever instrument damage is detected (e.g., time of receipt, during shipping or at any point of service thereafter).</li> </ul>                                                                                                                                                                                                                                                                                                                                          |          |        | X   |
| <ul style="list-style-type: none"> <li>Sensitive to environmental conditions including: temperature, humidity, static, cleanliness, and vibration; handling instruments per Appendix 5</li> </ul>                                                                                                                                                                                                                                                                                                                                       |          | X      |     |
| <ul style="list-style-type: none"> <li>Notifying the QA Manager, Customer, MP Division Manager and Sales Manager in the event an instrument is lost, damaged or stolen while in the possession of MP.</li> </ul>                                                                                                                                                                                                                                                                                                                        |          |        | X   |

**Table 2 – Handling, Storage, Preservation and Transport Requirements**

| Item            | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Handling</b> | <ul style="list-style-type: none"> <li>Use carts and bins to carry instruments and protect items from being dropped.</li> <li>Wear gloves or have clean hands (whichever is more appropriate) when handling sensitive surface.</li> <li>Protect the unique identification of instruments, reference standards and reference materials against loss or deterioration and to prevent confusion between similar items at all times.</li> <li><input type="checkbox"/> Guidelines of Appendix 5, Environmental Control Requirements are applicable. (See Appendix 5, Table 2 ESD Requirements)</li> </ul> |         |

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**Table 2 – Handling, Storage, Preservation and Transport Requirements**

| Item                | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Remarks |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Storage</b>      | <ul style="list-style-type: none"> <li>• All instruments will be stored and held secure within guidelines listed in Appendix 5, Environmental Control Requirements</li> <li>• Clearly mark and identify instruments held in storage for inventory control purposes.</li> <li>• A Traveler (form) will be prepared and maintained with each job at all times.</li> <li>• All jobs will be processed through initial Receiving Inspection (Appendix 13, Table 3) and Cleaning / Prep (Appendix 8).</li> <li>• No instruments will be stored on the ground or in a way which compromises the instrument's net value, cleanliness or accuracy, at any time.</li> <li>• Instruments which have passed final inspection and are ready for return to the customer will only be stored in the lab area environment.               <ul style="list-style-type: none"> <li>○ Instruments may be held in Shipping if being readied for immediate shipment.</li> <li>○ At no time will a calibrated instrument be stored in an environmentally uncontrolled area.</li> </ul> </li> </ul>                                                                     |         |
| <b>Preservation</b> | <ul style="list-style-type: none"> <li>• Dip seal thread plugs.</li> <li>• Keep power cords and cables, hoses or other lines, with their instrument, neatly wound (and/or tie wrapped using rubber bands).</li> <li>• Fill conductivity probes with de-ionized water prior to shipping.</li> <li>• Remove any external adapters of electronic instruments and ship separately to prevent damage.</li> <li>• Use cover caps for optical inputs.</li> <li>• Protect instruments from loss or theft through adequate security measures (i.e., locking doors to shipping areas when deemed necessary and always lock vehicle doors when unattended).               <ul style="list-style-type: none"> <li>○ Promptly notify appropriate individuals of loss/theft (Appendix 9, Table 1, Responsibilities)</li> <li>○ Amends and/or options will be made available to the customer to repair or replace the instrument with a unit of equal or greater value.</li> </ul> </li> <li>• Consumable reference materials and raw materials will be handled, stored and preserved based on manufacturer recommended instructions stated on MSDS.</li> </ul> |         |

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**Table 2 – Handling, Storage, Preservation and Transport Requirements**

| Item                           | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Packaging and Transport</b> | <ul style="list-style-type: none"> <li>• <b><u>General</u></b> <ul style="list-style-type: none"> <li>○ Place hand-held items that do not have cases in individual bubble bags.</li> <li>○ Use a plastic bin to keep instruments together when a job has numerous smaller instruments.</li> <li>○ Clamp and/or otherwise restrain movement of instruments with external moving parts (e.g., analytical balances) before shipment.</li> <li>○ Keep power cords and cables, hoses or other lines, with their instrument, neatly wound (and/or tie wrapped using rubber bands).</li> <li>○ Ship instruments so they do not rub against each other during transit.</li> </ul> </li> <li>• <b><u>Commercial Carrier</u></b> <ul style="list-style-type: none"> <li>○ Package instruments to eliminate both rattle and shift.</li> <li>○ Use enough packing material to provide 4" material (min.) from inside of all cartons (e.g., 1" of cushion material for every 10 lbs. of weight to be shipped).</li> <li>○ Split shipments when necessary to prevent overloading carton.</li> <li>○ Use 100% bubble wrap material or foam packaging device for larger electronic instruments, unless the instrument has it's own carrying case.</li> <li>○ Assure cartons are clearly labeled and that no old labels are still visible.</li> <li>○ Seal Calibration Reports and other documents in a large envelope and label the envelope "Reports Enclosed".</li> <li>○ See commercial shipping documentation requirements below.</li> </ul> </li> </ul> |         |
| <b>Shipping Documentation</b>  | <ul style="list-style-type: none"> <li>• If the customer's equipment has been serviced, at least one of the following documents must be completed and returned to the customer with each instrument: <ul style="list-style-type: none"> <li>○ Calibration Report</li> <li>○ Hold for Evaluation</li> <li>○ Service Report</li> <li>○ Quotation Report</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |

# Calibration System

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**Table 2 – Handling, Storage, Preservation and Transport Requirements**

| Item                               | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                    | <ul style="list-style-type: none"> <li>• Outbound Shipping Reports must contain:               <ul style="list-style-type: none"> <li>○ Customer name</li> <li>○ Customer shipping address</li> <li>○ Purchase order number or method of payment</li> <li>○ Itemization of instruments on Job Order, including:                   <ul style="list-style-type: none"> <li>- Calibration control number</li> <li>- Description</li> <li>- Manufacturer (if available)</li> <li>- Model number (if available)</li> <li>- Serial number (if available)</li> </ul> </li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                 |         |
|                                    | <ul style="list-style-type: none"> <li>○ Sign both copies of the Shipping Record, enter time and date delivered.</li> <li>○ Give one copy of the Shipping Record to the customer (see Commercial Carrier requirements above).               <ul style="list-style-type: none"> <li>- If using Commercial Carrier, have the Carrier sign and date the Shipping Record (their name must be legible and/or printed).</li> </ul> </li> <li>○ Forward signed copies of Shipping Records to Shipping Complete Basket.</li> <li>• Log the date shipped into the computer</li> </ul>                                                                                                                                                                                                                                                                                                                                                          |         |
| <b>Order Delivery by MP Driver</b> | <ul style="list-style-type: none"> <li>• Customer signature and driver signature are completed upon delivery.</li> <li>• Transport in such a way to prevent items from touching each other during transport.               <ul style="list-style-type: none"> <li>○ Use cartons, plastic trays and/or bubble bags as necessary for small parts.</li> </ul> </li> <li>• Use care to not allow any damage (see Table 3 (Receiving Inspection) in Appendix 13) or other result that would detract from any instrument's net worth.               <ul style="list-style-type: none"> <li>○ If damage occurs during transport, return the instrument to MP for disposition.</li> </ul> </li> <li>• If any instruments have signs of physical damage, then assure that a description of the damage is detailed on the shipping paperwork <u>before signing for the order</u> (see details under Damage in Appendix 13, Table 3).</li> </ul> |         |

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## Appendix 10 – Externally Provided Products and Services

Table 1 – Responsibilities

| Responsibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Corp. | Service Dept. | Lab Mgr. | Div. Mgr. | QA Mgr. /QC Supv. | Quality Director |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|---------------|----------|-----------|-------------------|------------------|
| <u>Approved Vendor List (AVL)</u> <ul style="list-style-type: none"> <li>Approves, maintains and controls list of calibration vendors used for <u>traceability</u> (Approved Traceability Vendor List), including setting the vendor rating level; and maintain copy on-line at MP Teamsite</li> <li>Notifies the Quality Directors of requests to add new vendors to the Approved Traceability Vendor List;</li> <li>Monitors Vendors' Performance and notifies the Quality Assurance Director when there is a problem encountered with approved vendor due to service, turn-around time, or on-going deficiencies.</li> <li>Approves, maintains and controls list of vendors used at the Division for <u>non-traceability</u> purchases.</li> </ul> |       |               |          |           |                   | X                |
| <u>Purchase Orders</u> <ul style="list-style-type: none"> <li>Initiating purchases for day-to-day parts and services.</li> <li>Responsible for purchasing activities at the division. Approving the order, assures that vendor is on approved vendors' list.</li> <li>Approving purchases of calibration for MP instruments, materials and services that affect the quality of the calibration.</li> </ul>                                                                                                                                                                                                                                                                                                                                            | X     | X             | X        | X         | X                 |                  |
| <u>Procurement Quality Control</u> <ul style="list-style-type: none"> <li>Review vendors' scope of accreditation and assures that the requirements for the subcontracted service shall be met.</li> <li>Assures that subcontracted service does not invalidate any specific customer contractual requirement.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                              |       |               | X        | X         | X                 |                  |

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**Table 1 – Responsibilities**

| Responsibility                                                                                                                                        | Corp. | Service Dept. | Lab Mgr. | Div. Mgr. | QA Mgr. /QC Supv. | Quality Director |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------|---------------|----------|-----------|-------------------|------------------|
| <ul style="list-style-type: none"> <li>Assures that customer approval has been documented before a customer's instrument is subcontracted.</li> </ul> |       | X             |          |           | X                 |                  |

**Table 2 – Procurement Requirements**

| Item                                                                                                                                                                         | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>General</b><br><br><i>Definitions</i><br><br><i>Unique P.O. Number</i><br><br><i>Job Number</i><br><br><i>Vendor Account</i><br><br><i>Traceability Vendor List (AVL)</i> | <p>The purchasing process is illustrated in the Procurement Process Map in this Appendix 10.</p> <ul style="list-style-type: none"> <li>Traceability Vendor – Calibration vendor used for traceability of MP instruments and accredited subcontracted jobs.</li> <li>Requisition Form – Requisition and price sourcing is conducted on the division level and forwarded to Corporate for approval of purchase requests.</li> <li>Calibration Purchase Order – used when ordering calibration or repair/calibration from the manufacturer or external provider (i.e., another MP division or a new instrument from the manufacturer for which a calibration report is needed).</li> <li>Regular Purchase Order – used for all non-calibration purchases (e.g., parts and supplies).</li> <li>Required for each order to identify and track order.</li> <li>Must be identified on order for all purchases of instrument Services</li> <li>Required for all vendors; must be properly coded for use.</li> <li>See Responsibilities (Table 1 above)</li> </ul> |         |
| <b>Data Entry</b>                                                                                                                                                            | <ul style="list-style-type: none"> <li>Complete:                             <ul style="list-style-type: none"> <li>Vendor Account Number</li> <li>Part or Service Description</li> <li>Part Number (when available)</li> <li>Itemized part or service cost</li> <li>Quantity being ordered</li> </ul> </li> <li>Competence of external products and services provided by vendors, to include required qualification of personnel and compliant to required standard, is confirmed by acceptance of this Purchase Order.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |

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| Item                                                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks                           |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
|                                                                       | <ul style="list-style-type: none"> <li>○ Shipping and handling charges</li> <li>○ Job Number (if applicable)</li> <li>○ Order Date</li> <li>○ Technician's Number (placing the order)</li> <li>○ Any special instructions</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                   |
| <b>Outside Calibration Orders</b>                                     | <ul style="list-style-type: none"> <li>• Reference ISO/IEC 17025 as a specific requirement of the order;               <ul style="list-style-type: none"> <li>○ Accredited work must be compliant with ISO/IEC 17025 standard requirements.</li> </ul> </li> <li>• Include specific instructions, as applicable, for the calibration to be performed (e.g., pre/post data).               <ul style="list-style-type: none"> <li>○ Approved Vendor's Scope of Accreditation must cover the necessary range and accuracy of the instruments or standards to be subcontracted.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                      | See also Table 1-Responsibilities |
| <i>Lab Accredited Calibrations</i><br><br><br><br><i>Traceability</i> | <ul style="list-style-type: none"> <li>• No subcontracting to non-lab accredited vendors, without the written authorization of the customer.               <ul style="list-style-type: none"> <li>• This includes other MP Divisions.</li> </ul> </li> <li>• MP will only use Lab Accredited vendors for traceability on instrumentation used for calibrations, which are covered under the vendor's lab accredited Scope.               <ul style="list-style-type: none"> <li>○ See requirements in Table 6 (Traceability) of Appendix 12, Control of Instruments and Equipment, for assuring Traceability when ordering or subcontracting MP instruments.</li> </ul> </li> <li>• Forward any specific customer requirements that would apply to the subcontracted service to the externally provider.</li> <li>• See Customer Approval requirements below.</li> </ul> |                                   |
| <b>Customer Approval</b>                                              | <ul style="list-style-type: none"> <li>• Document on the Request for Approval Form or the actual Quotation Form (also see Appendix 11, Order Processing).               <ul style="list-style-type: none"> <li>○ The identity of the externally provider and type of service to be performed is to be specific (e.g., Lab Accredited or Manufacturer).</li> </ul> </li> <li>• Approval is required in writing before any work is subcontracted.</li> <li>• The laboratory is responsible to the customer for the Externally provider work, except in the case where the customer or a regulatory authority specifies which externally provider is to be used.</li> </ul>                                                                                                                                                                                                 |                                   |

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**Table 2 – Procurement Requirements**

| Item                                                            | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                         | Remarks |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                 | <ul style="list-style-type: none"> <li>Inform the customer when using an OEM manufacturer who is an uncontrolled vendor (see definition in Table 3 below).</li> </ul>                                                                                                                                                                                                                                                                |         |
| <i>Nuclear Customers or as dictated by customer requirement</i> | <ul style="list-style-type: none"> <li>No work will be subcontracted unless the customer's approval has been obtained and specified on the customer's purchase order.</li> </ul>                                                                                                                                                                                                                                                     |         |
| <b>Consumable Reference Materials</b>                           | <ul style="list-style-type: none"> <li>Control like any other measurement standard (i.e., assign a calibration control number, calibration history file (including cycle and due date), to prevent use of the material without traceability documentation. Examples:                             <ul style="list-style-type: none"> <li>PH Solutions</li> <li>Reference Salts</li> <li>Conductivity Solutions</li> </ul> </li> </ul> |         |
| <b>Order Approval</b>                                           | <ul style="list-style-type: none"> <li>See Table 1 (above) in this Appendix 10.</li> </ul>                                                                                                                                                                                                                                                                                                                                           |         |
| <b>Order Issue and Filing</b>                                   | <ul style="list-style-type: none"> <li>Fax or email to vendor (if ordering replacement parts or supplies).</li> <li>Forward the order and a copy of the order to Shipping along with the instrument being shipped (if ordering subcontracted services for an instrument).</li> </ul>                                                                                                                                                 |         |

**Table 3 – Externally Control Requirements**

| Item                                     | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Remarks |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>General</b><br><br><i>Definitions</i> | <p>The externally provider approval process is illustrated in the Subcontractor Process Map in this Appendix 10.</p> <ul style="list-style-type: none"> <li>Traceability Vendor – Calibration performed by a vendor for MP instruments and accredited subcontracted jobs.</li> <li>Uncontrolled Vendor – An OEM manufacturer being used for customer calibration for which there is not an audit checklist on file.</li> <li>Lab Accredited Vendor – A vendor who has current ISO/IEC 17025 Accreditation.</li> <li>Foreign Parts Suppliers &amp; Distributors – A vendor used to obtain parts for repairs. All parts obtained from foreign vendors must be accompanied by a certificate of authenticity. Physical audits are always performed on foreign parts suppliers.</li> <li>Accreditation – Formal recognition by an authoritative body of an organization's technical competency to perform specific tests or types of tests/calibrations.</li> </ul> |         |

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**Table 3 – Externally Control Requirements**

| Item                                          | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                               | <ul style="list-style-type: none"> <li>Certification – The act of determining, verifying and attesting in writing to the qualifications of personnel, processes, procedures or items in accordance with specified requirements. The process of verifying compliance with a documented Quality System does not normally assess for technical competency and auditors are not normally technical experts. Certification is called registration in the United States and is performed by a Registrar organization.</li> <li>Registration – The qualification of management systems and associating certification with the qualification of either products or individuals (e.g., product certification or auditor certification). The term registration is used interchangeably with the term certification in the United States.</li> </ul>                                          |         |
| <b>Vendor Files and Approved Vendor Lists</b> | <ul style="list-style-type: none"> <li>See Table 1 above for responsibilities.</li> <li>All vendors will be maintained in the Division computer database.</li> <li>The Approved Traceability Vendor Survey will be kept on-line at the MP Teamsite. Vendor files are kept for: <ul style="list-style-type: none"> <li>NIST</li> <li>Other MP divisions that are accredited</li> <li>OEM manufacturers solely used for the customer (i.e., at the customer's request)</li> </ul> </li> <li>No vendor will be used if doing so will invalidate customer instructions or any MP quality procedure.</li> <li>Any lab accredited source to be used for calibration services must first be added to the Approved Traceability Vendor List (see responsibilities in Table 1 above).</li> <li>Notify the Corporate Quality Department for additions to the Approved Vendor List</li> </ul> |         |
| <b>Vendors Used for Traceability</b>          | <ul style="list-style-type: none"> <li>International Accreditation Services and Government Standards Board</li> <li>National Institute of Standards and Technology.</li> <li>Lab Accredited companies for covered discipline.</li> <li>Manufacturers for their own products.</li> <li>Accredited MP Laboratories</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
| <b>Vendor Surveys</b>                         | <ul style="list-style-type: none"> <li>Performed on all vendors used for traceability of MP instruments. <ul style="list-style-type: none"> <li>Focus on reviewing the vendor's Scope of Accreditation</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |
| <i>Quality Director</i>                       | <ul style="list-style-type: none"> <li>Review and consolidate vendor performance evaluation ratings of Approved Traceability Vendors submitted by divisions as well as reports on any non-conformances. (see Table 4 below).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |

# Calibration System Description

MP CSD

**Table 3 – Externally Control Requirements**

| Item                              | Requirements                                                                                                                                                                                                                                                                                                | Remarks |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                   | <ul style="list-style-type: none"> <li>○ If rating is below satisfactory , review to determine if physical audit should be conducted.</li> <li>○ Physical audits will be conducted in accordance with ISO 17025-2017</li> <li>• Conduct Vendors Performance Evaluation every two years</li> </ul>           |         |
| <b>Exceptions</b>                 | <ul style="list-style-type: none"> <li>• A Customer Instrument may be subcontracted to an OEM manufacturer who is not Lab accredited if: <ul style="list-style-type: none"> <li>○ The customer 's approval is obtained, and/or</li> <li>○ If the vendor's work can be verified by MP</li> </ul> </li> </ul> |         |
| <b>Vendor Calibration Reports</b> | See Appendix 13, Table 7                                                                                                                                                                                                                                                                                    |         |

**Table 4 – Vendor Performance Evaluation**

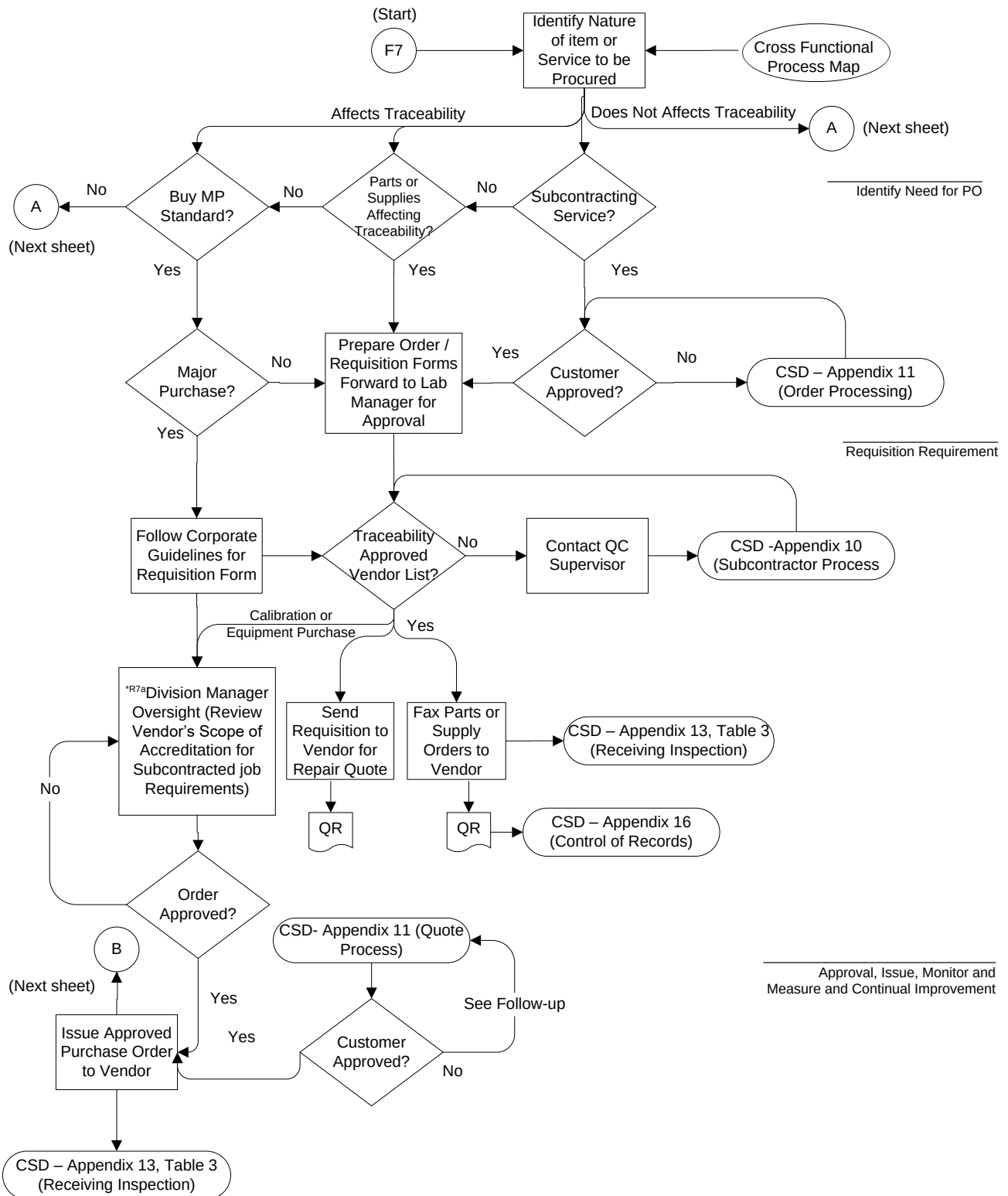
| Item                                            | Requirements                                                                                                                                                                                                                       | Remarks                                                                                                                     |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>Vendor's Performance Evaluation Criteria</b> | <ul style="list-style-type: none"> <li>• Cost</li> <li>• Delivery /Timeliness</li> <li>• Quality</li> <li>• Order Accuracy</li> <li>• Communication and Notification</li> <li>• Customer Support</li> <li>• Reliability</li> </ul> | Division Managers will complete a Vendor Performance Evaluation for each approved traceability vendor used at the division. |
| <i>Removal</i>                                  | <ul style="list-style-type: none"> <li>• May be exercised if the vendor rating drops to unacceptable level and/or a better price/service/product can be obtained from another source.</li> </ul>                                   |                                                                                                                             |
| <i>File Update</i>                              | <ul style="list-style-type: none"> <li>• Vendors' performance evaluation will be kept on file for References.</li> </ul>                                                                                                           |                                                                                                                             |
| <b>Adjusting (Traceability) Vendor's Rating</b> | <ul style="list-style-type: none"> <li>• Quality Director will adjust rating based on performance, commendation or problem with an Approved Traceability Vendor</li> </ul>                                                         |                                                                                                                             |

# Calibration System Description

## MP CSD

Ref. ISO/IEC 17025:2017 (Sections  
7.1.1, 6.6, 7.5, 7.8)  
Doc. F7

### Procurement Process

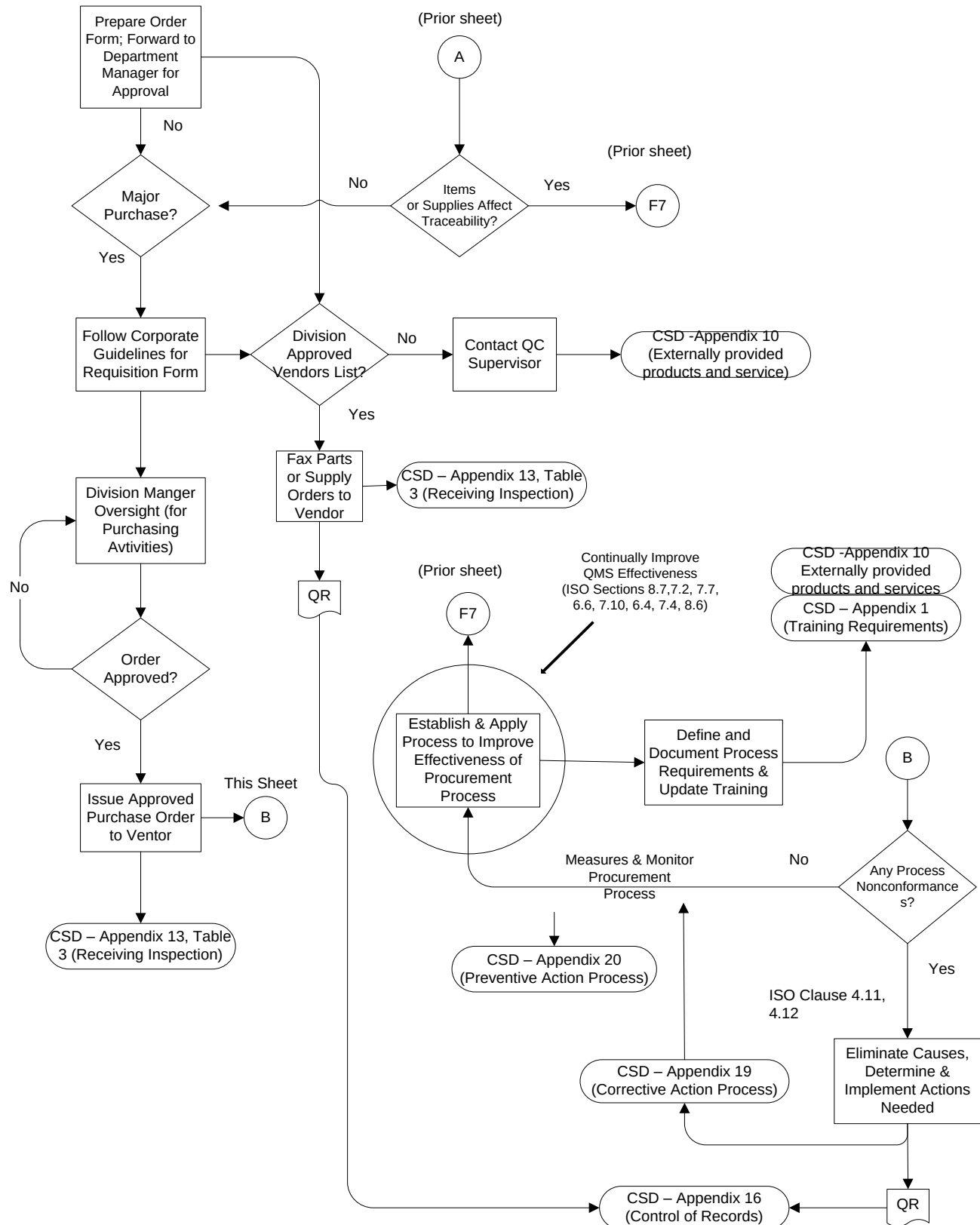


# Calibration System Description

MP CSD

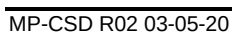
Ref. ISO/IEC 17025:2017 (Sections 6.6,  
4.1, 7.8, 8.7, 8.6, 8.4)  
Doc. F7 R2 02-03-12

## Procurement Process (Cont.)



## MP CSD

## Externally provided products and services Process



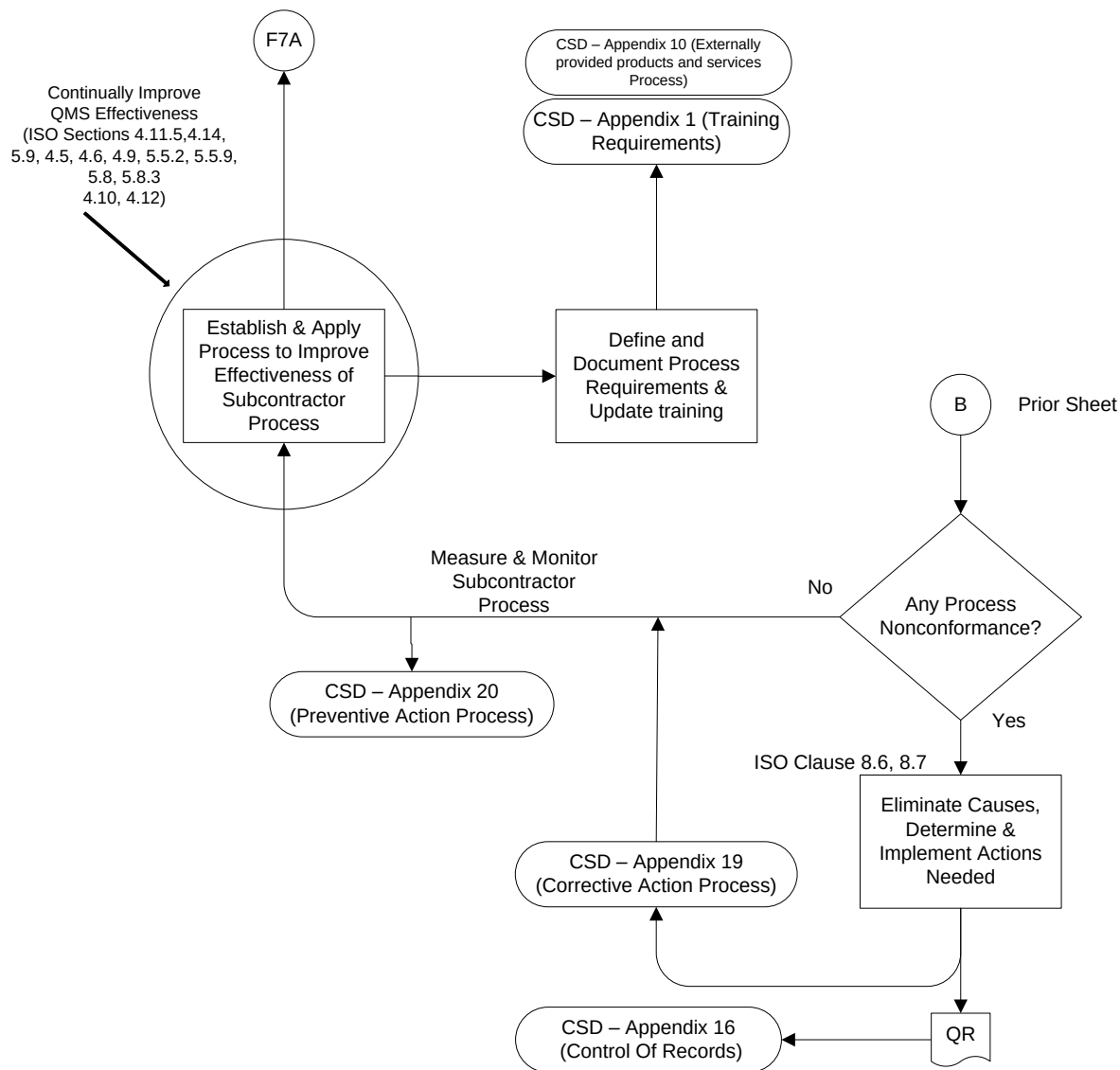
# Calibration System Description

MP CSD

## Externally provided products and services Process (Cont.)

Ref. ISO/IEC 17025:2017 (Sections  
4.1,6.6,8.6,8.7,8.4)  
Doc. F7a R2 02-03-12

Prior Sheet



# Calibration System Description

MP CSD

## Appendix 11 – Order Processing

Table 1 – Responsibilities

| Responsibility                                                                                                                                                                                                                                                     | Corp. | Sales Dept. | Lab Mgr. | QA Mgr. /QC Supv. | Receiving Inspector | Quality Director |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------------|----------|-------------------|---------------------|------------------|
| <u>Division Management Oversight:</u>                                                                                                                                                                                                                              |       |             |          |                   |                     |                  |
| <ul style="list-style-type: none"> <li>Ensuring that all work performed is within the Division's capability</li> </ul>                                                                                                                                             |       | X           | X        | X                 |                     | X                |
| <ul style="list-style-type: none"> <li>Ensuring there is adequate instrumentation, and technician experience and training to perform services by the Division</li> </ul>                                                                                           |       | X           | X        | X                 |                     | X                |
| <u>Capabilities and Price List</u>                                                                                                                                                                                                                                 |       |             |          |                   |                     |                  |
| <ul style="list-style-type: none"> <li>Annual review and update to the Capabilities List.</li> </ul>                                                                                                                                                               | X     |             |          |                   |                     | X                |
| <ul style="list-style-type: none"> <li>Periodic updating of the Capabilities List (either of these individuals may do so).</li> </ul>                                                                                                                              | X     |             | X        |                   |                     | X                |
| <ul style="list-style-type: none"> <li>Approving addition of instruments to the Capabilities List (either of these individuals has authority).</li> </ul>                                                                                                          | X     |             | X        |                   |                     | X                |
| <ul style="list-style-type: none"> <li>Interface between these individuals as necessary to determine if instrument can be added to capabilities list and price.</li> </ul>                                                                                         | X     | X           | X        |                   |                     | X                |
| <ul style="list-style-type: none"> <li>Keeps a copy of the Division capabilities and pricing.</li> </ul>                                                                                                                                                           | X     | X           |          |                   |                     | X                |
| <u>Quotes:</u>                                                                                                                                                                                                                                                     |       |             |          |                   |                     |                  |
| <ul style="list-style-type: none"> <li>Oversees the quotation process and consults with Division Manager when there are any questions concerning pricing or services to be provided.</li> </ul>                                                                    | X     | X           |          |                   |                     |                  |
| <ul style="list-style-type: none"> <li>Filing evaluation and quotation reports; performing follow-up contact on quote approval status with customers</li> </ul>                                                                                                    |       | X           |          |                   |                     |                  |
| <u>Order Review:</u>                                                                                                                                                                                                                                               |       |             |          |                   |                     |                  |
| <ul style="list-style-type: none"> <li>Oversee order review and responsible for                             <ul style="list-style-type: none"> <li>Safety of the order review records, including amendments, stored in Account Sales Files;</li> </ul> </li> </ul> |       | X           |          | X                 |                     | X                |

# Calibration System Description

MP CSD

**Table 1 – Responsibilities**

| Responsibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Corp. | Sales Dept. | Lab Mgr. | QA Mgr. /QC Supv. | Receiving Inspector | Quality Director |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------------|----------|-------------------|---------------------|------------------|
| <ul style="list-style-type: none"> <li>Ensuring pertinent information is readily retrievable for technicians and other personnel who execute the order (either of these individuals has responsibility);</li> <li>Ensures order review records are maintained, filed, stored and held secure at the Division; while on-line copy are always available on-line at MP Teamsite.</li> <li>Interfaces as necessary with the QA Manager to resolve quality issues pertaining to contract review</li> <li>Performing Order Review and signing Review Record (all individuals listed participate in this activity).</li> <li>Data provided by the customer shall be clearly identified on the Order review. The selection of customer specifies procedure should be selected. In addition, the Laboratory will indicate a disclaimer on the report, notes when the information is supplied by the customer and can affect the validity of results.</li> </ul> |       | X           | X        | X                 |                     |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           | X        | X                 |                     |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           | X        | X                 |                     | X                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           | X        | X                 |                     | X                |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           | X        |                   |                     |                  |
| <u>Customer Purchase Orders:</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |       |             |          |                   |                     |                  |
| <ul style="list-style-type: none"> <li>Logging / filing customer purchase orders (either one of these are responsible).</li> <li>Reviewing purchase orders for specific jobs; updating computer with purchase order info and customer instructions.</li> <li>Notifying QC Supervisor when purchase order contains special instructions.</li> <li>These individuals have responsibility to interface as needed when equipment arrives ahead of order paperwork, etc.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       | X           |          |                   | X                   |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           |          |                   | X                   |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           |          |                   | X                   |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       | X           | X        | X                 | X                   |                  |

**Table 2 – Overview of Customer Order Processing**

| Item                                                        | Requirements                                                                                                                                                                         | Remarks                                                |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <b>Overview of Work Flow and Processes During Servicing</b> | <ul style="list-style-type: none"> <li>See Appendix 13, Table 2 (Overview of Work Flow and Processes During Servicing)</li> </ul>                                                    |                                                        |
| <b>Computer Updates and Process Control</b>                 | <ul style="list-style-type: none"> <li>Monitoring of updates that reflect the progress of the work through the organization is made available online through MP Database.</li> </ul> | All personnel are responsible for their areas of work. |

# Calibration System

## Description

**MP CSD**

**Table 2 – Overview of Customer Order Processing**

| Item                                                                                                        | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Remarks |
|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                                                             | <ul style="list-style-type: none"> <li>○ Review current job status information;</li> <li>○ Assure information is up-to-date, after any disposition has changed;</li> <li>○ Enter applicable status codes into the Work Order as soon as the status disposition changes.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |         |
| <b>Types of Orders</b><br><br><i>Contract</i><br><br><i>Purchase Order</i><br><br><i>Amendment to Order</i> | <ul style="list-style-type: none"> <li>• A written agreement between a customer and MP.</li> <li>• A document issued and signed by the customer, which describes the customer requirements, terms, conditions, service required, delivery / shipping information, etc.</li> <li>• Change or revision in the terms, conditions, requirements or services to be rendered under an existing contract.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |
| <b>Order Arrival and Request for Servicing</b>                                                              | <ul style="list-style-type: none"> <li>• Customer orders may arrive as follows: <ul style="list-style-type: none"> <li>○ Customer drops off order;</li> <li>○ MP driver picks up customer order;</li> <li>○ Order arrives by common carrier.</li> <li>○ Customer sends approved purchase order via electronic mail.</li> </ul> </li> <li>• Service requirements / instructions may be communicated in one or more of the following ways: <ul style="list-style-type: none"> <li>○ Customer may provide a packing list of the equipment with clear description of the type of service to be rendered.</li> <li>○ Customer may identify service requirements through issue of its Purchase Order;</li> <li>○ Either MP and/or customer may provide a listing of customer equipment requiring servicing;</li> <li>○ MP may provide a formal written quotation for servicing;</li> <li>○ Appropriate test and/or calibration method is selected and capable of meeting the customers' requirements.</li> </ul> </li> </ul> |         |
| <b>Order Review Requirements</b>                                                                            | <ul style="list-style-type: none"> <li>• All orders will be reviewed to ensure that: <ul style="list-style-type: none"> <li>○ Requirements related to the service to be provided are defined;</li> <li>○ Requirements differing from those previously expressed are resolved; and</li> <li>○ MP has the ability to meet the defined requirements.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |

# Calibration System

## Description

MP CSD

**Table 2 – Overview of Customer Order Processing**

| Item                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Amendments</i>         | <ul style="list-style-type: none"> <li>• <u>Amendments to orders</u> will be reviewed where service or order requirements are changed so that: <ul style="list-style-type: none"> <li>○ Relevant documents are amended (e.g., Contract Review Record, computer update, formal MP contract, etc.) and</li> <li>○ Relevant personnel are made aware of the changed requirements.</li> <li>○ Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements in the note section of on the database.</li> <li>○ The customer shall be informed of any deviation from the contract.</li> </ul> </li> </ul>                                                                                                                                   |         |
| <i>Records Required</i>   | <ul style="list-style-type: none"> <li>• <u>Record</u> and maintain results of the review and actions arising from the review, including: <ul style="list-style-type: none"> <li>○ Specific customer instructions;</li> <li>○ Pertinent discussions with the customer relating to customer requirements;</li> <li>○ Results of the work.</li> <li>○ Retain in readily retrievable form for MP personnel access during processing work.</li> </ul> </li> <li>• Examples of specific customer instructions include: <ul style="list-style-type: none"> <li>○ Requested accuracies;</li> <li>○ Requested compliance to non-ISO standards;</li> <li>○ Documentation requirements outside of normal MP scope;</li> <li>○ Specific legal requirements or legal standards.</li> </ul> </li> </ul> |         |
| <i>Subsequent Reviews</i> | <ul style="list-style-type: none"> <li>• <u>Obtain written customer approval</u> if any service to be performed will not comply with the customer's instructions.</li> <li>• <u>Interface</u> with the Sales Manager, as appropriate, when addressing contract review issues subsequent to initial services to ensure information is properly documented. <ul style="list-style-type: none"> <li>○ Keep new or amended instructions received from the customer with the original contract documentation;</li> <li>○ Designated managers will review new or amended instructions before implementation;</li> <li>○ Document new or amended instructions consistent with the initial order review.</li> </ul> </li> </ul>                                                                    |         |

# Calibration System

## Description

**MP CSD**

**Table 2 – Overview of Customer Order Processing**

| Item                             | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Remarks                                                   |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <i>Non-conformances</i>          | <ul style="list-style-type: none"> <li>• <u>Document</u> any possible non-conformances pertaining to: <ul style="list-style-type: none"> <li>○ Customer requirements;</li> <li>○ MP quality requirements;</li> <li>○ Calibration capabilities;</li> <li>○ Other service capabilities.</li> </ul> </li> <li>• <u>Initiate a Corrective Action Report</u> for any condition found that would allow a nonconformance (see Appendix 19, Table 2, CAR Processing Requirements) <ul style="list-style-type: none"> <li>○ Close all CARs initiated during the customer order review in their entirety well in advance of providing the service that may be impacted.</li> </ul> </li> </ul> | See Appendix 18, Control of Non-conformances              |
| <b>Quotes</b>                    | <ul style="list-style-type: none"> <li>• Responsibilities are identified in Table 1 of this Appendix 11.</li> <li>• Repair quotes are sent to the customer for approval prior to processing (see Appendix 13, Calibration Servicing Process).</li> <li>• Formal quotes for new work are prepared by Sales and presented or sent to customers for approval.</li> <li>• Issues are mutually resolved before the order is agreed upon between MP and the customer.</li> <li>• The Quotation Process is illustrated in the Quote Process Map (New Orders and Repairs) in this Appendix 11.</li> <li>• Requirements are described in Table 5 of this Appendix 11.</li> </ul>              |                                                           |
| <b>Order Review Requirements</b> | <ul style="list-style-type: none"> <li>• The order review process begins either during or after the customer has approved the formal quotation to provide services</li> <li>• An <u>Order Review Record</u> form will be used for the following types of orders: <ul style="list-style-type: none"> <li>• Services covered under an MP Service Agreement;</li> <li>• Services covered under a blanket or contract Purchase Order;</li> </ul> </li> <li>• Review of the customer instrument listing and customer quality requirements will be documented in the Order Review Record form.</li> <li>• See Table 4 in this Appendix 11 for Order Review criteria.</li> </ul>            | See above Responsibilities in Table 1 of this Appendix 11 |

# Calibration System Description

MP CSD

**Table 2 – Overview of Customer Order Processing**

| Item                                         | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Remarks |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Order Review Requirements</b>             | <ul style="list-style-type: none"> <li>The following applies for all work not <u>preceded by a formal instrument list and quote</u>: <ul style="list-style-type: none"> <li><u>Review</u> the incoming purchase order for special instructions and/or customer requirements. Special instructions include: <ul style="list-style-type: none"> <li>Special servicing requirements;</li> <li>Turn -around requirements;</li> <li>Customer feedback</li> <li>Specific calibration requirements.</li> </ul> </li> <li><u>Contact Sales or the Division Manager</u> if there is any question concerning special instructions or customer requirements.</li> <li><u>Contact the customer</u> to clarify any specific customer instructions before initiating service.</li> <li><u>Process</u> all verbal or written customer instructions and requirements into the job file, and update the computer database.</li> <li><u>Document</u> receipt of instruments on the incoming shipping document and initial customer purchase order. <ul style="list-style-type: none"> <li>Use an MP Shipping Memorandum when there is no incoming shipping document (e.g., customer delivers or will call for the order).</li> <li>See Appendix 13, Table 3 for additional Receiving Inspection activities.</li> </ul> </li> <li>See Subcontracting Work outside MP Capability in Table 3 in this Appendix 11, if service requested is outside the Division's capability.</li> </ul> </li> </ul> |         |
| <b>Resolution of Requirement Differences</b> | <ul style="list-style-type: none"> <li>Interface as necessary with customer to resolve issues. <ul style="list-style-type: none"> <li>Record discussions with customer pertaining to customer's requirements or results of the work during processing.</li> <li>Record any actions taken if discrepancies are found.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |
| <b>Recording Results</b>                     | <ul style="list-style-type: none"> <li><u>Document</u> order review using Order Review Form : <ul style="list-style-type: none"> <li>Update database as equipment is received for induction (see Receiving Inspection in Table 3, Appendix 13).</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |

# Calibration System Description

**MP CSD**

**Table 3 – Capability and Price List Control**

| Item                                                | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                              |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| <b>General</b>                                      | <ul style="list-style-type: none"> <li>No calibration or service will be performed by a facility which is outside that facility's capability</li> <li>Adequate instrumentation and technician experience and training is a pre-requisite of accepting work for service.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | See Table 1 in this Appendix 11 for Responsibilities |
| <i>Format Media</i><br><br><i>Authorities</i>       | <ul style="list-style-type: none"> <li>The Capability Price List is maintained on CRM Database</li> <li>Maintenance for the List contents is defined in Table 1 above. Management approval is required for: <ul style="list-style-type: none"> <li>Inducting instruments for service, that are not on the Capability Price List ;</li> <li>Establishing the applicable service price for the new instrument being added to the Capability Price List.</li> </ul> </li> <li>The following are to be considered when inducting an instrument for service (during order review or when adding an item to the Capability Price List): <ul style="list-style-type: none"> <li>Availability of test standards;</li> <li>Facility and personnel;</li> <li>Cost to perform service;</li> <li>Market competition pricing;</li> <li>Customer requirements.</li> </ul> </li> </ul> <p>No instrument will be added to the Capability Price List and inducted for service unless the service to be performed complies with all applicable procedures.</p> |                                                      |
| <b>Capability Price List</b><br><br><i>Contents</i> | <ul style="list-style-type: none"> <li>Identifies all instruments which can be calibrated by the Division.</li> <li>A current copy of the Capability Price List (instrument and pricing) will be kept on the CRM Database for internal use. The instrument description only will be made available on the public web site.</li> <li><u>Capability Price List contents:</u> <ul style="list-style-type: none"> <li>Instrument description;</li> <li>Manufacturer;</li> <li>Model;</li> <li>Calibration price of all instruments</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                      |

# Calibration System Description

MP CSD

**Table 3 – Capability and Price List Control**

| Item                                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                               |
|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
|                                                       | <p><u>Note</u>: One entry is required for redundant items (e.g., micrometers, thread plugs, etc.)</p> <ul style="list-style-type: none"> <li>Review and update Capability Price Lists at least annually. <ul style="list-style-type: none"> <li>Transmit changes to a facility capability for update in the Capability Price List controlled by Corporate.</li> <li>Reflect price changes in the update of the Capability Price List.</li> </ul> </li> </ul> | See Table 1 of this Appendix 11, for Responsibilities |
| <b>Subcontracting Work Outside of MP's Capability</b> | <ul style="list-style-type: none"> <li>If <u>work is received that is outside MP's</u> capabilities: <ul style="list-style-type: none"> <li>Notify customer that service must be subcontracted.</li> <li>Obtain customer's written approval <u>prior</u> to sending work to Externally Provider.</li> </ul> </li> </ul>                                                                                                                                      |                                                       |

**Table 4 – Order Review Criteria**

| Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <ul style="list-style-type: none"> <li>Review the following criteria, as appropriate</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |
| <ul style="list-style-type: none"> <li><u>Personnel</u> <ul style="list-style-type: none"> <li>Are there a sufficient number of qualified people available?</li> <li>Are personnel qualifications <u>current and aligned with</u> customer requirements?</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                            |         |
| <ul style="list-style-type: none"> <li><u>Turn -Around Time</u> <ul style="list-style-type: none"> <li>Can the customer's requested time periods be met with the staff available?</li> <li>Have delivery dates and other special requirements been satisfactorily reviewed and agreed to by customer?</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                               |         |
| <ul style="list-style-type: none"> <li><u>Test Equipment</u> <ul style="list-style-type: none"> <li>Are sufficient test standards available to perform the requested service?</li> <li>Are test standards of the required accuracy, stability, range and resolution required for the equipment to be calibrated, and in-calibration?</li> <li>Has Automatic Test Equipment (ATE) and its software been evaluated (verified) as adequate and approved for use?</li> <li>Will customer's test standard(s) be used to perform the calibration? If yes the following are also required:</li> </ul> </li> </ul> |         |

# Calibration System Description

MP CSD

**Table 4 – Order Review Criteria**

| Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <ul style="list-style-type: none"> <li>- Document details;</li> <li>- Verify suitable measures will be taken to induct customer's test standards into MP's calibration system prior to use;</li> <li>- Evaluation and addition of customer to MP Approved Vendor List (for traceability).</li> </ul>                                                                                                                                                                                                                                                                       | See Appendix 10, Externally provided products ad services |
| <ul style="list-style-type: none"> <li>o <u>Calibration Methods</u> <ul style="list-style-type: none"> <li>• Are the required calibration procedures or manufacturer procedures available to perform the work?</li> <li>• Is MP proposed calibration <u>method hierarchy</u> acceptable to customer? (see Appendix 6, Table 2)</li> <li>• Are customer-specified calibration methods / procedures applicable? (If yes, obtain written approval from customer and details.)</li> </ul> </li> </ul>                                                                          |                                                           |
| <ul style="list-style-type: none"> <li>o <u>Environment</u> <ul style="list-style-type: none"> <li>• Are there a sufficient number of temperature and humidity recorders available and in-calibration where the work will be performed?</li> <li>• Are the facility environmental requirements suitable for the customer's equipment calibration service requirements?</li> <li>• Have all other environmental requirements applicable to the services to be rendered been met?</li> </ul> </li> </ul>                                                                     |                                                           |
| <ul style="list-style-type: none"> <li>o <u>Quality Assurance</u> <ul style="list-style-type: none"> <li>• Are there any special customer-specified requirements applicable?</li> </ul> <p><u>Examples:</u><br/>Nonconformance reporting;<br/>References to special Codes or Standards;<br/>Passing on certain clauses to external provider;<br/>Government cooperation (e.g., right of access, etc.);<br/>Written notice to subcontract work;<br/>QC provisions.</p> <ul style="list-style-type: none"> <li>• Can these be fulfilled as requested?</li> </ul> </li> </ul> |                                                           |
| <ul style="list-style-type: none"> <li>o <u>Quality System</u> <ul style="list-style-type: none"> <li>• Has customer approved MP's Quality System? (Work will be performed under MP's QS, unless otherwise provided.)</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                               |                                                           |
| <ul style="list-style-type: none"> <li>o <u>Equipment to be Serviced</u> <ul style="list-style-type: none"> <li>• <u>Document and reconcile</u> (with the customer and on Order Review Record)</li> <li>• Are changes to the originally established number of instruments requiring calibration service clearly define?</li> <li>• Are there any changes in the type of service to be provided under the existing contract?</li> <li>• What is the calibration interval for each item of equipment? (Customer is to specify Calibration Interval.)</li> </ul> </li> </ul>  |                                                           |

# Calibration System Description

MP CSD

**Table 4 – Order Review Criteria**

| Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Remarks |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <ul style="list-style-type: none"> <li>○ <u>Type of Calibration Service Required:</u> <ul style="list-style-type: none"> <li>• Is <u>Lab Accredited</u> work to be performed (e.g., service under MP's Scope of Accreditation)?                             <ul style="list-style-type: none"> <li>• If yes, has the lab's <u>Scope of Accreditation</u> been provided to and discussed with customer to assure equipment parameters are within the Scope and can be performed as requested?</li> <li>• If yes, has customer been furnished the lab's <u>Best Measurement Capability</u>?</li> <li>• If yes, have the lab's <u>Measurement Uncertainties</u> been reviewed with the customer to the customer's satisfaction?</li> <li>• If yes, work will be performed according to ISO/IEC 17025, which will be listed on the Calibration Certificate.</li> <li>• If yes, is the applicable MP Certificate of Accreditation current?</li> </ul> </li> <li>• Are there any open audit issues that could impact the work to be performed?                             <ul style="list-style-type: none"> <li>• If yes, have they been reviewed internally and with the customer, if applicable?</li> </ul> </li> <li>• Is <u>non-accredited</u> work to be performed?                             <ul style="list-style-type: none"> <li>• If yes, has customer specified Standards preference (e.g., ISO/IEC 17025 or none specified)?</li> </ul> </li> </ul> </li> </ul> |         |
| <ul style="list-style-type: none"> <li>○ <u>Traceability</u> <ul style="list-style-type: none"> <li>• Have traceability policy requirements been satisfied?</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
| <ul style="list-style-type: none"> <li>○ <u>Data Readings</u> <ul style="list-style-type: none"> <li>• Does customer want full data readings?</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |
| <ul style="list-style-type: none"> <li>○ <u>Subcontracting</u> <ul style="list-style-type: none"> <li>• Is the externally provided products and services acceptable with customer?</li> <li>• Does customer request that MP use a specific external provider? (If yes, customer retains responsibility for the quality of the external providers work; this external provider may or may not appear on MP Approved Vendor List.)</li> <li>• If <u>lab accredited work</u>, identify proposed external provider to customer and obtain written approval to use.</li> <li>• If <u>non -accredited work</u>, the external provider name may or may not be identified to customer. Obtain customer written approval to subcontract.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |

## MP CSD

| Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| <ul style="list-style-type: none"> <li>○ <u>Capability Price List</u> <ul style="list-style-type: none"> <li>● Has the price list been reviewed with appropriate management for applicable discounts and payment terms, customer requirements, etc.? (See Capability Price List Processing Requirements in Table 3 of this Appendix 11.)</li> <li>● Is equipment or service required outside MP's capabilities (see Subcontracting Work Outside of MP's Capabilities in Table 3 of this Appendix 11).</li> </ul> </li> </ul> | Communicated with the customer through quote process |
| <ul style="list-style-type: none"> <li>○ <u>Payment Terms</u> <ul style="list-style-type: none"> <li>● Have all payment terms, invoicing and other MP conditions been discussed and found acceptable and agreed to by customer?</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                       |                                                      |

| Item                                                     | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks                                           |
|----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Quote Process</b>                                     | <ul style="list-style-type: none"> <li>See the Quote Process Map (New Orders and Repairs) in this Appendix 11.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | See Table 1 in this Appendix for Responsibilities |
| <i>Preparation</i><br><br><br><br><i>Update Database</i> | <ul style="list-style-type: none"> <li><u>Prepare a quote</u> when service involves:               <ul style="list-style-type: none"> <li><u>Repair</u> to a customer's instrument (unless already provided for in the customer's Purchase Order);</li> <li><u>Subcontracting</u> the work;</li> <li>A list of customer equipment is involved and a <u>formal contract</u>.</li> </ul> </li> <li><u>Update the customer's Work Order</u> in the database with relevant information, such as:               <ul style="list-style-type: none"> <li>Pertinent comments concerning quotes and customer communications;</li> <li>Date needed, approval sent, approved by, date, Purchase Order number, and approval received by information;</li> <li>Technical and repair information (repair comments should be as comprehensive as possible);</li> <li>Projected turn-around time;                   <ul style="list-style-type: none"> <li>If turn-around time is expected to exceed customer requirements or exceed established standards for calibration and repair services;</li> </ul> </li> </ul> </li> </ul> |                                                   |

# Calibration System

## Description

MP CSD

**Table 5 – Customer Quotation Process**

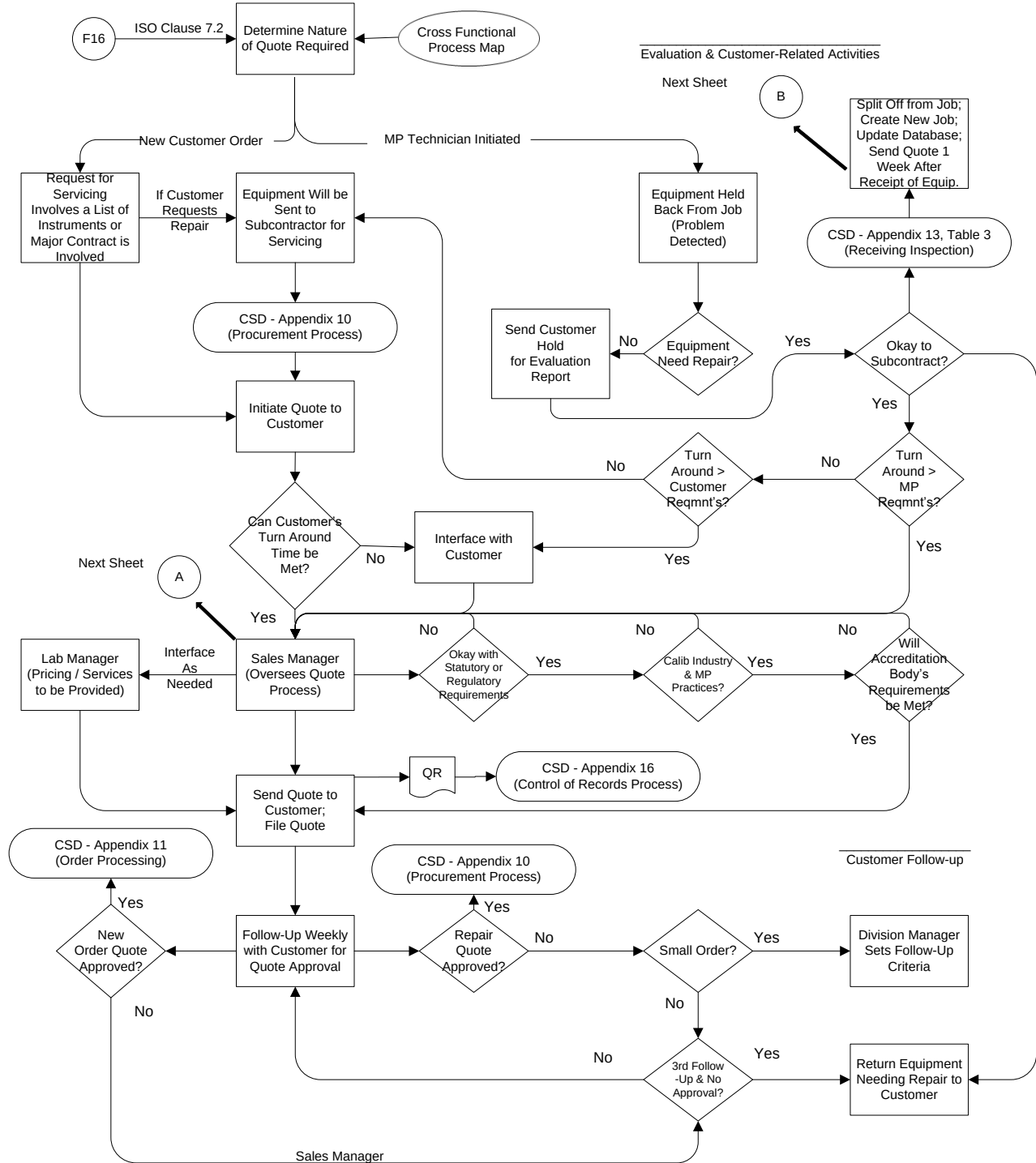
| Item                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks                           |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| <i>Approval and Distribution</i>          | <ul style="list-style-type: none"><li>• See Appendix 10, Externally Provided Products and Services, for vendor purchase order requirements (e.g., vendor quotes for repairs).</li><li>• File evaluation and quotation reports.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | See Table 1 for Responsibilities. |
| <i>Follow-Up With Customer (Approval)</i> | <p><u>Repair Quotes:</u></p> <ul style="list-style-type: none"><li>• Use a calendar system to contact customers weekly via fax or e-mail until response is received (e.g., call all "Waiting Approvals" every Wednesday.)<ul style="list-style-type: none"><li>○ If customer does not respond (either approve or reject) the quote after the third call, then return the equipment to the customer.</li><li>○ Each Division is responsible for setting its own guidelines on how many times to contact the customer (e.g., three times may not be practical for small orders);<ul style="list-style-type: none"><li>▪ As a minimum, send one fax or e-mail quote and one follow-up service call before returning the equipment unrepaired.</li></ul></li></ul></li></ul> |                                   |

# Calibration System Description

MP CSD

Ref. ISO/IEC 17025:2017 (Sections 6.6, 7.5)  
Doc. F16 R1 6-09-03  
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## Quote Process

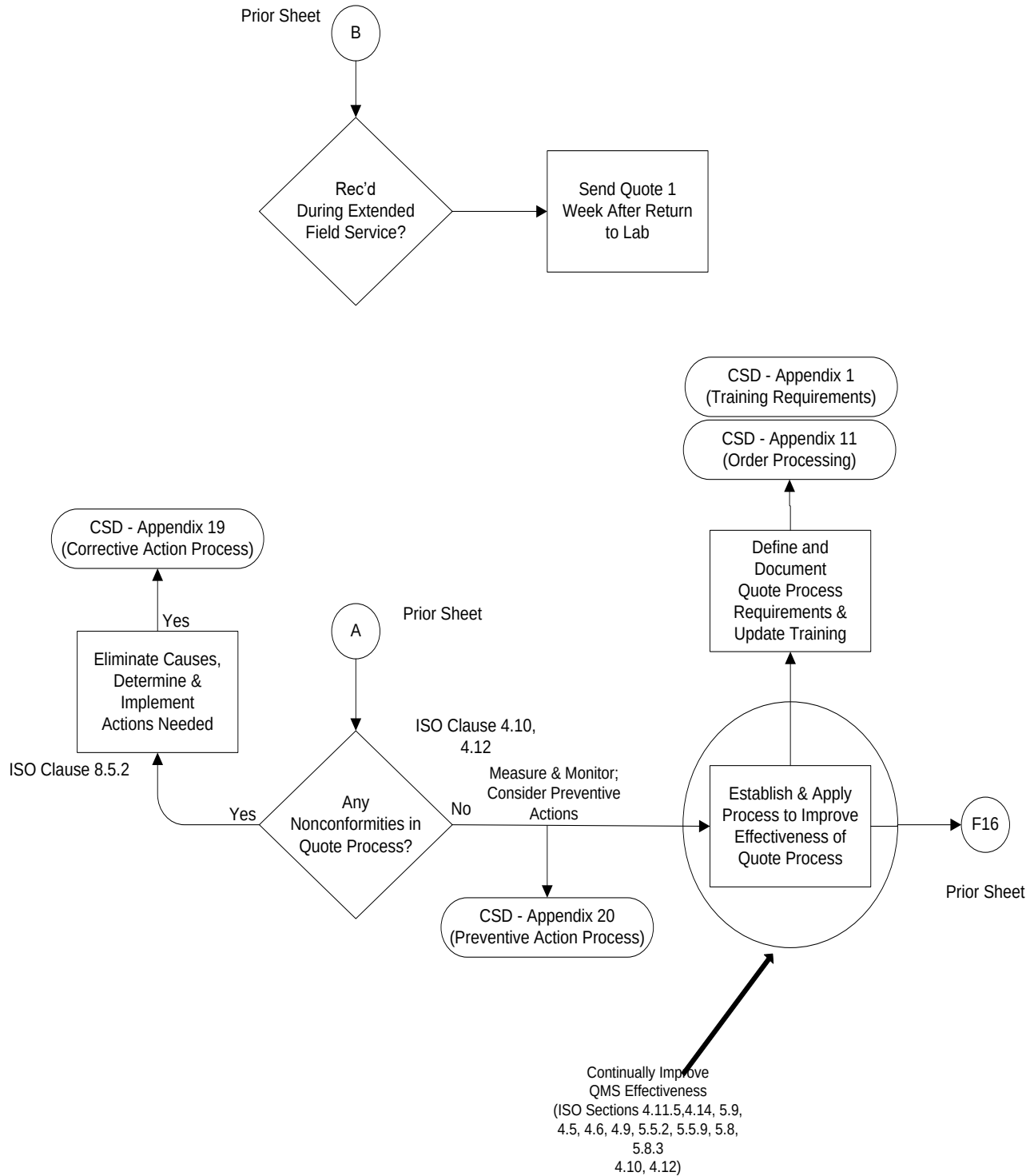


# Calibration System Description

MP CSD

## Quote Process

Ref. ISO/IEC 17025:2017 (Sections  
4.1,8.7,8.6,6.6)  
Doc. F16 R1 6-09-03  
Page 2 of 2



# Calibration System Description

MP CSD

## Appendix 12 – Control of Instruments and Equipment

**Table 1 – Responsibilities**

| Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Customer          | Customer Service  | Lab Mgr.                            | Division Mgr. |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|-------------------------------------|---------------|
| <u>Recall:</u> <ul style="list-style-type: none"> <li>Verify receipt of Recall Notices and schedule work to be performed.</li> <li>Establish and formally request and approve Calibration Interval, in writing (except where mandated by regulatory or legal requirements).</li> <li>Monitor Recall Notices sent to customers in accordance with contractual requirements, for equipment with MP Control Numbers.</li> <li>Review Recall status and notify / schedule work with the customer, when practical.</li> </ul> | <p>X</p> <p>X</p> | <p>X</p> <p>X</p> |                                     |               |
| <u>MP Instruments:</u> <ul style="list-style-type: none"> <li>Monitor instrument accuracies and capabilities and report on Measurement Capability Planning during management reviews.</li> <li>Implementing and maintaining MP instrumentation Service Reports</li> <li>Assuring continuous line of traceability for all test standards used.</li> <li>Conduct Annual Proficiency Test Program</li> </ul>                                                                                                                |                   |                   | <p>X</p> <p>X</p> <p>X</p> <p>X</p> | <p>X</p>      |

# Calibration System Description

MP CSD

**Table 2 – MP Major Instrumentation**

| Item                                                            | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks                                                                                                                |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>MP Equipment</b>                                             | <ul style="list-style-type: none"> <li>All MP laboratories must be furnish will all measurement and equipment required fir the correct performance of calibrations, including preparation of calibration items, processing and analyzing</li> <li>MP equipment and its software used for calibration shall be capable of achieving the accuracy required and shall comply with specifications relevant to calibration concerned. Calibration Programs shall be established for key values of the instruments where these properties have significant effect on the results.</li> <li>Before being placed into service, equipment shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with relevant standard specifications. It shall be checked and/or calibrated before use</li> <li>MP equipment shall be operated by authorized personnel, up-to-date instruction on the use and maintenance of equipment shall be readily available.</li> <li>MP Equipment shall be uniquely identified using specified assigned CAL (calibration ID)</li> <li>MP equipment information and records are maintained and monitored in the MP database</li> </ul> | <p>Also see Table 5 in this Appendix 12</p> <p>See Appendix 16, Control of Records</p>                                 |
| <b>Annual Proficiency Test</b>                                  | <ul style="list-style-type: none"> <li>Perform annually to validate the instrument's accuracy, including accuracy of primary instruments used for calibration.</li> <li>Collect accuracy of standards, accumulated degraded accuracy of test, and methods for which these accuracies were determined.</li> <li>Use the latest MP Uncertainty Spreadsheet and associated work instructions to calculate the total expanded uncertainty.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <p>See Appendix 16, Control of Records.</p> <p>Also see Table 6 in this Appendix 12 for Traceability requirements.</p> |
| <b>New Instruments or Recalibration of Existing Instruments</b> | <ul style="list-style-type: none"> <li>Verify the instrument's accuracy internally when received. <ul style="list-style-type: none"> <li>If not possible to verify the instrument's accuracy when received, use an Approved Traceability Vendor.</li> <li>See Table 6 in this Appendix for Traceability requirements.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                        |

# Calibration System

## Description

**MP CSD**

**Table 3 – MP Instrument Control**

| Item                                            | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks                         |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| <b>Recall List</b>                              | <ul style="list-style-type: none"> <li>List of active MP instruments with calibration due dates (ref. Inventory Control elsewhere in this table).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Appendix 16, Control of Records |
| <b>Calibration Interval</b>                     | <ul style="list-style-type: none"> <li>Mandatory for all instruments and standards.</li> <li>Initial interval will be reflective of other similar models, types and manufacturer.</li> <li>Industrial standard is established based on use and exposure.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |
| <b>Bases for Determining Interval</b>           | <ul style="list-style-type: none"> <li>“State-of-the-art” practices</li> <li>Manufacturers recommendations</li> <li>Recognized Commercial standards</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                 |
| <b>Considerations in establishing Intervals</b> | <ul style="list-style-type: none"> <li>Degree of use (daily, monthly)</li> <li>Usage or time since standards were last calibrated or verified</li> <li>Stability and required accuracy</li> <li>Manufacturers requirements</li> <li>Mode of use (lab standard, mobile service, field service)</li> <li>Purpose and location in testing (primary , secondary)</li> <li>Exposure risk (e.g. biochemical, aviation, nuclear – consider reducing the calibration interval)</li> <li>Other characteristics or conditions affecting the measurement</li> <li>Service report documentation (including special services identified on the Service Report)</li> <li>Uncertainty impact</li> </ul> |                                 |
| <b>Out-of-Tolerance</b>                         | <ul style="list-style-type: none"> <li>Reduce the calibration cycle if found to be out-of-tolerance by more than twice the instrument’s expected accuracy either during or before the instrument’s scheduled calibration.               <ul style="list-style-type: none"> <li>Shorten the instrument’s Recall cycle by one-half if there have been less than 5 calibration cycles in the instrument’s history.</li> <li>Notify the MP Division that owns the instrument.</li> </ul> </li> </ul>                                                                                                                                                                                         | Appendix 16, Control of Records |

# Calibration System

## Description

**MP CSD**

**Table 3 – MP Instrument Control**

| Item                                            | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks                                                            |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| <b>Reliability Target</b>                       | <ul style="list-style-type: none"> <li>Recall and calibration practices will support that an instrument is within its allowable tolerance at least 80% of the time.                             <ul style="list-style-type: none"> <li>Shorten the instrument's Recall cycle by one-half if the above minimum reliability target is exceeded.</li> <li>See Appendix 18, Table 2 for Control of Nonconforming Instruments.</li> </ul> </li> </ul>                                                                                                                                                                           | Appendix 16, Control of Records                                    |
| <b>Recall Notices</b>                           | <ul style="list-style-type: none"> <li>MP Instruments Recall requirements will be monitored to assure that no instrument becomes unintentionally out-of-calibration.                             <ul style="list-style-type: none"> <li>Table 4 criteria for Recall Notices may also be applied to MP Instruments.</li> </ul> </li> <li>The MP database includes security measures to prevent the use of any instrument or standard with overdue calibration dates.</li> </ul>                                                                                                                                             |                                                                    |
| <b>Intermediate Checks</b>                      | <ul style="list-style-type: none"> <li>Intermediate checks are carried out in between calibration intervals to check functionality of the reference standards. Intermediate checks are carried out using higher, better references, or using reference of the same level, and comparing the drift in reading.</li> <li>Identified reference standards that requires checking and its schedules shall be cover by annual intermediate check plan.                             <ul style="list-style-type: none"> <li>Records of Intermediate checks shall be checked and monitored at each division.</li> </ul> </li> </ul> | Appendix 16, Control of Records                                    |
| <b>Equipment Records</b>                        | <ul style="list-style-type: none"> <li>Required for all MP Instrumentation maintained in each MP Laboratory.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | See Table 1, Responsibilities and Appendix 16, Control of Records. |
| <b>Instruments Outside MP Permanent Control</b> | <ul style="list-style-type: none"> <li>Verify calibration accuracy and traceability upon receipt and when used for calibration outside the permanent control of the lab.                             <ul style="list-style-type: none"> <li>Ensure that function and status of equipment is correct and shown as satisfactory for use (i.e., verified by the Division that borrowed the instrument and by the receiving Division upon return of the instrument).</li> <li>A Calibration Report will be filed before the instrument is used for calibration and after its last use for calibration.</li> </ul> </li> </ul>  | Appendix 16, Control of Records.                                   |
| <b>Interdivision Loan or Transfer</b>           | <ul style="list-style-type: none"> <li>The sending Division will include documentation needed to support the instrument's traceability status:                             <ul style="list-style-type: none"> <li>Equipment Records</li> <li>Current Calibration</li> <li>Attached Data Report</li> <li>Charts and/or</li> <li>Manufacturer Calibration Reports</li> </ul> </li> </ul>                                                                                                                                                                                                                                     | Appendix 16, Control of Records.                                   |

## MP CSD

| Item                                                                                               | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks                      |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|                                                                                                    | <ul style="list-style-type: none"> <li>○ Calibration Reports of standards used to calibrate the instrument being shipped.</li> <li>● Recalibrate the instrument at the receiving Division before using as a test instrument if full traceability documentation is not available from the sending Division.</li> <li>● If traceability documentation is provided, fitness for use check must still be performed before using.</li> <li>● Continue to use any existing Calibration Control Number originally applied to the instrument.</li> <li>○ Outside Vendor Calibration Label processing is applicable.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                              |
| <b>Inventory Control</b>                                                                           | <ul style="list-style-type: none"> <li>● The current location (i.e., Division name, mobile unit, customer facility, etc.) and status of all MP instruments will be kept updated in the database.</li> <li>● The instrument's accuracy or traceability level (e.g., primary, secondary or tertiary) will be indicated.</li> <li>● Only equipment belonging to and under the control of MP shall be used for calibration service. Technicians are not permitted, under any circumstances, to utilize personal equipment to perform calibration.</li> <li>● Remove permanently retired instruments from the active instrument recall.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                              |
| <b>Traceability Control</b><br><br><i>Records Required</i><br><br><i>Traceability Requirements</i> | <ul style="list-style-type: none"> <li>● Normally use only primary standards which have been calibrated externally or by a secondary standard which is at the top of the measurement discipline for realization of SI units.</li> <li>● <u>Example:</u> A Supermic is a secondary standard, but it is calibrated with Gage Blocks, which is are primary standard. Therefore, the Supermic could be considered to be at the top of the measurement discipline.</li> <li>● Check all secondary standards to assure that no traceability loop exists. If found:               <ul style="list-style-type: none"> <li>○ Perform an impact study.</li> <li>○ Recalibrate the standard and/or affected instruments.</li> </ul> </li> <li>● If prior calibration performed has been found to impact customer instruments, implement all requirements of Appendix 18, Control of Nonconforming Instruments.</li> <li>● See Appendix 16, Control of Records, for a list of minimum records to be maintained to establish traceability.</li> <li>● See Table 6 in this Appendix 12 for Traceability Requirements.</li> </ul> | See Table 1-Responsibilities |

# Calibration System Description

MP CSD

**Table 3 – MP Instrument Control**

| Item                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                        | Remarks |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Calibration Records</b><br><br><i>Records Required</i> | <ul style="list-style-type: none"><li>• A record conforming to requirements of the Calibration System Description will be kept for each calibration performed.</li><li>• Data and calculations will be recorded at the time made and will be subject to checks.</li><li>• See Appendix 16, Control of Records, for a list of records to be maintained for MP instruments.</li></ul> |         |

**Table 4 – Customer Equipment Control**

| Item                                       | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Calibration Interval</b>                | <ul style="list-style-type: none"><li>• Obtain (in writing) the customer's preferred Calibration Interval for each instrument.</li><li>• Customer's Calibration Interval governs. MP will not determine customer equipment Calibration Interval.</li></ul>                                                                                                                                                                    |         |
| <b>Customer Recall Notices</b>             | <ul style="list-style-type: none"><li>• Recall Notices is automatically generated in MP database.</li><li>• Recall Notices will be send to customers via electronic mail containing the following:<ul style="list-style-type: none"><li>○ Overdue instruments (from first of prior month)</li><li>○ Instruments due the current month</li><li>○ Instruments due next month, to the end of the next month.</li></ul></li></ul> |         |
| <b>Customer Out-of-Tolerance Equipment</b> | <ul style="list-style-type: none"><li>• See Appendix 18, Control of Nonconforming Instruments, Table 2.</li></ul>                                                                                                                                                                                                                                                                                                             |         |

**Table 5 – Status Labeling**

| Item                     | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                   | Remarks |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Labels in General</b> | <ul style="list-style-type: none"><li>• Status labels will be placed immediately on an instrument after it has either passed or failed calibration (applies to customer and MP instruments).</li><li>• Only the technician performing the work will fill out and affix the status label.</li><li>• Labels will only be used by authorized MP personnel or their agents.</li><li>• Equipment and calibration software will be safeguarded and uniquely</li></ul> |         |

## MP CSD

| Item                                                                                         | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Remarks                                                                                               |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <p><b>Calibration Labels in Accredited Work</b></p> <p><b>Calibration Control Number</b></p> | <ul style="list-style-type: none"> <li>identified to prevent unauthorized modifications that would invalidate results.</li> <li>Calibration labels containing the “accredited symbol” <u>may</u> be affixed <u>only</u> to equipment that has been calibrated by an accredited MP Division under their Scope of Accreditation.</li> <li>Calibration labels containing the “accredited symbol” shall include at least the following: <ul style="list-style-type: none"> <li>The name of the accredited calibration laboratory or its Accredited Laboratory Certificate number.</li> <li>The instrument identification</li> <li>The date of the current calibration.</li> <li>Cross-reference to the accredited Calibration Certificate issued with respect to this calibration.</li> </ul> </li> <li>Unique identification label affixed to customer and MP instruments.</li> <li>White label with two black capital letter and four numbers (commercially preprinted serialized numbers).</li> <li>Affix label to all instruments in a visible location before calibration is initiated. <ul style="list-style-type: none"> <li>On large devices, affix near the customer control label if one is present.</li> <li>If no customer label, then affix next to the manufacturer/serial number label.</li> <li>If neither of the above options is viable, then affix to the right front panel.</li> <li>May be affixed on the panel next to the meter being calibrated (for mounted meter where meter face has no room to support labels).</li> <li>If the instrument is too small for the label, it may be applied to card stock wired to the instrument.</li> </ul> </li> <li>If permitted by the customer, the Control Number may be engraved on the instrument.</li> <li>Worn labels will be replaced with a label with the Control Number written on it.</li> </ul> | <p>Also see requirements in Appendix 13, Table 7 for Calibration Certificates of Accredited Work.</p> |
| <b>White Calibration Label</b>                                                               | <ul style="list-style-type: none"> <li>Shows calibration date, due date, technician number or names and Calibration Control Number.</li> <li>Different sized labels are available for use.</li> <li>May be affixed on the panel next to the meter being calibrated (for mounted meter where meter face has no room to support labels).</li> <li>Calibration labels will only be affixed on instruments that have valid certifications of calibration.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                       |

# Calibration System

## Description

MP CSD

**Table 5 – Status Labeling**

| Item                            | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks                                                 |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
|                                 | <p><u>Large Calibration Label</u></p> <ul style="list-style-type: none"> <li>Complete as follows: <ul style="list-style-type: none"> <li>Date Calibrated</li> <li>Next Calibration Date</li> <li>Technician initials or name</li> </ul> </li> <li>Affix to all instruments large enough to support it. <ul style="list-style-type: none"> <li>Standard placement: Top right of instrument (when possible).</li> <li>Place in a visible location.</li> </ul> </li> <li>Also attach to instrument cases.</li> </ul>                                                                                                                                                                           |                                                         |
|                                 | <p><u>Small Calibration Label</u></p> <ul style="list-style-type: none"> <li>Use when there is insufficient space to affix a Large Calibration Label.</li> <li>Complete as follows: <ul style="list-style-type: none"> <li>Date calibrated</li> <li>Next Calibration Date</li> <li>Technician's initials or name</li> </ul> </li> <li>If item is too small to support a Small Calibration Label (e.g., a small thread ring gage), then the label may be cut down to fit onto the instrument or fix the calibration label on the case of the instrument. <ul style="list-style-type: none"> <li>As a minimum, the next due date will be written on the reduced label.</li> </ul> </li> </ul> |                                                         |
| <b>Yellow Limited Use Decal</b> | <ul style="list-style-type: none"> <li>Includes a service date, technician's initials or name, and the reason for being limited in use.</li> <li>If acceptable to the customer, a Limited Use label will be used to allow for the use of an instrument that has a non-critical function impairment.</li> <li>Note the impairment and full explanation in the Calibration Report .</li> </ul>                                                                                                                                                                                                                                                                                                |                                                         |
| <b>Red Reject Decal</b>         | <ul style="list-style-type: none"> <li>Includes the date, the technician's initials, and reason for being rejected.</li> <li>Use immediately when an instrument is found nonconforming (including instruments waiting customer approval, parts or additional service time to be scheduled). <ul style="list-style-type: none"> <li>Note the reason for the rejection on the Red Reject label.</li> <li>If MP instrument is overdue for calibration, note "Cal-Before-Use" (or CBU).</li> </ul> </li> </ul>                                                                                                                                                                                  | Also see Appendix 18, Control of Nonconforming Products |

# Calibration System

## Description

**MP CSD**

**Table 5 – Status Labeling**

| Item                                                        | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks |
|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Tamper Seal</b>                                          | <ul style="list-style-type: none"> <li>White, “Calibration Void if Broken” seal placed on customer accessible controls, that if moved would invalidate the calibration.</li> <li>All internal and external calibration adjustments on customer’s instruments will be sealed, when possible.</li> <li>All chassis on customer’s instruments will be sealed with a “Calibration Void if Broken” seal.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |
| <b>For Reference Only<br/>(or Calibration Not Required)</b> | <ul style="list-style-type: none"> <li>Label which identifies MP instruments that do not require calibration.</li> <li>Use on any instrument the Lab Manager determines does not require calibration.</li> <li>Attach a Calibration Control Number label to instruments not requiring calibration.</li> <li>Maintain a Service Report on the instrument’s service history.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |
| <b>Outside Vendor Calibration Labels</b>                    | <ul style="list-style-type: none"> <li>Do not remove the calibration label affixed by an external calibration source, unless a different cycle will be used for the instrument.</li> <li>Affix an MP Calibration Label to the instrument (whether the vendor’s calibration label is left on or removed) to indicate that the instrument has been updated and will be controlled under the MP Recall system.</li> <li>If the instrument is borrowed from another Division, then the original Calibration Control Number will be left on the instrument and used as the instrument’s control number.</li> </ul>                                                                                                                                                                                                                                                                                                                  |         |
| <b>Calibration Report Status</b>                            | <ul style="list-style-type: none"> <li>IN TOLERANCE - Term used when compliance statement is given for measurement plus uncertainty that falls within a specified tolerance</li> <li>OUT OF TOLERANCE - Term used when statement is given for measurement plus uncertainty that falls outside a specified tolerance</li> <li>AS FOUND-AS LEFT / AS REPORTED – Term used for measurements wherein tolerance plus uncertainty exceeded the specifications, and compliance statement was not provided.</li> <li>AS FOUND –AS LEFT / REPORT OF VALUE –Term used when statement is given for measurement where there is no specified tolerance</li> <li>LIMITED – When an instrument fails calibration but is still functional in a limited manner , the following will be shown in Calibration Certificate: <ul style="list-style-type: none"> <li>Received: “Out of Tolerance” and Returned “Limited Use”.</li> </ul> </li> </ul> |         |

# Calibration System

## Description

MP CSD

**Table 5 – Status Labeling**

| Item                  | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Remarks |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                       | <ul style="list-style-type: none"> <li>LIMITED USE – When an instrument is received with an existing “Limited Use” identifier (i.e. Limited Label) then following will be shown in the Calibration Certificate: <ul style="list-style-type: none"> <li>Received: “Limited Use” and Returned “Limited Use”.</li> <li>Supporting data concerning the existing limitations will be reported on the Calibration Certificate in either the "Notes" section or "Data" section of the certificate, as appropriate.</li> </ul> </li> <li>REJECTED - When an instrument fails calibration and is rejected, the following will be shown in the Calibration Certificate: <ul style="list-style-type: none"> <li>Received: “Out of Tolerance” or “Inoperative”.</li> <li>Returned: “Rejected” or “Inoperative”</li> <li>Supporting data concerning the existing limitations will be reported on the Calibration Certificate in either the "Notes" section or "Data" section of the certificate, as appropriate.</li> </ul> </li> <li>ADJUSTED - When adjustments are made to an instrument which changes its original accuracy from the accuracy that existed when it was received, the following will be shown on the calibration certificate: <ul style="list-style-type: none"> <li>Received: “Out of Tolerance” and Returned: “In Tolerance”.</li> </ul> </li> <li>REPAIRED - When an instrument is received inoperative or found to be out of tolerance and cannot be adjusted to specification and a repair is completed on the unit, the following will be shown on the calibration certificate: <ul style="list-style-type: none"> <li>Received: “Inoperative” or “Out of Tolerance”</li> <li>Returned: “Repaired and Adjusted”</li> </ul> </li> </ul> |         |
| <b>Decision Rules</b> | <p>Statements of Pass or Fail Conformance</p> <p>All measurements and test results guard banded to ensure the probability of false-accept does not exceed 2% in compliance with ANSI/NCSL Z540.3-2006.</p> <p>The status of compliance with the acceptance criteria is reported as:</p> <p>PASS - Compliant with specification</p> <p>PASS<sup>2</sup> - The measured value is within acceptance limits. However, a portion of the expanded uncertainty of measurement at 95% exceeds the specified tolerance.</p> <p>FAIL<sup>2</sup> - The measured value is not within the acceptance and specified tolerance limits. However, a portion of the expanded uncertainty of measurement at 95% is within the specified tolerance.</p> <p>FAIL - Not compliant with specification.</p> <p>The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k=2, which for a normal distribution corresponds to a coverage probability of approximately 95%, unless otherwise stated.</p> <p>This calibration report complies with ISO/IEC 17025:2017 and ANSI/NCSL Z540.3-2006, Method 6 – Guard Bands Based on Test Uncertainty Ratio.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |

# Calibration System

## Description

MP CSD

**Table 6 – Traceability**

| Item                                         | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Traceability Definition</b>               | <ul style="list-style-type: none"> <li>Traceability is the property of a measurement result whereby the result can be related to reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
| <b>Purpose of Requiring Traceability</b>     | <ul style="list-style-type: none"> <li>To ensure that measurements are accurate representation of specific quantity subject to measurement, within the uncertainty of measurement.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |         |
| <b>Traceability Essential Elements</b>       | <ul style="list-style-type: none"> <li>An unbroken chain of comparison going back to a standard acceptable to the parties, usually a national or international standard and ending with laboratory working reference standards used.</li> <li>The uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to defined methods and must be stated so that an overall uncertainty for the whole chain maybe calculated or estimated.</li> <li>Probability of False Accept (PFA) must be calculated for any standard on the scope of accreditation for ANSI/NCSL Z540.3 accredited laboratory and included in standards certificate file.</li> <li>Documentation of each step in the chain must be performed according to documented and generally acknowledged procedures; and the results must be recorded. (Calibration Certificate)</li> <li>Technical competence: the laboratories performing one or more step in the chain must supply evidence for their technical competence. (laboratory must be accredited)</li> <li>Reference to SI units: the chain of comparisons must, where possible, end at primary standards for realization of SI units.</li> <li>Calibration Intervals: calibration must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables. (e.g. uncertainty required, frequency of use, way of use, stability of equipment)</li> </ul> |         |
| <b>Establishing Measurement Traceability</b> | <ul style="list-style-type: none"> <li>Calibration and verifications of all MP's measuring and test equipment and reference standards must be conducted by:               <ul style="list-style-type: none"> <li>An ISO/IEC 17025 Accredited Calibration laboratories;</li> <li>A recognized national or international standard laboratories;</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| <b>OEM: Original Equipment Manufacturer</b>  | <ul style="list-style-type: none"> <li>Calibrations requires to be accredited.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |

# Calibration System Description

**MP CSD**

**Table 6 – Traceability**

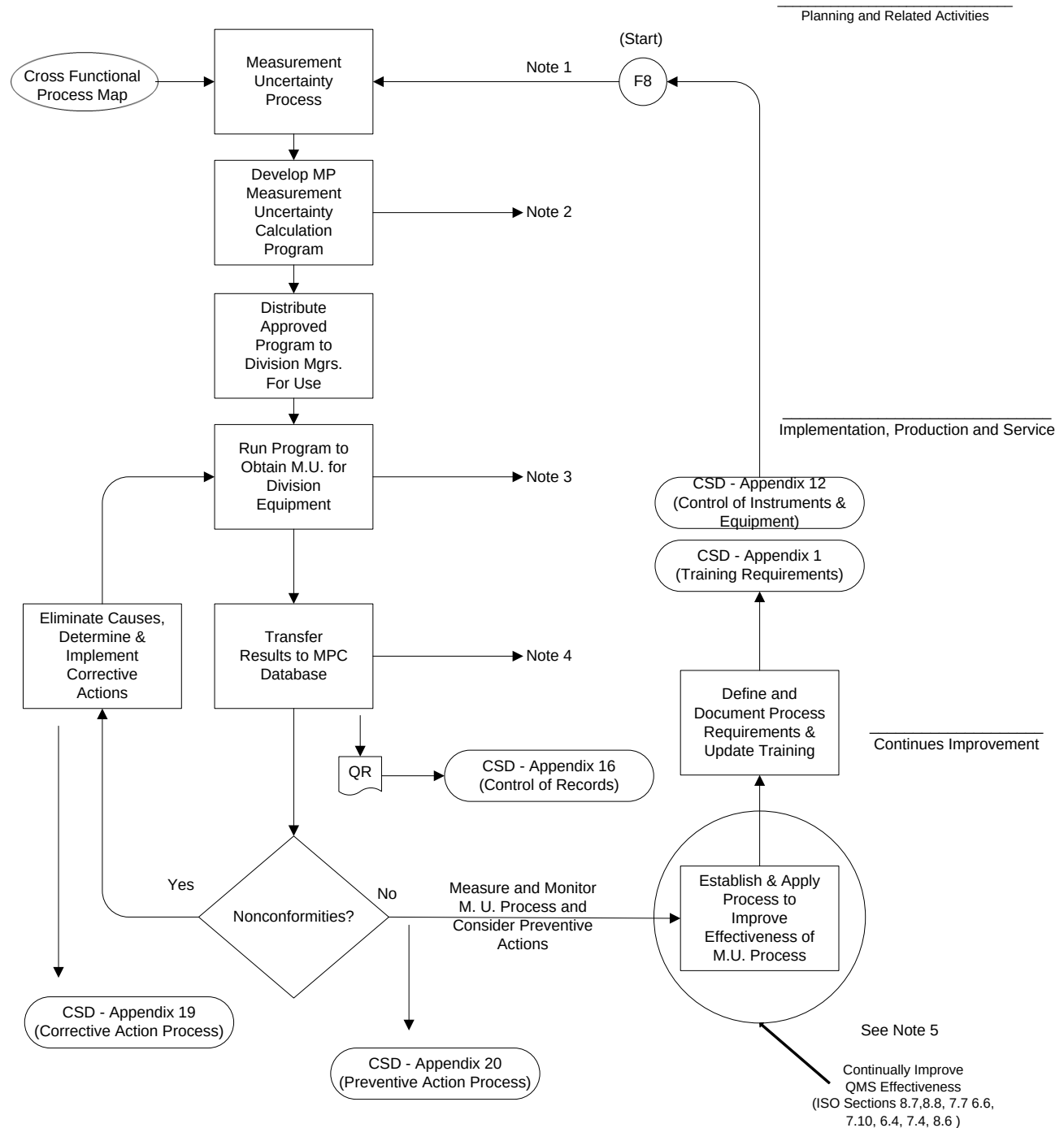
| Item                                                            | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Remarks                                                         |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| <b>New Instruments or Recalibration of Existing Instruments</b> | <ul style="list-style-type: none"> <li>Requirements to ensure Traceability in Subcontracted Orders:                             <ul style="list-style-type: none"> <li>Include all necessary information on the Purchase Order to assure that all measurement and accuracy requirements are met.</li> <li>"Service to comply with ISO/IEC 17025" is to appear on calibration service Purchase Orders.</li> <li>Services or accredited work will be consistent with Traceability Policy, competency and accreditation requirements. The accredited laboratory Certificate Number and accreditation body symbol will be required on certificates.</li> </ul> </li> </ul>                                   | Also See Appendix 10, Externally provided products and services |
| <i>Definition of In-house Calibration</i>                       | <ul style="list-style-type: none"> <li>If the calibration service is performed within the same physical location as the customer and if the calibrations are performed in a permanent calibration laboratory (i.e., customer equipment to be calibrated is transported to the calibration laboratory), then the calibration should be considered to be an in-house calibration not subject to accreditation requirements.</li> <li>If the calibration service is performed at a location other than a permanent calibration laboratory (i.e., if reference standards are being transported to the customer equipment to be calibrated), then such a calibration service should be accredited.</li> </ul> |                                                                 |
| <i>ISO/IEC 17025 Accredited Laboratories</i>                    | <ul style="list-style-type: none"> <li>Accredited test and calibration results, reported by MP accredited laboratories in a test or calibration report endorsed by the accrediting body's symbol, or which otherwise makes reference to accredited status, by a specific recognized accreditation body that is accompanied by an indication of the type of entity accredited (e.g. through inclusion of an accreditation certificate number, words such as "calibration laboratory" etc.), are recognized by <i>ISO/IEC 17025 accrediting body</i> as satisfying the requirements pertaining to measurement traceability.</li> </ul>                                                                     |                                                                 |

# Calibration System Description

## MP CSD

Ref. ISO/IEC 17025:2017 (Sections 6.4,  
4.1,8.7,8.6,8.4)  
Doc. F8

### Measurement Uncertainty Process



# Calibration System Description

MP CSD

## Process Map Notes for Flowchart F8 (Measurement Uncertainty)

### Note 1

- Review requirements in the Calibration System Description (MP-CSD)

### Note 2

- Use the GUM and example given in F8-1
- Uncertainty Budget is prepared by either the Quality Manager or Technical Manager or a designated technical person.
- Use a full validation process to check the uncertainty budget for adequacy. This validation must be conducted by someone that did NOT develop the uncertainty budget.
- Review documentation adequacy

### Note 3

- Update using new subcontractor values
- Validate as indicated in Note 2 above.

### Note 4

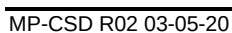
- Send copy of updated program to Corporate (web site)

### Note 5

- Monitor customer satisfaction (e.g., surveys on future requirements, etc.)
- Industry trends from various sources (e.g., Registrar, accreditation body, etc.)
- State-of-the-art developments and impact to approach (current/future)
- Revisions in quality policies and objectives
- Audit results
- Reevaluate entire uncertainty process if ILC or Proficiency Testing results are inadequate.

## MP CSD

## Interlaboratory Comparison Process



## MP CSD

## MP Standard Process

(Determining Instruments Required for Servicing)



# Calibration System

## Description

MP CSD

### Process Map Notes for Flowchart F3 (MP Standards Process)

#### Note 1

- Type of standard (i.e., reference, primary, transfer or working standard)
- Contract review/order request considerations
- Personnel (operator) capabilities for standard
- Quality policy and objectives pertaining to internal or external considerations.

#### Note 2

- Customer surveys and contract review results
- Sales and marketing inputs
- Quality policy and objectives pertaining to customers
- Customer communications

#### Note 3

- Obtain from another MP Division
- Procedure from OEM
- Procure from NIST or similar
- Lease (e.g., commercial or loan from customer)
- Choice affected by in-house capability, characteristics, function requirements, targeted market or customer, vendor approval status, statutory/regulatory requirements, historical information, etc.

#### Note 4

- Procurement vehicle (e.g., purchase order or formal contract)
- Required statements in procurement vehicle (e.g., MP language, QMS requirements, full data readings, measurement uncertainties, OEM manual, etc. (e.g., procurement document form and content))
- Records from other MP Division
- Extent of subsequent verification/repeatability study activities
- Provisions for inducting and return of loaned customer equipment used as standard

#### Note 5

- Receiving on site, pick-up or delivered to lab; applicable work instructions/procedures
- Unique ID labeling
- Inducting OEM manual and technical literature
- Using Check Standard
- Recalibration/function checks
- Equipment repeatability study and procedures
- Selection, use and development of calibration procedures
- Status labeling and tamper protection
- Vendor calibration certificate and MP Certificate
- Induction by qualified technical personnel
- Updating the database
- History and service records
- Handling, transport, storage and preservation
- Nonconformities and disposition

#### Note 6

- Calibration methods, repeatability study of methods
- Measurement uncertainty program form, format and approach
- Annual repeatability study requirements
- Identification of primary/reference standards (major standards at lab)
- Periodic Checks

# Calibration System

## Description

MP CSD

- Recall system and readjustments
- Handling, transport, storage and preservation
- Labeling and tamper protection
- Nonconformities, corrective and preventive actions
- Environmental Controls
- Equipment History

### Note 7

- QC monitoring of standards process
- Review ILC results and measurement uncertainties
- Review results of laboratory accreditation and Registrar certification assessments, and internal audit results
- Review customer complaints and feedback, CARs/PAPs and trend analysis
- Review personnel qualifications necessary to operate new standards, etc.

### Note 8

- Monitor customer satisfaction (e.g., surveys on future requirements, etc.)
- Industry trends from various sources (e.g., Registrar, customers, vendors, competitors, business publications, etc.)
- State-of-the-art developments (improvements in standards and impact to business approach – current and future)
- Improvements and revisions in quality policies and objectives
- Audit results
- ILC Improvements

# Calibration System Description

MP CSD

## Appendix 13 – Calibration Servicing Process

**Table 1 –Responsibilities**

| Responsibility Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Service Personnel             | IT | Techs | Lab Mgr.            | QC Supv. | Div. Mgr. | QA Mgr. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----|-------|---------------------|----------|-----------|---------|
| <u>Database</u> <ul style="list-style-type: none"> <li>Design, maintenance and controls, including documentation, security, servers, functionality and associated hardware/software.</li> </ul>                                                                                                                                                                                                                                                                                                                                              |                               | X  |       |                     |          |           |         |
| <u>Receiving Inspection:</u> <ul style="list-style-type: none"> <li>Assure nomenclature and instrument identification is accurate and complete.</li> <li><input type="checkbox"/> (Quality Control) Assure that all Receiving Inspection requirements have been implemented before moving job to next stage of processing.</li> </ul>                                                                                                                                                                                                        | X<br><br>Receiving Inspectors |    |       |                     |          |           |         |
| <u>In-Process Calibration:</u> <ul style="list-style-type: none"> <li>Assure calibration data is accurate and sufficient to allow for complete reproducibility.</li> <li>Verification of traceability on all MP standards</li> <li>Ensures Certificate of Calibration is accurate and contains all information requested by the customer.</li> <li>Verify reported results, calibration procedures used, functions tested, reference standards used and standard's traceability identification, for accuracy and reproducibility.</li> </ul> |                               |    | X     | X<br><br>X<br><br>X |          |           |         |
| <u>QC and Final Inspection</u> <ul style="list-style-type: none"> <li><input type="checkbox"/> Assure that no individual performs final inspection of calibration, or to initial /or sign any Certificate of Calibration, unless they have been qualified and to assure that individuals perform their duties within their qualification and certification levels.</li> <li>Overall responsibility for final inspection service quality at the Division.</li> <li>Interface as needed on inspection-related requirements.</li> </ul>         |                               |    |       | X                   |          | X         |         |
| <ul style="list-style-type: none"> <li>At least one of these indicated authorities will inspect all Certificates of Calibration before filing or returning the Report to the customer.</li> </ul>                                                                                                                                                                                                                                                                                                                                            |                               |    |       | X                   | X        |           |         |

# Calibration System Description

MP CSD

**Table 1 –Responsibilities**

| Responsibility Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Service Personnel | IT | Techs      | Lab Mgr.   | QC Supv.            | Div. Mgr. | QA Mgr. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----|------------|------------|---------------------|-----------|---------|
| <ul style="list-style-type: none"> <li>Inspect all Certificate of Calibration for compliance with requirements of Appendix 13, Table 7 (Lab Manager or designee is responsible).</li> <li>Ensures that no status label is applied to any instrument unless there is supporting calibration and/or service documentation, which justifies the label being applied.</li> <li>Inspect all status labeling on MP instrumentation, before calibration and/or service documents are filed.</li> <li>Maintain online file at MP Teamsite, records of personnel qualification and certification for Lab Managers and QC Supervisors with authority to perform final inspection on calibration work performed (also see Appendix 1, Table 1).</li> <li>Maintain online file at MP Teamsite, records of Division QC inspection personnel (also see Appendix 1).</li> </ul> |                   |    |            | X          | X<br><br>X<br><br>X |           | X       |
| <u>Travelers</u> <ul style="list-style-type: none"> <li>Ensures that the Traveler document (similar to a Shipping Form) moves with the Work Order and equipment to the next department.</li> <li>At least one of the identified personnel who complete the <u>Receiving Inspection</u> will electronically sign, date and enter time on the Traveler prior to moving the Work Order out of their department.</li> <li>Overall responsibility for not allowing Work Order to remain in their department unless all preceding departments have electronically signed off on the Traveler.</li> <li>Final responsibility for not allowing instruments to ship unless Traveler has been electronically signed off. (Either of these individuals or qualified designee.)</li> </ul>                                                                                   | X<br><br>X        |    | X<br><br>X |            | X<br><br>X<br><br>X |           |         |
| <u>Scheduling</u> <ul style="list-style-type: none"> <li>Responsible for turn-around of jobs and timely processing of paperwork (i.e., field service reports)</li> <li>Ensures that status reports are printed and/or posted in a central area.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                   |    |            | X<br><br>X |                     |           |         |

# Calibration System Description

MP CSD

**Table 1 –Responsibilities**

| Responsibility Requirements or Activity                                                                                                                                                                                 | Service Personnel | IT | Techs | Lab Mgr. | QC Supv. | Div. Mgr. | QA Mgr. |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----|-------|----------|----------|-----------|---------|
| <ul style="list-style-type: none"> <li>Projects accurate completion dates for the Service Department to quote to customers.</li> </ul>                                                                                  |                   |    |       | X        |          |           |         |
| <u>MP Proficiency Test Study</u> <ul style="list-style-type: none"> <li>Ensures annual Proficiency Test Study is performed in accordance with the 4-year proficiency test plan and maintains results online.</li> </ul> |                   |    |       |          | X        |           |         |

**Table 2 – Overview of Work Flow and Processes During Servicing**

| Item                                                                                                                                          | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Remarks                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>General</b><br><br><i>Processing Control Center</i><br><br><i>Quality of Work</i><br><br><i>Overview and Cross-Functional Process Maps</i> | <ul style="list-style-type: none"> <li>Responsibilities for a given process are described in Table 1 of each Appendix of this CSD. <ul style="list-style-type: none"> <li>Responsibilities for receiving, in-process and final inspection activities appear in this Appendix 13, Table 1 (above).</li> </ul> </li> <li>The <u>MP Proprietary Database</u> is the control center for communications, customer requirements, corrective actions, quotes, calibration, invoicing, and tracking all items being serviced, from time of receipt through shipping. <ul style="list-style-type: none"> <li>The database is continuously updated by personnel as work is performed.</li> <li>The database is automatically backed up daily.</li> </ul> </li> <li>Service personnel and technicians will ensure the quality of work performed is consistent with the requirements of Appendix 13, Table 1 (above).</li> <li>The <u>Cross-Functional Process Map</u> illustrates the co-dependencies and interrelationships between departments for MP's product.</li> <li>The Overview of Calibration Servicing Process Map illustrates the concepts discussed in this Table 2 of Appendix 13. <ul style="list-style-type: none"> <li>Specific Process Maps are included in Appendices, as appropriate to illustrate key process concepts described.</li> <li>Process (or sub-processes) or requirements may be described through Tables included in Appendices.</li> </ul> </li> </ul> |                                      |
| <b>Personnel Qualifications and Certifications</b>                                                                                            | <ul style="list-style-type: none"> <li>Work is assigned to qualified personnel who perform calibration service according to their qualifications and their certification level (see Appendix 1).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | See Appendix 16, Control of Records. |

# Calibration System

## Description

MP CSD

**Table 2 – Overview of Work Flow and Processes During Servicing**

| Item                                                                      | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks                           |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
|                                                                           | <ul style="list-style-type: none"> <li>Evidence of qualification and certification level will be readily retrievable for customers or other concerned party's review</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | See Appendix 13, Table 1 (above). |
| <b>Requests for Service and Order Review</b>                              | <ul style="list-style-type: none"> <li>See Appendix 11 for <u>Overview of Customer Order Processing</u>.                             <ul style="list-style-type: none"> <li>Table 1 addresses Responsibilities;</li> <li>Table 2 addresses:                                     <ul style="list-style-type: none"> <li>Quotes</li> <li>Order Review Requirements</li> <li>Subcontracting Work outside of MP's Capability</li> </ul> </li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                  |                                   |
| <b>Receiving Inspection</b><br><i>Induction</i>                           | <ul style="list-style-type: none"> <li>All instruments are inducted through receiving prior to servicing to determine the nature of services required:                             <ul style="list-style-type: none"> <li>See Table 3 of this Appendix 13 addresses <u>Receiving Inspection</u> requirements and activities;</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                          |                                   |
| <i>Field Services</i><br><i>Traveler</i><br><i>Routing and Scheduling</i> | <ul style="list-style-type: none"> <li>See Appendix 3 for additional requirements applicable to receiving customer equipment during field service activities.</li> <li>A Traveler is initiated during Receiving Inspection to identify the equipment processing status and accompanies each instrument through processing.</li> <li>Equipment may be serviced:                             <ul style="list-style-type: none"> <li>In the field using the mobile unit or at customer facilities;</li> <li>In the permanent lab; and</li> <li>At externally provider facilities (e.g., repairs, warranty work, etc.).</li> </ul> </li> <li>The MP database is used in monitoring and scheduling equipment turn-around processing (see Table 4 in this Appendix 13).</li> </ul> |                                   |
| <b>Calibration and Repair Service</b><br><i>MP Standards</i>              | <ul style="list-style-type: none"> <li>The work flow process is designed to meet servicing requirements of both customer and MP test standards where work is performed (e.g., at the MP Division permanent lab, the mobile unit, or customer facility.)</li> <li>Calibration requirements for MP test standards are described in Table 5 of Appendix 13 and the following process flow diagram:                             <ul style="list-style-type: none"> <li>In-Process Inspection Servicing for MP Test Standards.</li> </ul> </li> <li>MP standards will be repaired as follows:                             <ul style="list-style-type: none"> <li>Repair in-house (where possible);</li> <li>Send to manufacturer;</li> </ul> </li> </ul>                          |                                   |

# Calibration System Description

MP CSD

**Table 2 – Overview of Work Flow and Processes During Servicing**

| Item                                                                                                                 | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Customer Equipment</i>                                                                                            | <ul style="list-style-type: none"> <li>○ Replace, if not cost effective to repair;</li> <li>○ Borrow from other Divisions.</li> <li>• MP standards will be controlled and maintained as described in Appendix 12. The following process flow diagrams also apply: <ul style="list-style-type: none"> <li>○ MP Instruments Process Map</li> <li>○ Measurement Uncertainty Process Map</li> <li>○ Inter-laboratory Comparisons Process Map</li> </ul> </li> <li>• MP standards (new or existing) that are identified as Primary Standards will undergo initial and periodic equipment proficiency test. (see Appendix 12, Table 2).</li> <li>• Calibration requirements for customer equipment are described in Table 6 of Appendix 13 and the following process flow diagram: <ul style="list-style-type: none"> <li>○ In-Process Inspection Servicing for Customer Equipment</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <i>Equipment Repairs / Damage</i><br><br><i>Calibration Methods</i><br><br><i>Environment</i><br><br><i>Database</i> | <ul style="list-style-type: none"> <li>• The calibration service process is designed to address customer equipment or MP test standards received damaged, or identified subsequent to induction, as requiring repair prior to calibration. <ul style="list-style-type: none"> <li>○ Table 3 in Appendix 13 addresses Receiving Inspection, including processing damaged equipment or equipment requiring repair;</li> <li>○ Table 5 in Appendix 13 addresses MP Test Standards;</li> <li>○ Table 6 in Appendix 13 addresses customer equipment;</li> </ul> </li> <li>• All equipment (both MP standards and customer equipment) will be calibrated using appropriate calibration methods described in Appendix 6. The process is illustrated in the following diagram: <ul style="list-style-type: none"> <li>○ Calibration Methods Process Map</li> </ul> </li> <li>• The work environment (see Appendix 5) will be monitored and designed so as to facilitate the service requirements, including work benches, temperature and humidity, ESDC, use of MP standards, computers for data entry, etc.</li> <li>• The MP Database will be reviewed and updated as calibration activities progress. <ul style="list-style-type: none"> <li>○ Improvements required to the MP Database design will be processed through Corporate, including: <ul style="list-style-type: none"> <li>▪ Clearly communicating deficiencies or improvements needed (e.g., verbal and written notice, including email, PAPs, CARs, etc. as appropriate)</li> </ul> </li> </ul> </li> </ul> |         |

# Calibration System Description

MP CSD

**Table 2 – Overview of Work Flow and Processes During Servicing**

| Item                                                                                                                   | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Remarks                 |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <i>Calibration Reports</i>                                                                                             | <ul style="list-style-type: none"> <li>▪ Identifying pertinent time frames or impact to work in connection with implementing requested improvements or changes.</li> <li>▪ Updates to the database software will be documented by the authorized individual making the updates so as to be readily retrievable and traceable.</li> <li>▪ Contingency plans will be maintained by the authorized individual as Corporate for maintaining the integrity, correctness and currency of the database, including backups, retrievability of data, protection from virus and other disasters.</li> <li>• Database records and Certificate of Calibration document the results of the calibration servicing. Certificate of Calibration contains requirements that are described in Appendix 13, Table 7 (below). Records address:               <ul style="list-style-type: none"> <li>○ Lab Accredited work (MP Laboratory's Scope of Accreditation);</li> <li>○ Non-Accredited work;</li> </ul> </li> <li>• Externally provider work</li> </ul> |                         |
| <i>Equipment Status Labels</i><br><br><i>Approved Signatories</i>                                                      | <ul style="list-style-type: none"> <li>• The calibration status of equipment is physically identified through status labels and tamper seals affixed to each instrument (Appendix 12, Table 5).</li> <li>• Personnel authorized to perform calibration servicing are identified in the Authorized Signatories List. (see Appendix 4)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |
| <b>Final Inspection</b>                                                                                                | <ul style="list-style-type: none"> <li>• Equipment and servicing paperwork are inspected prior to releasing the equipment for use (e.g., to the customer or releasing MP test standards for use by MP) (Appendix 13, Table 8 (below))</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |
| <b>Handling, Packaging, Storage and Transport</b>                                                                      | <ul style="list-style-type: none"> <li>• Sensitivity and controls are implemented throughout processing in the handling, storage, packaging and transport of equipment (both customer equipment and MP test standards).</li> <li>• Requirements are described in Appendix 9.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                         |
| <b>Monitoring and Measurement</b><br><br><i>Departures from Requirements</i><br><br><i>Control of Non-conformances</i> | <ul style="list-style-type: none"> <li>• Quality is controlled throughout the process, including post processing management reviews and measurements.</li> <li>• Pre-approved departures from requirements during any stage of processing will be handled per Appendix 7. Pre-approved departures are not considered non-conformances.</li> <li>• See Appendix 18 and the following flow diagram:</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Equipment or processes. |

# Calibration System Description

**MP CSD**

**Table 2 – Overview of Work Flow and Processes During Servicing**

| Item                                                                                                                                              | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Remarks                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                   | <ul style="list-style-type: none"> <li>○ Control of Non-conformances Process Map</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                     |
| <p><i>Corrective Action Process</i></p> <p><i>Preventive Action Process</i></p> <p><i>Internal Audits</i></p> <p><i>Continual Improvement</i></p> | <ul style="list-style-type: none"> <li>• See Appendix 19 and the following:               <ul style="list-style-type: none"> <li>○ Corrective Action Process Map</li> <li>○ Customer complaints;</li> </ul> </li> <li>• Preventive action processing is designed to address potential Non-conformances and prevent their occurrence.</li> <li>• Personnel are also encouraged to identify areas for improvement in systems, processes and tools used to perform their work.</li> <li>• See Appendix 20, Preventive Action Process</li> <li>• Prevention of non-conformances through various methods such as:               <ul style="list-style-type: none"> <li>○ Trend analysis;</li> </ul> </li> <li>• QMS activities will be audited at the Division level and globally as described in Appendix 17.</li> <li>• See Appendix 14, Management Responsibilities and Continual Improvement Process.</li> </ul> | <p>Current action taken to correct an existing error or deficiency.</p> <p>Action taken now to prevent non-conformances in the future. ISO 17025 requires continual improvement be implemented.</p> |

**Table 3 – Receiving Inspection Process**

| Item                                                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Entry Point for Receiving Inspection (Inputs)</b> | <ul style="list-style-type: none"> <li>• <u>Customer Order:</u> <ul style="list-style-type: none"> <li>○ <b>Equipment</b> (either incoming from customer, or returned from the Lab after detecting repair required);                   <ul style="list-style-type: none"> <li>▪ Equipment determined to be in need of repair will be removed from the original work order and placed on a separate repair work order.</li> </ul> </li> <li>○ <b>Incoming paperwork</b> (either from customer with equipment, or to be prepared by MP (Shipping Memorandum).                   <ul style="list-style-type: none"> <li>▪ Equipment returned from the Lab for repair processing will be accompanied by its associated paperwork.</li> <li>▪ Travelers are filed until instrument returns from repair.</li> </ul> </li> </ul> </li> </ul> |         |

## MP CSD

[illegible]

# Calibration System Description

MP CSD

**Table 3 – Receiving Inspection Process**

| Item                                                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks                                           |
|-----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <p><b>MP Picks Up Order</b></p>                                       | <ul style="list-style-type: none"> <li>○ Device value exceeds \$1,000.</li> <li>○ Damage is not easily described in writing.</li> <li>○ When outside packaging has been damaged.</li> </ul> <ul style="list-style-type: none"> <li>• Sign and date all incoming paperwork. Record the time of pickup.</li> <li>• Transport in such a way to prevent items from touching each other during transport.               <ul style="list-style-type: none"> <li>○ Use cartons, plastic trays and/or bubble bags as necessary for small parts.</li> <li>○ Keep customer orders segregated and shipping paperwork with each order.</li> </ul> </li> <li>• Use care to not allow any damage (see below) or other result that would detract from any instrument's net worth.</li> <li>• Also see <i>Outside Carrier Delivers Damaged Package or Item</i> above.</li> <li>• If damaged containers or instruments are received and the specific damage was not already documented on the incoming Shipping paperwork from the customer, then:               <ul style="list-style-type: none"> <li>○ Note the damage on the incoming customer or MP generated paperwork;</li> <li>○ Prepare a Damage Report and submit to the Customer:</li> <li>○ Perform no work on the instrument until the customer has signed and returned the Damage Report.</li> </ul> </li> </ul> |                                                   |
| <p><b>Record</b></p>                                                  | <ul style="list-style-type: none"> <li>• If damage is discovered after processing through Receiving, then stop work on the order and immediately contact Service so a Damage Report can be generated.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>May occur during calibration of equipment.</p> |
| <p><b>Work Order Set-Up</b></p> <p><i>Database Control Center</i></p> | <ul style="list-style-type: none"> <li>• Review that the paperwork accompanying the equipment contains the following information required to set up the Work Order in the database:               <ul style="list-style-type: none"> <li>○ Customer name;</li> <li>○ Equipment information (including customer-specified recall cycle);</li> <li>○ Any special service and/or handling instructions;</li> <li>○ Purchase Order or method of payment;</li> <li>○ Date received.</li> </ul> </li> <li>• If the customer is an <u>existing account</u>, the incoming paperwork must include the above information as a minimum.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                   |

# Calibration System

## Description

MP CSD

**Table 3 – Receiving Inspection Process**

| Item                                                                                                                                                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Remarks                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
|                                                                                                                                                                       | <ul style="list-style-type: none"> <li>If the customer is new (<u>account has not been established</u>), then the following are required in addition to the above: <ul style="list-style-type: none"> <li>Complete shipping address</li> <li>Complete mailing address (if other than shipping address)</li> <li>Contacts and phone numbers for both receiving and purchasing</li> </ul> </li> <li>If no paperwork accompanies <u>incoming</u> equipment, then prepare an MP Shipping Memorandum to document the receipt and review of the order. <ul style="list-style-type: none"> <li>Either incoming customer paperwork or an MP Shipper must exist in order to induct a job.</li> </ul> </li> <li>Equipment returned from the lab requiring job split off for repair processing will be identified with a new job number.</li> <li>Verify that all customer instructions detailed on incoming paperwork are logged properly into the database.</li> <li>Print out a Traveler for each item of equipment.</li> </ul>                                                                                                                                                                                                                                                                                                                                         | Appendix 16, Control of Records |
| <b>Order Review and Verification</b><br><br><i>Customer Orders (Requests for Servicing)</i><br><i>Supplier Orders (MP Purchases)</i><br><br><br><br><i>All Orders</i> | <ul style="list-style-type: none"> <li>Required for all incoming and outgoing purchase orders and associated equipment / items.</li> <li>Order Review: <ul style="list-style-type: none"> <li>Check that order requirements are defined; MP has the capability to perform the work, and resolve any issues satisfactorily with the customer, record the conversation. (see Table 2 in Appendix 11, for Informal order review processing).</li> <li>Order review is also applicable to orders from other MP Divisions.</li> </ul> </li> <li>Proceed to Customer Purchase Order Verification (below)</li> <li>Order Verification: <ul style="list-style-type: none"> <li>Verify if all items in Purchase Orders/Packing List are received. Verify customer requirements to ensure there is no effect on the quality of calibration. This applies to all: <ul style="list-style-type: none"> <li>Verify if all items in Purchase Orders/ Packing List are received.</li> <li>Verify customer requirements to ensure there is no effect on the quality of calibration. This applies to all: <ul style="list-style-type: none"> <li>Incoming purchased equipment;</li> <li>Services, including subcontracted services;</li> <li>Consumable materials.</li> </ul> </li> </ul> </li> <li>Check off the Purchase Order as each item is reviewed.</li> </ul> </li> </ul> |                                 |

# Calibration System

## Description

MP CSD

**Table 3 – Receiving Inspection Process**

| Item                           | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Paperwork Documentation</i> | <ul style="list-style-type: none"> <li>Physically count the number of <u>items</u> and verify against the count on the incoming paperwork. <ul style="list-style-type: none"> <li>Perform a physical inventory to account <u>if there is any discrepancy</u> in count of either individual items or packages.</li> <li>Complete a Shipper listing the correct count. <ul style="list-style-type: none"> <li>Itemize, if the order has 12 items or less;</li> <li>Note general info such as “10 micrometers, 2 calipers”, if the order has more than 12 items.</li> </ul> </li> </ul> </li> <li>If instruments arrive in an unopened package, then note the number of packages on the incoming paperwork (e.g., next to the receiving signature).</li> <li>Always verify that loose accessories not enclosed in an instrument’s carrying case are <u>noted on paperwork</u>, including: <ul style="list-style-type: none"> <li>carrying case</li> <li>cables, power cords</li> <li>probes</li> <li>manuals</li> <li>parts</li> <li>hardware</li> </ul> </li> <li>Label all customers packaging that will be retained for return shipment (e.g., cardboard boxes with foam inserts and hard cases).</li> </ul> |         |
| <i>Database Documentation</i>  | <ul style="list-style-type: none"> <li>Record on the work order notes, any loose accessories received with an instrument and print as a separate item on both the Traveler and the Shipper. <ul style="list-style-type: none"> <li>Separately note any accessories attached to the instrument that can be easily removed (e.g., power cords, cables, hoses and other lines).</li> <li>If accessory is removed during service and was not recorded during initial receipt, add it to the computer database so it will be included when the Shipper is generated.</li> </ul> </li> <li>Instruments with an accessory case can be listed as “Case with Accessories”, eliminating the requirement to list each item in the case; however, listing all accessories is the preferred process.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                           |         |
| <i>Quality Control</i>         | <ul style="list-style-type: none"> <li>Assure that all of the Receiving Inspection requirements in this table have been completed as required.</li> <li>Temporarily store the items received in carts, or bins as appropriate (see Appendix 9, Table 2).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |

# Calibration System Description

MP CSD

**Table 3 – Receiving Inspection Process**

| Item                                                                                                     | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Remarks |
|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                                                          | <ul style="list-style-type: none"> <li>○ If instruments will be cleaned by Receiving Inspection, complete this activity next (see Appendix 8, Table 2).</li> <li>○ If instruments will be cleaned by Service Technicians, refer to the Cleaning and Prep (Appendix 8, Table 2)</li> </ul>                                                                                                                                                                                                                                                                           |         |
| <b>Receiving Inspection Outputs</b>                                                                      | <ul style="list-style-type: none"> <li>• Print the Travelers associated with each instrument processed through Receiving.</li> <li>• Print the list of control numbers associated with the job (number of instruments) processed through Receiving Inspection.</li> </ul>                                                                                                                                                                                                                                                                                           |         |
| <b>Cleaning &amp; Prep</b>                                                                               | <ul style="list-style-type: none"> <li>• Move the Work Order to the Cleaning and Prep (Appendix 8) area,</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |
| <b>Monitoring and Measurement</b><br><br><i>Non-conformances</i><br><br><i>Corrective Action Reports</i> | <ul style="list-style-type: none"> <li>• Report all non-conformances found to the Supervisor and see Appendix 18, Control of Nonconforming Product.</li> <li>• See Appendix19, Corrective Action Processing.</li> </ul>                                                                                                                                                                                                                                                                                                                                             |         |
| <b>Parts and Supplies</b>                                                                                | <ul style="list-style-type: none"> <li>• Check the incoming shipment against the Purchase Order.</li> <li>• Note any discrepancies on the incoming shipping document.</li> <li>• Enter date received on all documents and in the Customer Relation Management (CRM) database.</li> <li>• Make a copy of the Purchase Order and keep with the received part or supply on the Received Parts Shelf.</li> <li>• Attach the incoming shipping documents to the back of the Purchase Order and send Purchase Order to Corporate Headquarter Accounts Payable.</li> </ul> |         |

**Table 4 – Traveler and Equipment Turn-Around**

| Item                           | Requirements                                                                                                                                                                                                                                                                                         | Remarks                                                                       |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| <b>Completion and Sign-off</b> | <ul style="list-style-type: none"> <li>• Travelers at each key processing stage: <ul style="list-style-type: none"> <li>○ Receiving Inspection (Receiving Traveler in Table 3 of this Appendix 13).</li> <li>○ Clean / Prep (Clean / Prep Traveler in Table 2 of Appendix 8).</li> </ul> </li> </ul> | Also see Appendix 13, Table 1 – Responsibilities (Traveler and Scheduling for |

# Calibration System Description

MP CSD

**Table 4 – Traveler and Equipment Turn-Around**

| Item                                                                                                                                                                                        | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------|-------|--------|--------|--------|---------|---------|---------|--------|--------|--------|--------|--------|--------|--|
|                                                                                                                                                                                             | <ul style="list-style-type: none"> <li>Calibration servicing (Appendix 13, Table 5, Calibration Service).</li> <li>Final Inspection (Final Inspection Traveler) in Table 8 of this Appendix 13).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | turnaround processing) |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| <b>Traveler Contents</b>                                                                                                                                                                    | <ul style="list-style-type: none"> <li>Travelers will be designed to identify the Job number, customer name, shipping method, special handling instructions, permanent account service instructions and details of the equipment:               <ul style="list-style-type: none"> <li>Calibration Control Number</li> <li>Equipment description</li> <li>Manufacturer (if available)</li> <li>Model Number (if available)</li> <li>Serial Number (if available)</li> <li>Calibration Interval</li> </ul> </li> <li>The MP Database will be checked for communications and job activities, prior to proceeding on any job process.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                        |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| <b>Turn-Around Guidance</b><br><br><i>Turn-Around Processing Times:</i><br><br><i>Job Check-in Cleaning Prep</i><br><br><i>Calibrated</i><br><i>QC Inspection</i><br><i>Complete / Ship</i> | <ul style="list-style-type: none"> <li>Maximum (Normal, repairs and unusual calibration): 45 days.</li> <li>Customer approval and/or Division Manager approval is required.</li> <li>Return to customer “as is” or subcontract early enough to keep within this parameter.</li> </ul> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;">5 Days</td><td style="width: 33%; text-align: center;">6 Days</td><td style="width: 33%; text-align: center;">7 Day</td></tr> <tr> <td style="text-align: center;">8 hrs.</td><td style="text-align: center;">8 hrs.</td><td style="text-align: center;">8 hrs.</td></tr> <tr> <td style="text-align: center;">16 hrs.</td><td style="text-align: center;">24 hrs.</td><td style="text-align: center;">32 hrs.</td></tr> <tr> <td style="text-align: center;">8 hrs.</td><td style="text-align: center;">8 hrs.</td><td style="text-align: center;">8 hrs.</td></tr> <tr> <td style="text-align: center;">8 hrs.</td><td style="text-align: center;">8 hrs.</td><td style="text-align: center;">8 hrs.</td></tr> </table> <p>Note: Based on 8 hr. workday (e.g. if task performed last 2 hrs. of a day and finished 1 hr. later on next day, total time lapsed is 3 hrs.)</p> | 5 Days                 | 6 Days | 7 Day | 8 hrs. | 8 hrs. | 8 hrs. | 16 hrs. | 24 hrs. | 32 hrs. | 8 hrs. | 8 hrs. | 8 hrs. | 8 hrs. | 8 hrs. | 8 hrs. |  |
| 5 Days                                                                                                                                                                                      | 6 Days                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 7 Day                  |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| 8 hrs.                                                                                                                                                                                      | 8 hrs.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 8 hrs.                 |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| 16 hrs.                                                                                                                                                                                     | 24 hrs.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 32 hrs.                |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| 8 hrs.                                                                                                                                                                                      | 8 hrs.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 8 hrs.                 |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| 8 hrs.                                                                                                                                                                                      | 8 hrs.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 8 hrs.                 |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |
| <b>Status Controls</b>                                                                                                                                                                      | <ul style="list-style-type: none"> <li>Keep status information current in the computer on on-going basis.               <ul style="list-style-type: none"> <li>Maintained by the Technicians, Service Department, Repair Coordinator, Shipping and Receiving personnel.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                        |        |       |        |        |        |         |         |         |        |        |        |        |        |        |  |

# Calibration System Description

MP CSD

**Table 4 – Traveler and Equipment Turn-Around**

| Item                | Requirements                                                                                                                                                                                                                                                                                                                                                   | Remarks |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Status Lists</i> | <ul style="list-style-type: none"> <li>Status Lists support the Calibration Management Software System. <ul style="list-style-type: none"> <li>Status List will be maintained in the Calibration Management Software and displayed on a monitor at the facility. The status list to be viewable by all personnel in a central location.</li> </ul> </li> </ul> |         |
| <i>Field Work</i>   | <ul style="list-style-type: none"> <li>See Appendix 3, Table 2 (for Completing Calibration Certificates).</li> </ul>                                                                                                                                                                                                                                           |         |

**Table 5 – Calibrating and Servicing MP Instruments**

| Item                                                                                                                         | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| <b>Entry Point for Servicing MP Instruments (Inputs)</b><br><br><i>Prerequisites</i><br><br><i>Select Job to be Serviced</i> | <ul style="list-style-type: none"> <li>The job has been inducted by Receiving Inspection (Table 3 of this Appendix) and has been located with associated paperwork on the designated shelves in the Laboratory.</li> <li>Traveler must be forwarded by Receiving and Clean/Prep. <ul style="list-style-type: none"> <li>If instrument requires further cleaning by calibration technician, clean in accordance with Appendix 8, Table 2.</li> </ul> </li> <li>Review Status Lists to select next job and instruments requiring servicing. <ul style="list-style-type: none"> <li>If test standard is a <b>secondary standard</b> (i.e., working standard), then instrument may be calibrated in-house by MP using a primary standard. <ul style="list-style-type: none"> <li>Proceed to In-process Inspections (below).</li> </ul> </li> <li>If test standard is a <b>primary standard</b> (i.e., identified as a major test equipment in Appendix 12, Table 2), then instrument is to be sent to either the manufacturer or an accredited calibration laboratory listed on the Approved Vendor List. <ul style="list-style-type: none"> <li>Proceed to Evaluating Calibration Results (below).</li> </ul> </li> </ul> </li> </ul> | Appendix 13, Table 3, Receiving Inspection<br><br>See Appendix 13, Table 1, Responsibilities (Scheduling) |

# Calibration System

## Description

MP CSD

**Table 5 – Calibrating and Servicing MP Instruments**

| Item                                                                                                                                                                                                                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>In-Process Inspections:</b><br><br><i>Missing Parts</i><br><br><i>Physical Damage</i><br><br><i>Function Check Results</i><br><br><i>Repairs</i><br><br><i>Environment</i><br><br><i>Test instruments</i><br><br><i>Procedures</i> | <ul style="list-style-type: none"> <li>Check Work Order for instructions. <ul style="list-style-type: none"> <li>Update Work Order for processing instrument (e.g., code the instrument location / status, etc.)</li> </ul> </li> <li>Inspect for missing parts; if missing, see Clean / Prep Instrument, Appendix 8, Table 2.</li> <li>Inspect instrument for physical damage (mishandling, abuse, etc.) <ul style="list-style-type: none"> <li>If no evidence of damage or abuse, and instrument will be calibrated by MP, perform function check</li> <li>If evidence of damage or abuse is found, or if instrument gives suspect results, shown by verification, or otherwise to be defective, or outside specified limits, see Nonconformance processing (Appendix 18, Table 2)</li> </ul> </li> <li>If instrument will be repaired and/or calibrated by manufacturer or external provider, see: <ul style="list-style-type: none"> <li>Quote Process Map (ref. Order Review (Process), Appendix 11);</li> <li>Externally provider products and services (Appendix 10, Table2).</li> </ul> </li> <li>Check environmental controls (e.g., temperature and humidity, etc.) and record in Worksheet or in computer. <ul style="list-style-type: none"> <li>If environment is outside specifications (Appendix 5, Table 2), see Nonconformance processing (Appendix 18, Table 2);</li> <li>For dimensional, no work is performed outside of dimensional limits.</li> </ul> </li> <li>Check status and availability of MP test instruments (computer and Appendix 12, Table 3) <ul style="list-style-type: none"> <li>Instruments or standards with calibration dates that are overdue will not be used.</li> <li>If nonconformance is found in MP test instruments, see Nonconformance processing (Appendix 18, Table 2).</li> </ul> </li> <li>Determine calibration method to be implemented and that required calibration procedures are available (see Appendix 6, Table 2)</li> </ul> |         |
| <b>Begin Calibrating MP Instrument</b><br><br><i>Test Standards</i>                                                                                                                                                                   | <ul style="list-style-type: none"> <li>Appendix 12 addresses MP instrument control requirements.</li> <li>Use test instrument(s) and follow calibration method to calibrate instrument under test.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |

# Calibration System

## Description

MP CSD

**Table 5 – Calibrating and Servicing MP Instruments**

| Item                                                                                                                                                                                                        | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Remarks                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <p><i>Departures</i></p> <p><i>Recall</i></p> <p><i>MP Instrument Repeatability Study</i></p> <p><i>Inter-laboratory Calibration</i></p> <p><i>Before and After Readings</i></p> <p><i>Traceability</i></p> | <ul style="list-style-type: none"> <li>○ If necessary to deviate from procedure requirements, see permitting departures process, Appendix 7, Table 2.</li> <li>• Establish the recall cycle for the MP instrument being calibrated.</li> <li>• If this is a new, major MP instrument, perform initial repeatability study</li> <li>• If this is an existing, major MP instrument, and it has been a year since the last repeatability study, perform the annual repeatability study</li> <li>• Use the applicable repeatability study procedure (determined by the Lab Manager). <ul style="list-style-type: none"> <li>○ Complete repeatability study records.</li> </ul> </li> <li>• If this instrument is being calibrated as part of an inter-laboratory comparison, the following occurs: <ul style="list-style-type: none"> <li>○ Accumulate data and update the existing composite of results from all laboratories;</li> <li>○ The updated composite is published on the team site;</li> <li>○ Accrediting bod reviews the data either prior to assessment or during the lab assessment;</li> <li>○ Analyzed results are shown for any outliers and a follow-up report prepared showing the current status/conclusions; <ul style="list-style-type: none"> <li>• A CAR is prepared and determination made of what caused the outlier.</li> <li>• Control limits are estimated to reduce the likelihood of outliers.</li> </ul> </li> </ul> </li> <li>• If a Reference Standard is being calibrated, perform the calibration before and after making any adjustments.</li> <li>• Take full data readings as instrument is calibrated. <ul style="list-style-type: none"> <li>○ Record readings as measured and enter into computer database (use Worksheet if computer is not available and update database later). See Appendix 13, Table 7, Calibration Report Requirements.</li> <li>○ Update MP instrument Service Report for repairs and calibrations. <ul style="list-style-type: none"> <li>• Service records may not need to be updated if the MP standard is a dimensional item with no moving parts.</li> </ul> </li> </ul> </li> <li>• Assure that the required Traceability is achieved: <ul style="list-style-type: none"> <li>○ Accredited laboratories must satisfy the Traceability Policy (see Appendix 12, Table 6).</li> </ul> </li> </ul> | <p>Appendix 13, Table 1, Responsibilities</p> <p>Appendix 16, Control of Records</p> |

# Calibration System

## Description

MP CSD

**Table 5 – Calibrating and Servicing MP Instruments**

| Item                                                                                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks                                            |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
|                                                                                                                           | <ul style="list-style-type: none"> <li>Records listed in the Table 2 in Appendix 16, Control of Records are mandatory to establish traceability</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                    |
| <p><b>Evaluate Calibration Results:</b></p> <p><i>Nonconforming MP Instrument</i></p> <p><i>OOT (Accredited Work)</i></p> | <ul style="list-style-type: none"> <li>If the calibration results <b>are satisfactory</b>:               <ul style="list-style-type: none"> <li>Complete and affix the calibration label and tamper seals to the instrument (Appendix 12, Table 5).</li> <li>For subcontracted calibration services, review the Externally Provider Calibration Report for compliance with order requirements, ISO / IEC 17025, etc. as applicable.</li> <li>Print and sign the MP Calibration Report (Appendix 13, Table 7).</li> </ul> </li> <li>If the MP instrument calibration results are unsatisfactory:               <ul style="list-style-type: none"> <li>Complete and affix the red reject label and segregate the instrument (Appendix 12, Table 5).</li> <li>Update the database.</li> <li>Notify the Lab Manager.</li> <li>Prepare a CAR (see Appendix 19).</li> <li>Evaluate the impact (see Control of Nonconforming Product, Appendix 18).</li> </ul> </li> <li>In addition to NC processing, laboratory personnel will also:               <ul style="list-style-type: none"> <li>Take into consideration the measurement uncertainty of the affected measurement point.</li> <li>If the OOT can be brought into tolerance by subtracting one standard deviation of the total combined uncertainty, then report this information on the Calibration Certificate.</li> </ul> </li> <li>Select alternate measurement techniques when available to reduce measurement uncertainty and/or to substantiate both intolerance and out-of-tolerance conditions.</li> </ul> | <p>Applies to either customer or MP equipment.</p> |
| <b>Complete the Calibration (Outputs)</b>                                                                                 | <ul style="list-style-type: none"> <li>Prepare to move the order to the next stage of processing:               <ul style="list-style-type: none"> <li>Record the completion time on the Traveler (Appendix 13, Table 4);</li> <li>Update the database with the equipment location, etc.</li> <li>Move the instruments and its paperwork to Final Inspection.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                    |

# Calibration System Description

MP CSD

**Table 5 – Calibrating and Servicing MP Instruments**

| Item                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Remarks |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Exit Point for Servicing (Outputs)</b> | <ul style="list-style-type: none"> <li>Updated database</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |
|                                           | <ul style="list-style-type: none"> <li>Serviced MP test instrument (i.e., calibrated and/or repaired)                             <ul style="list-style-type: none"> <li>Calibration Report</li> <li>Traveler</li> <li>Incoming documents (Purchase Order, Shipper, Etc.)</li> </ul> </li> <li>Equipment without service (i.e., not calibrated nor repaired)                             <ul style="list-style-type: none"> <li>Hold for Evaluation Report</li> <li>Traveler</li> <li>Incoming documents (Purchase Order, Shipper, Etc.)</li> </ul> </li> </ul> |         |

**Table 6 – Calibrating and Servicing Customer Equipment**

| Item                                                                                                                             | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Remarks                                                                                                                |
|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>Entry Point for Servicing Customer Equipment (Inputs)</b><br><br><i>Prerequisites</i><br><br><i>Select job to be serviced</i> | <ul style="list-style-type: none"> <li>The job has been inducted by Receiving Inspection (Table 3 of this Appendix) and has been located with associated paperwork on the designated waiting for service shelves in the Laboratory.</li> <li>Traveler must be initiated in Receiving and Clean/Prep stage.                             <ul style="list-style-type: none"> <li>If instrument requires further cleaning by calibration technician, clean in accordance with Appendix 8, Table 2.</li> </ul> </li> <li>Review database and/or status list to select next job and instruments requiring servicing.</li> </ul>                              | Appendix 13,<br>Table 3<br>– Receiving Inspection<br><br>See Appendix 13,<br>Table 1,<br>Responsibilities (Scheduling) |
| <b>In-Process Inspections:</b><br><br><i>Missing Parts</i><br><br><i>Physical Damage</i>                                         | <ul style="list-style-type: none"> <li>Check database for customer special instructions                             <ul style="list-style-type: none"> <li>Update database for processing instrument (e.g., code the instrument location / status, etc.)</li> </ul> </li> <li>Inspect for missing parts; if missing, see Clean / Prep Instrument, Appendix 8, Table 2.</li> <li>Inspect instrument for physical damage (mishandling, abuse, etc.)                             <ul style="list-style-type: none"> <li>If no evidence of damage or abuse, <u>and instrument will be calibrated</u> by MP, perform function check.</li> </ul> </li> </ul> |                                                                                                                        |

# Calibration System

## Description

MP CSD

**Table 6 – Calibrating and Servicing Customer Equipment**

| Item                                        | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Remarks |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Repairs</i>                              | <ul style="list-style-type: none"> <li>○ If instrument will be repaired and/or calibrated by manufacturer or external provider: <ul style="list-style-type: none"> <li>• If customer has requested repair service when equipment was sent to MP, then see:</li> <li>• Quote Process Map (New Orders and Repairs) (ref. Order Processing, Appendix 11);</li> <li>• Externally provider products and services (Appendix 10, Table 2 and Procurement Process Map).</li> </ul> </li> <li>○ If equipment was identified by MP as needing repair servicing (e.g., could not be calibrated without repair), then see: <ul style="list-style-type: none"> <li>• Quote Process Map (ref. Order Processing, Appendix 11);</li> <li>• Receiving Inspection processing (Table 3 in this Appendix 13).</li> </ul> </li> </ul> |         |
| <i>Environment</i>                          | <ul style="list-style-type: none"> <li>• Check environmental controls (e.g., temperature and humidity, etc.) and record in Worksheet or in computer. <ul style="list-style-type: none"> <li>○ If calibration is a field service, see Appendix 3.</li> <li>○ If environment is outside specifications (Appendix 5, Table 2), see Control of Nonconforming Product, Appendix 18, Table 2).</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <i>Test instruments</i>                     | <ul style="list-style-type: none"> <li>• Check status and availability of MP test instruments (computer and Appendix 12, Table 3) <ul style="list-style-type: none"> <li>○ Instruments or standards with calibration dates that are overdue will not be used.</li> <li>○ If nonconformance is found in MP test instruments, see Control of Nonconforming Product, Appendix 18, Table 2).</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <i>Procedures</i>                           | <ul style="list-style-type: none"> <li>• Determine calibration method to be implemented and that required calibration procedures are available (see Appendix 6, Table 2).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |
| <b>Begin Calibrating Customer Equipment</b> | <ul style="list-style-type: none"> <li>• Appendix 12, Table 4 addresses controls for customer equipment.</li> <li>• Use test instrument(s) and follow calibration method to calibrate instrument under test.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |
| <i>Departures</i>                           | <ul style="list-style-type: none"> <li>○ If necessary to deviate from procedure requirements, see Permitting Departures process, Appendix 7, Table 2.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |

## MP CSD

| Item                                                                                                                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                     |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| <i>Recall</i><br><br><i>New Instruments</i><br><br><i>Taking Readings</i><br><br><br><i>Traceability</i>             | <ul style="list-style-type: none"> <li>Obtain the recall cycle from the customer for the instrument being calibrated. (see Appendix 12, Table 4)</li> <li>If this is a new customer instrument, select the calibration procedure.</li> <li>Read measurements as instrument is being calibrated and compare to allowable and tolerance.               <ul style="list-style-type: none"> <li>Record either pass/fail or full data readings, according to customer requirements.</li> <li>Record results in computer (use Worksheet if computer is not available and update computer later). See Appendix 13, Table 7 (Calibration Report Requirements) and Appendix 3 (if performing a field service calibration).</li> </ul> </li> <li>Assure that the required Traceability is achieved (see Appendix 12, Table 6).</li> </ul>                                                                                                                                                                                                                                                                                              | Appendix 16, Control of Records.            |
| <b>Evaluate Calibration Results:</b><br><br><br><br><br><br><br><br><br><br><i>Nonconforming customer Instrument</i> | <ul style="list-style-type: none"> <li>If the calibration results <b>are satisfactory</b>:               <ul style="list-style-type: none"> <li>Complete and affix the calibration label and tamper seals to the instrument (Appendix 12, Table 5)</li> <li>Print and review the Calibration Report (Appendix 13, Table 7).                   <ul style="list-style-type: none"> <li>The printed technician's name will appear in the printed Report.</li> </ul> </li> </ul> </li> <li>If the calibration results are unsatisfactory:               <ul style="list-style-type: none"> <li>Complete and affix the red reject label to and segregate the instrument (Appendix 12, Table 5)</li> <li>Update the database.</li> <li>Notify the Lab Manager</li> <li>Contact the customer</li> <li>Print a Calibration Report and identify in the report that the equipment has been rejected.                   <ul style="list-style-type: none"> <li>If customer does not require hard copies of their calibration reports, notify the customer concerning any out-of-tolerance condition.</li> </ul> </li> </ul> </li> </ul> |                                             |
| <i>OOT (Accredited Work)</i>                                                                                         | <ul style="list-style-type: none"> <li>In addition to NC processing, laboratory personnel will also:               <ul style="list-style-type: none"> <li>Take into consideration the measurement uncertainty of the affected measurement point.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Applies to either customer or MP equipment. |

# Calibration System Description

MP CSD

**Table 6 – Calibrating and Servicing Customer Equipment**

| Item                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                           | <ul style="list-style-type: none"> <li>○ If the OOT can be brought into tolerance by subtracting one standard deviation of the total combined uncertainty, then report this information on the Calibration Certificate.</li> <li>• Select alternate measurement techniques when available to reduce measurement uncertainty and/or substantiate both intolerance and out-of-tolerance conditions.</li> </ul>                                                                                                                                                                                                                                                                                                  |         |
| <i>Repair Required</i>                    | <ul style="list-style-type: none"> <li>○ If the instrument requires repair, see “<i>Repairs</i>” under In-Process Inspection (above) in this Table.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| <b>Complete the Calibration</b>           | <ul style="list-style-type: none"> <li>• Prepare to move the order and its paperwork to the next stage of processing:               <ul style="list-style-type: none"> <li>○ Record the completion time on the Traveler (Appendix 13, Table 4);</li> <li>○ Update the database with the instrument’s location, etc.</li> <li>○ Move the job / instruments and its paperwork to Final Inspection. Paperwork includes:                   <ul style="list-style-type: none"> <li>• Shipper;</li> <li>• Calibration Report (either successful calibration or identified as rejected);</li> <li>• Hold for Evaluation</li> <li>• Quote (if instrument is being returned as is);</li> </ul> </li> </ul> </li> </ul> |         |
| <b>Exit Point for Servicing (Outputs)</b> | <ul style="list-style-type: none"> <li>• Undated database;</li> <li>• Serviced equipment (i.e., calibrated and/or repaired) or               <ul style="list-style-type: none"> <li>○ Calibration Report</li> <li>○ Traveler</li> <li>○ Incoming documents (Purchase Order, Shipper, Etc.)</li> </ul> </li> <li>• Equipment without service (i.e., not calibrated nor repaired)               <ul style="list-style-type: none"> <li>○ Hold for Evaluation Report</li> <li>○ Traveler</li> <li>○ Incoming documents (Purchase Order, Shipper, Etc.)</li> </ul> </li> </ul>                                                                                                                                    |         |

## MP CSD

[illegible]

## MP CSD

| Item                               | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks                                                                         |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
|                                    | <ul style="list-style-type: none"> <li>• Customer name and address;</li> <li>• Date of receipt of calibrated or tested item               <ul style="list-style-type: none"> <li>○ Where critical to the validity and application of the results.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                 |                                                                                 |
| Unit Under Test                    | <ul style="list-style-type: none"> <li>• Description, condition and unique identification of equipment Calibrated</li> <li>• Characterization and condition of the calibrated or tested item (e.g., In-Tolerance, Out-of-Tolerance, Inoperative, As-Is, or Limited Use).</li> <li>• Date of calibration or test (where appropriate).</li> <li>• Units of measure.</li> </ul>                                                                                                                                             | Where relevant.<br><br>This requirement may be superseded by legal regulations. |
| Results Pre/Post Calibration       | <ul style="list-style-type: none"> <li>• Calibration results obtained after any adjustment and repair (data and/or condition status) and unit of measurement.</li> <li>• Calibration results obtained before any adjustment and repair (data and/or condition status) and units of measurement</li> </ul>                                                                                                                                                                                                                |                                                                                 |
| Calibration Cycle                  | <ul style="list-style-type: none"> <li>• Calibration due date and assigned calibration interval</li> </ul> <p>Note: No recommendation on the calibration interval will be shown on the Certificate of Calibration or Calibration Label, except where it has been agreed (in writing) with the customer</p>                                                                                                                                                                                                               |                                                                                 |
| Methods Used                       | <ul style="list-style-type: none"> <li>• Identification of the Calibration Procedure or test method used, or unambiguous description of any non-standard method used.</li> </ul>                                                                                                                                                                                                                                                                                                                                         |                                                                                 |
| MP Standards Used                  | <ul style="list-style-type: none"> <li>• List of calibration standards used, calibration expiration date and unique number that can be used for reverse traceability.</li> </ul>                                                                                                                                                                                                                                                                                                                                         |                                                                                 |
| Reporting Traceability             | <ul style="list-style-type: none"> <li>• Traceability statement               <ul style="list-style-type: none"> <li>○ Evidence that the measurements are traceable.</li> </ul> </li> <li>• Designated limits of permissible error.</li> </ul>                                                                                                                                                                                                                                                                           |                                                                                 |
| Reporting Environmental Conditions | <ul style="list-style-type: none"> <li>• Relevant environmental conditions having an influence on the measurable results, including:               <ul style="list-style-type: none"> <li>○ A statement about any corrections thus necessary, including:                   <ul style="list-style-type: none"> <li>- Deviations from, additions to or exclusions from the calibration or test method, and</li> <li>- Any other information relevant to a specific calibration or test.</li> </ul> </li> </ul> </li> </ul> |                                                                                 |

## MP CSD

| Item                                                                          | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                               | <ul style="list-style-type: none"> <li>Measurements, examinations and derived results such as pre/post readings and/or parameters tested with final results, including any failures identified, supported, where appropriate, by:               <ul style="list-style-type: none"> <li>Attached relevant tables, graphs, sketches and photographs, as appropriate.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| Reporting Estimated Uncertainties                                             | <ul style="list-style-type: none"> <li>The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k=2, which for normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined based on:               <ul style="list-style-type: none"> <li>EA-4/02-Expression of Uncertainty of Measurement In Calibration.</li> <li>NIST Technical Note 1297, 1994 Edition, Guides for Evaluating and Expressing the Uncertainty of NIST Measurement Results.</li> <li>Guide to the Expression of Uncertainty in Measurement (GUM)</li> <li>UKAS M3003 Edition 2, Jan 2007</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                         |         |
| Reporting Maintenance Details<br><br>Personnel Identification and QC Controls | <ul style="list-style-type: none"> <li>Maintenance details such as:               <ul style="list-style-type: none"> <li>Servicing</li> <li>Adjustment and repairs, including before and after results</li> <li>New value assigned</li> <li>De-rating</li> </ul> </li> <li>Modifications carried out</li> <li>Any special limitations in use</li> <li>Identification of person(s) preparing and performing the calibration               <ul style="list-style-type: none"> <li>Signature and title or equivalent identification.</li> </ul> </li> <li>Identification of person(s) responsible for accepting responsibility for and ensuring the correctness of the recorded information (however produced) and date of use.               <ul style="list-style-type: none"> <li>Signature and title or an equivalent identification.</li> </ul> </li> <li>Statement that results relate only to the items calibrated or tested (where relevant).</li> <li>Statement that the Certificate of Calibration shall not be reproduced except in full, without the written approval of MP QA Manager.</li> <li>Warranty statement.</li> </ul> |         |

## MP CSD

| Item                                                                                                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Remarks                                                            |
|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| <b>MP Lab Accredited Calibration Certificate</b>                                                     | <ul style="list-style-type: none"> <li>This section is applicable for both field and permanent Lab Accredited work.</li> <li>In addition to meeting Certificate / Report requirements listed above, MP accredit Divisions performing Scope of Accreditation work are also subject to the policies and requirements in this section.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Also see Appendix 2 for other Accredited lab advertising policies. |
| <p><i>Logo and Lab Certificate Number</i></p><br><br><br><p><i>Using the "Accredited symbol"</i></p> | <ul style="list-style-type: none"> <li>Display both the Accredited Lab Certificate Number and "Accredited" symbol in a prominent location on the Certificate of Calibration issued under the laboratory's Scope of Accreditation.               <ul style="list-style-type: none"> <li>The accredited symbol shall always be accompanied by the Accredited Lab Certificate Number and an indication of the type of organization accredited</li> </ul> </li> <li>The accredited symbol shall be used by accredited MP Divisions only under the MP Division's name in which it holds accreditation.</li> <li>The accredited symbol may be displayed on all Certificate of Calibration that contains results from calibrations that have been carried out within the accredited MP Division's official Scope of Accreditation.</li> <li>The accredited symbol shall not be used on Certificates of Calibration if none of the results presented are from activities included on their Scopes of Accreditation.               <ul style="list-style-type: none"> <li>The following reference may be included in a prominent place on the Certificate when none of the tests or calibrations is covered under the accreditation to provide customers assurance that the calibration meets the requirements of ISO/IEC 17025:<br/><br/> <i>"This laboratory maintains accreditation to ISO/IEC 17025 for the specific tests/calibrations listed in Accredited Lab Certificate No.XXX, and meets the relevant quality systems requirements. The calibration results included in this calibration, however, are not covered by this accreditation."</i> </li> </ul> </li> <li>Where both accredited and non-accredited calibrations are included on an endorsed report or Certificate, non-accredited results shall be clearly and unambiguously identified as such.               <ul style="list-style-type: none"> <li>This can be done by placing an asterisk after each result along with a footnote stating:<br/><br/> <i>"The test/calibration results are not covered by our current Scope of accreditation."</i> </li> </ul> </li> </ul> |                                                                    |

# Calibration System Description

**MP CSD**

**Table 7 – Calibration Report Requirements**

| Item                                                                                                         | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Field Calibrations<br/>(Accredited Work)</b>                                                              | <ul style="list-style-type: none"> <li>Calibration Certificates for field calibrations under Scope of Accreditation will also:               <ul style="list-style-type: none"> <li>Identify results obtained from field calibrations, whether they form part or all of the information presented;</li> <li>List the date(s) of the field services.</li> <li>Record original observations, calculations, data transfers and checks at the time made.</li> <li>Protect and safeguard data from damage and/or deterioration.</li> </ul> </li> <li>On reports where results are reported within a field where accreditation exists but in a technology that is not included in the Scope, they must be indicated.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>Also see Appendix 16, Control of Records</p> <p>Also see Appendix 15, Control of Documents, in Table 3 for Customer Confidentiality and Proprietary Rights</p> |
| <b>Customer Meeting<br/>Traceability<br/>Policy<br/>Requirements</b><br><br><i>OOT<br/>(Accredited Work)</i> | <ul style="list-style-type: none"> <li>If the intent is to ensure that the customer meets the requirements of the Traceability Policy, then:               <ul style="list-style-type: none"> <li>Calibrations performed by an accredited MP Laboratory must be included on the laboratory's Scope of Accreditation, and</li> <li>The Certificate of Calibration issued must contain accredited symbol, the Accredited Lab Certificate number and an indication of the type of entity accredited.</li> </ul> </li> <li>See Appendix 13, Table 5 (MP Instruments) and Table 6 (Customer Equipment).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                   |
| <b>Externally Provider<br/>Certificates<br/>(Accredited Work)</b>                                            | <ul style="list-style-type: none"> <li>If the final report or certificate contains only results of the subcontracted activity, an Accredited MP Divisions may include the results of subcontracted activities in its endorsed reports or certificates (i.e., containing the accredited symbol) and may portray the results as being "accredited" only if:               <ul style="list-style-type: none"> <li>The externally provider is accredited for the work by Accrediting bodies and recognized MRA partner and submitted their results on an endorsed report or certificate to the contracting organization; and</li> <li>The accredited organization has informed the client in writing of the proposed subcontracting and has obtained prior approval; and</li> <li>The externally provided work appears on the organization's own Scope of Accreditation; and</li> <li>The accredited organization has obtained approval from their Externally Provider to report excerpts from the externally provider report or certificate (where relevant); and</li> <li>The subcontracted activity results are clearly and unambiguously identified as such on the final certificate or report issued to the customer.</li> </ul> </li> </ul> |                                                                                                                                                                   |

# Calibration System Description

**MP CSD**

**Table 7 – Calibration Report Requirements**

| Item | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|      | <ul style="list-style-type: none"> <li>• If the final report or certificate contains only results of the subcontracted work and this activity is not covered by the accredited organization's Scope of Accreditation, the final report shall not include the accredited symbol and shall not imply accreditation for the work done.</li> <li>• If the final report or certificate contains only results of the subcontracted work and the externally provider is not an ISO/IEC 17025 accredited laboratory, the final report shall not include the accredited symbol and shall not imply accreditation for the work done</li> <li>• If the final report contains both externally provided work and work performed by the accredited organization itself, then the results may be included in the accredited organization's endorsed report or certificate containing accredited symbol, and maybe portrayed as being accredited only if:               <ul style="list-style-type: none"> <li>○ Any externally provided work that falls within the accredited organization's Scope of Accreditation is performed by an external provider that is itself accredited for the specific activities concerned and that submitted results on an endorsed report or certificate to the contracting organization.</li> <li>○ The accredited organization has informed the client in writing of the proposed externally provided work done and has obtained prior approval; and</li> <li>○ The accredited organization has obtained approval from their Externally provider to report excerpts from the external provider report or certificate (where relevant); and</li> <li>○ The externally provided activity results are clearly and unambiguously identified as such on the final certificate or report issued to the customer and;</li> <li>○ Any work performed outside of the accredited organization's own Scope of Accreditation and performed by an Externally Provider that is not accredited is clearly identified as "non-accredited";</li> <li>○ Any work within the accredited organization's own Scope of Accreditation but performed by an Externally Provider that is not accredited by is clearly identified as "non-accredited".</li> </ul> </li> </ul> |         |

# Calibration System Description

**MP CSD**

**Table 7 – Calibration Report Requirements**

| Item                                                       | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks                                                           |
|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| <b>Misrepresentations of Accreditation in Certificates</b> | <ul style="list-style-type: none"> <li>There shall be nothing in 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. <ul style="list-style-type: none"> <li>Calibration Certificates will clearly report on the actual work performed and the true condition of the instrument being certified.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                       | Also see Appendix 2 for MP Policy on the use of accredited symbol |
| <b>Opinions and Interpretation</b>                         | <ul style="list-style-type: none"> <li>Where statements of opinions and interpretations are included on an organization's endorsed report or certificate, such statements must be based on results from work for which the organization is accredited; otherwise the accredited organization is required to include a disclaimer such as the following in the certificate or report:<br/><br/> <i>"The opinions/interpretations identified/expressed in this report are outside the scope of this organization's Accreditation."</i> </li> <li>It is preferable, however, to express opinions and interpretations that are outside the Scope of Accreditation on a separate letter which is not part of the endorsed certificate or report and that does not carry the accredited symbol or other reference to accreditation.</li> </ul> |                                                                   |
| <b>Amendments to Certificates of Calibration</b>           | <ul style="list-style-type: none"> <li>If reissuing a Certificate of Calibration, instruct the customer to destroy the obsolete report once the new report is received, and include the following statement in the new Certificate:<br/><br/> <i>"This report replaces obsolete report number #####"</i> </li> <li>Only authorized MP technicians may amend the Certificate of Calibration maintained as quality records.</li> <li>When an issue report needs to be changed, amended or re-issued any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.</li> </ul>                                                                                                                                                                                             | Applies to accredited and non-accredited work.                    |
| <b>Handling Corrections</b>                                | <ul style="list-style-type: none"> <li>Do not erase, make illegible or delete mistakes on Certificate of Calibration.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                   |
| <b>Questionable Results</b>                                | <ul style="list-style-type: none"> <li>Recalibrate the instrument if test results are questionable, or recorded test data is insufficient to create a new Calibration report.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                   |

## MP CSD

| Item                                                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Remarks |
|-------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Entry point for Final Inspection</b>                                                   | <p>The following activities must be completed :</p> <ul style="list-style-type: none"> <li>• Receiving Inspection</li> <li>• Cleaning / Prep</li> <li>• Calibration Servicing</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <b>Inspection Activities:</b><br><br><i>Accessories</i><br><br><i>Record Requirements</i> | <ul style="list-style-type: none"> <li>• Check that Certificate of Calibration has been electronically signed by Quality Control, and authorized technicians.</li> <li>• Check that the accredited symbol only appears on Certificate of Calibration for accredited work (see Table 5, Status Labels in Appendix 12 and Appendix 2, Accredited Work).</li> <li>• Check that status labels (Appendix 12, Table 5) on equipment agree with information shown on Certificate of Calibration and supporting documents, such as:               <ul style="list-style-type: none"> <li>○ “In Tolerance”, “Limited”, “Rejected”, or “Report of Value”</li> <li>○ Calibration date</li> <li>○ Identification of technician performing the calibration.</li> <li>○ Check that each instrument has an MP calibration Control Number.</li> <li>○ Verify the MP calibration Control Number against the Shipping report.</li> <li>○ Check that the correct status label has been affixed properly.</li> </ul> </li> <li>• If the Report indicates that the instrument is either limited or <b>rejected</b>, then the instrument will be physically verified against the Report to assure that there is a correct “Limited” or “Rejected” status label attached to the instrument.</li> <li>• Check that instrument accessories are attached and/or labeled so they do not become separated from their instrument.</li> <li>• If the instrument has been successfully calibrated, a Certificate of Calibration must be sent to the customer.</li> <li>• If an instrument is on hold, awaiting quotation from an Externally Provider, (and it is not being returned with the rest of the customer’s order) then a “Quotation” form must be sent in place of the Certificate of Calibration.</li> <li>• If an instrument is on hold, awaiting further evaluation (i.e., needs parts, etc. or has been rejected, and is not being returned with the rest of the customer’s order), then a “Hold for Evaluation” report must be sent in place of the Certificate of Calibration.</li> </ul> |         |

# Calibration System Description

**MP CSD**

**Table 8 – Final Inspection**

| Item                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Remarks                                                   |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <i>Customer Instructions</i>          | <ul style="list-style-type: none"> <li>• Check that outbound Shipping Reports contain: <ul style="list-style-type: none"> <li>○ Customer information (name, contact, shipping address).</li> <li>○ Purchase Order or method of payment.</li> <li>○ Itemization of instruments on job order (calibration control number; description; manufacturer, model number and serial number (if each are available); accessories with instrument and number of instruments being shipped).</li> </ul> </li> <li>• Check that : <ul style="list-style-type: none"> <li>○ All reports for rejected instruments being returned to the customer has been initialed by a Service Clerk.</li> <li>○ Rejected instruments are monitored by the Service Department to assure that all practical avenues cost effective for both the customer and MP have been addressed;</li> <li>○ The customer has been notified by the Service Department that the instrument is being returned rejected.</li> </ul> </li> <li>• Check that all customer special handling instructions and customer requirements have been met, <ul style="list-style-type: none"> <li>○ Or that customer approval has been received when all requirements cannot be met.</li> <li>○ Update the job file.</li> </ul> </li> <li>• Check for the method of shipping and update the job file: <ul style="list-style-type: none"> <li>○ If the customer “will-call” then notify the customer the order is ready for pickup.</li> <li>○ If other carrier, then notify the carrier of pickup.</li> <li>○ If MP driver will deliver the order, then driver will deliver instrument with Shipper.</li> </ul> </li> </ul> |                                                           |
| <b>Non-conformances</b>               | <ul style="list-style-type: none"> <li>• Report all non-conformances found to the Supervisor</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Also see Appendix 18 for Control of Nonconforming Product |
| <b>Prepare the Order for Shipment</b> | <ul style="list-style-type: none"> <li>• If the instrument was successfully calibrated, attach the Calibration Report behind the Shipping Report.</li> <li>• If the instrument was not calibrated or was rejected, attach the Shipping Report behind the Hold for Evaluation, Quotation and Rejected Reports.</li> <li>• Check that all shipping instructions have been followed.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                           |

# Calibration System Description

MP CSD

**Table 8 – Final Inspection**

| Item                                             | Requirements                                                                                                                                                                                                                                                                                                                                              | Remarks        |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Final Inspection</b>                          | <ul style="list-style-type: none"><li>• When all final inspection activities are complete, prepare to move the order to the next stage of processing:<ul style="list-style-type: none"><li>○ Record time on Traveler after Final Inspection is completed (see personnel responsibilities for Traveler in Table 1 of this Appendix 13)</li></ul></li></ul> |                |
| <b>Exit Point for Final Inspection (Outputs)</b> | <ul style="list-style-type: none"><li>• Move the order with the completed paperwork to the appropriate shelf in Shipping (e.g., Will-call carrier, MP delivery, or Waiting P.O. Hold Area)</li></ul>                                                                                                                                                      | See Appendix 9 |

# Calibration System Description

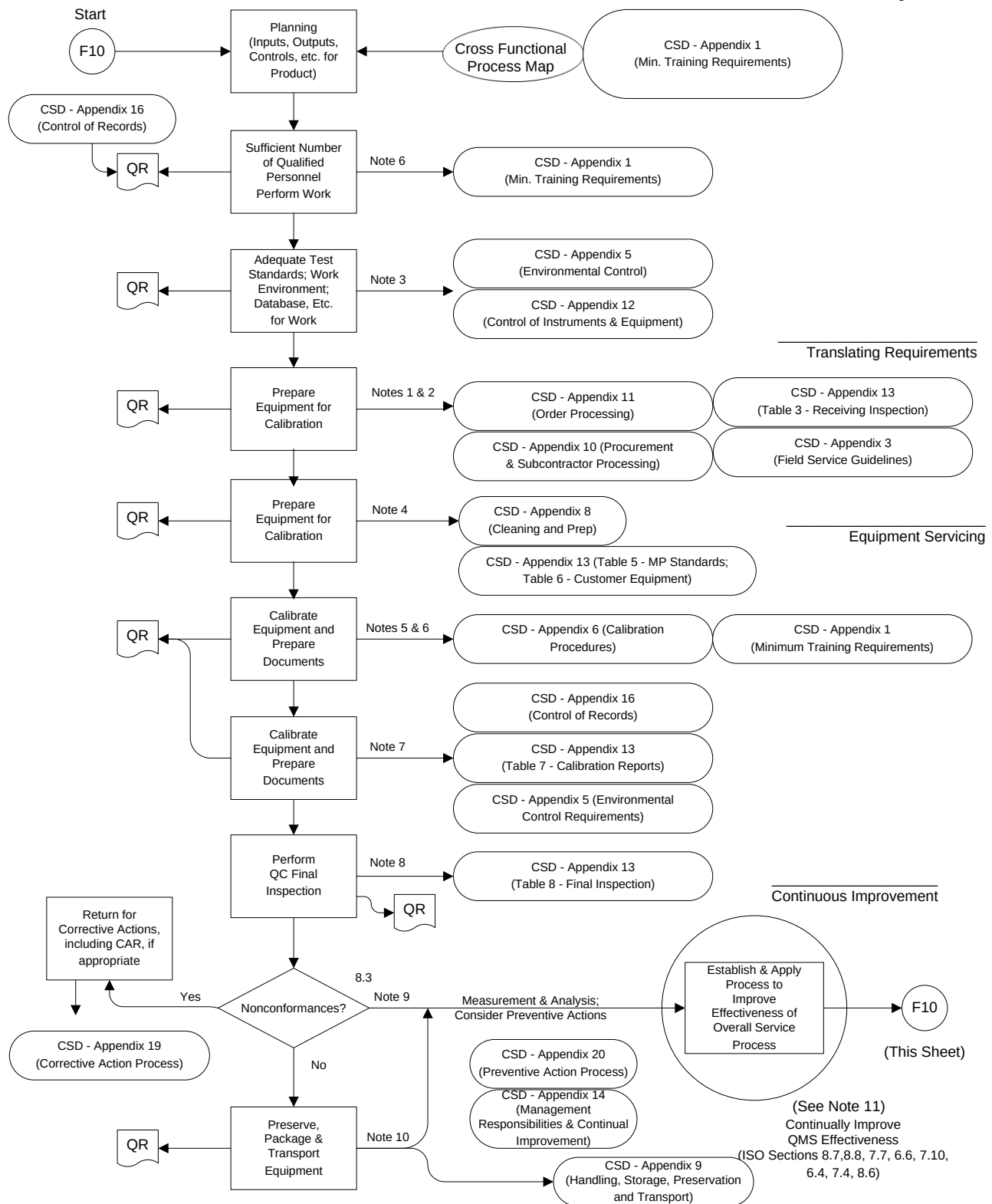
MP CSD

## Overview of Calibration Servicing Process

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.5,  
6.3, 6.4, 6.6, 7.8, 7.11, 8.9, 8.7, 8.66.5)  
Doc. F10 R2 6-20-03

Corrective Action / Nonconformance Controls are Applicable Throughout All Processes

Planning Activities



# Calibration System

## Description

MP CSD

Note 1 (Cross-Functional Process Map Illustrates Department Interrelationships)

- Customer Equipment, MP Test Standard or ILC Artifact?
- If MP Test Standard, review type of standard (i.e., reference, primary, transfer or working standard), adequacy, accuracy
- Review Recall requirement and/or contract review/order request considerations
- Consider MP personnel (operator) capabilities for standard
- Review quality policy and objectives pertaining to internal or external considerations
- Determine if field service, in-house lab, external provider (i.e., warranty / repair) servicing is required.
- Review turn-around / schedule constraints

Note 2 (Implement Appendix 3, Field Service Guidelines, Appendix 11, Order Processing and Appendix 13, Calibration Servicing Process)

- Receiving on site, pick-up or delivered to lab; applicable work instructions/procedures
- Review type of service required (e.g., warranty, repair, calibration, etc.) and recall status and requirements
- Assure unique ID labeling of equipment
- Induct OEM manual and technical literature, if applicable
- Check Traveler and Database Requirements
- Implement Field Service Guidelines, if work is to be performed in field
- Perform Function Check of Equipment
- Implement Nonconformance Processing, if applicable
- Interface with Customer and obtain written authorizations, as necessary
- Update database / records, as needed
- Prepare procurement documents (e.g., purchase order or formal contract), if subcontracting work
- Review AVL status for traceability vendor(s)
- Ensure required statements are in procurement vehicle (e.g., MP language, QMS requirements, full data readings, measurement uncertainties, OEM manual, etc. (e.g., procurement document form and content)

Note 3 (Implement Appendix 12, Control of Instruments and Equipment)

- Check equipment status, adequacy, accuracy, traceability and location
- Obtain equipment and records from another MP Division, if permitted and necessary
- Procure from OEM (requires management approval), if approved and necessary
- Lease (e.g., commercial or loan from customer), if permitted and necessary
- Interface as necessary with Division management
- Choice of test standards and acquisition method is dependent upon in-house capability, characteristics, function requirements, availability of equipment, accuracy, targeted market or customer, vendor approval status, statutory/regulatory requirements, historical information, etc.

Note 4 (Implement Appendix 8, Cleaning and Prep)

- Use check standards
- Check condition and function test equipment
- Clean (if needed) and prepare equipment for calibration
- Route for parts / repair processing, if applicable
- Implement Nonconformance processing, if applicable
- Determine extent of verification/repeatability study activities required
- Review provisions for inducting and return if any loaned customer equipment is used as test standard

Note 5 (Implement Appendix 6, Calibration Procedures)

- Select, use / develop calibration method; validate nonstandard methods
  - Use OEM instructions
  - Interface with Division management and customer, as appropriate
  - Obtain customer approval of methods used, as appropriate

# Calibration System

## Description

MP CSD

Note 6 (Implement Appendix 1, Minimum Training Requirements)

- Assure technician performing calibration is currently qualified, is competent and appropriately supervised per requirements.
- Initiate Corrective Action Reports for deficiencies or non-conformances with requirements
- Periodically review currency of ILC processing of designated test standards (also supports qualification of technicians) and closure of associated Corrective Action Reports

Note 7 (Implement Appendices 5, Environmental Control Requirements, and Appendix 13, Table 7, Calibration Reports)

- Assure measurement uncertainty program has been implemented and values are current for test standards
- Assure annual repeatability study requirements implemented on major test standards is current
- Check identification and status of primary/reference standards (major standards at lab)
- Conduct periodic checks of equipment as required through processing
- Review recall system requirements and document any readjustments
- Implement appropriate handling, transport, storage and preservation of equipment
- Implement appropriate labeling and tamper protection on equipment
- For any Nonconformities, implement appropriate NC processing and corrective and preventive actions
- Review and document environmental conditions
- Review equipment history
- Record data, as appropriate; update database
- Prepare Certificate of Calibration

Note 8 (Implement Appendix 13, Table 8, Final Inspection)

- Check status labeling and tamper protection labeling
- Check vendor calibration certificate and MP Certificate
- Assure induction of vendor calibrations by qualified technical personnel
- Assure the database has been updated
- History and service records completed
- Check Certificates of Calibration and reroute for corrections, as needed
- Handling, transport, storage and preservation per requirements
- Nonconformities and disposition processing implemented
- QC monitoring of MP standards process and calibration servicing
- Review ILC results and measurement uncertainties when performed
- Review results of laboratory accreditation and Registrar certification assessments, and internal audit results
- Review customer complaints and feedback, initiate and/or review status of CARs/PAPs and trend analysis
- Propose preventive actions and promote continuous implementation activities
- Review personnel qualifications necessary to operate new standards, and perform calibrations, as authorized, etc.

Note 9 (Implement Appendices 19, Corrective Action Process and/or Appendix 20, Preventive Action Process, Appendix 18, Control of Nonconforming Product)

- Implement segregation and reject labeling
- Initiate Corrective Action Reports
- Implement required corrective actions
- Contact customer and concerned parties, as applicable
- Consider appropriate Preventive Actions and initiate Preventive Action Proposals

Note 10 (Implement Appendix 9, Handling, Storage, Preservation and Transport)

- Preservation includes: identification, handling, packaging, storage and protection activities in addition to equipment preservation itself (e.g., dipping threads, etc.)

Note 11

- Re-review the QMS Process and QMS Documentation Development and Improvement Process to develop new or further refine existing processes and improvements to processes.

# Calibration System

## Description

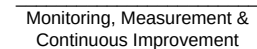
**MP CSD**

- Monitor customer satisfaction (e.g., surveys on future requirements, etc.)
- Consider industry trends from various sources (e.g., Registrar, customers, vendors, competitors, business publications, etc.)
- Consider state-of-the-art developments (improvements in standards and impact to business approach, current and future)
- Initiate improvements and revisions in quality policies and objectives
- Review and consider Audit results
- ILC improvements

## MP CSD

### Equipment / Paperwork Arrive

### Order Receiving Induction Activities

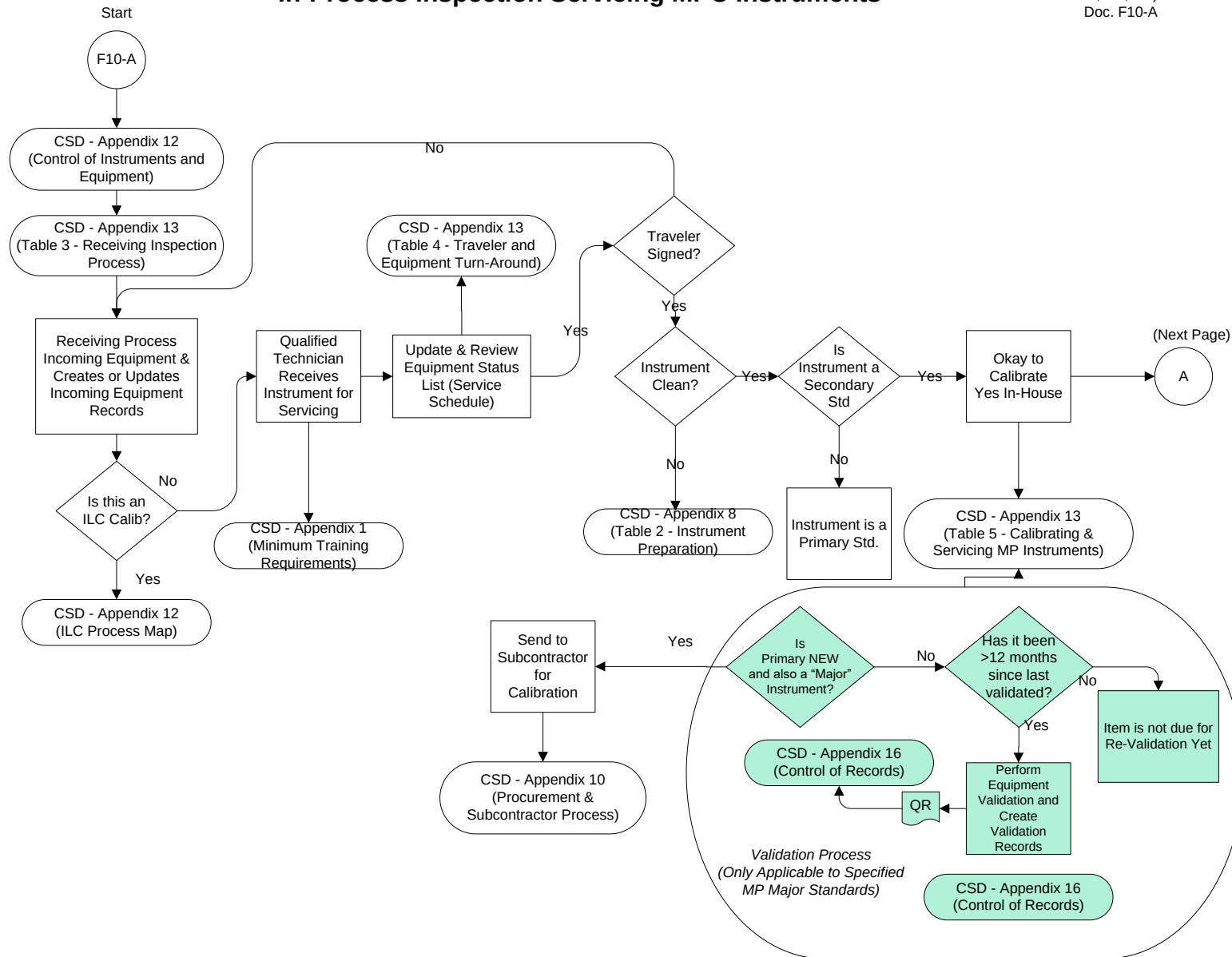


# Calibration System Description

MP CSD

## In-Process Inspection Servicing MPC Instruments

Ref. ISO/IEC 17025:2017 (Sections 4.1, 6.4,  
7.8, 6.6, 7.5)  
Doc. F10-A

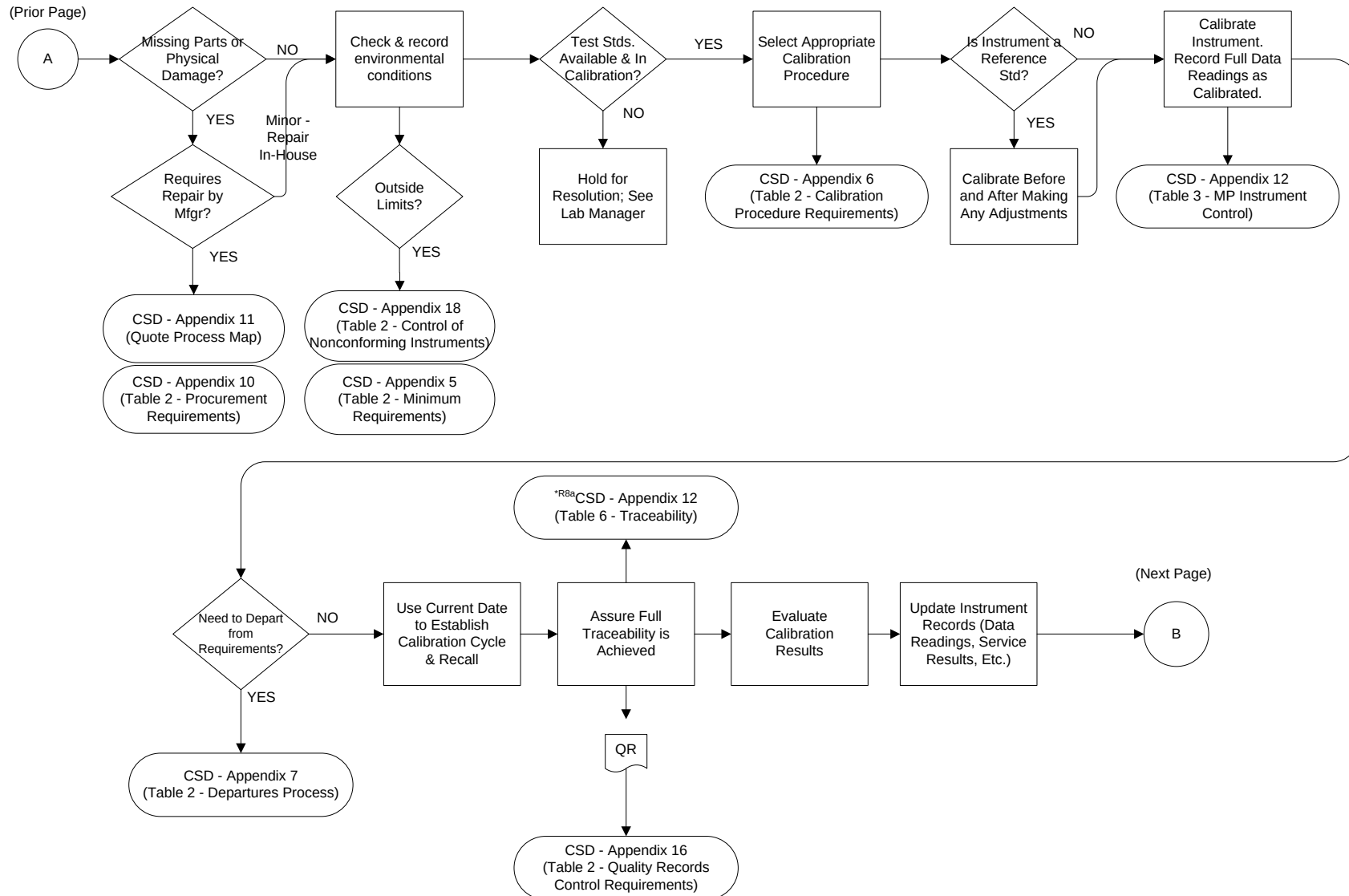


# Calibration System Description

MP CSD

## In-Process Inspection Servicing MP Instruments (Continued)

Ref. ISO/IEC 17025:2017 (Sections 7.4, 7.10, 7.6, 6.4, 7.10, 6.6, 6.3,7.4,7.5)Doc. F10-A R2  
7-14-03

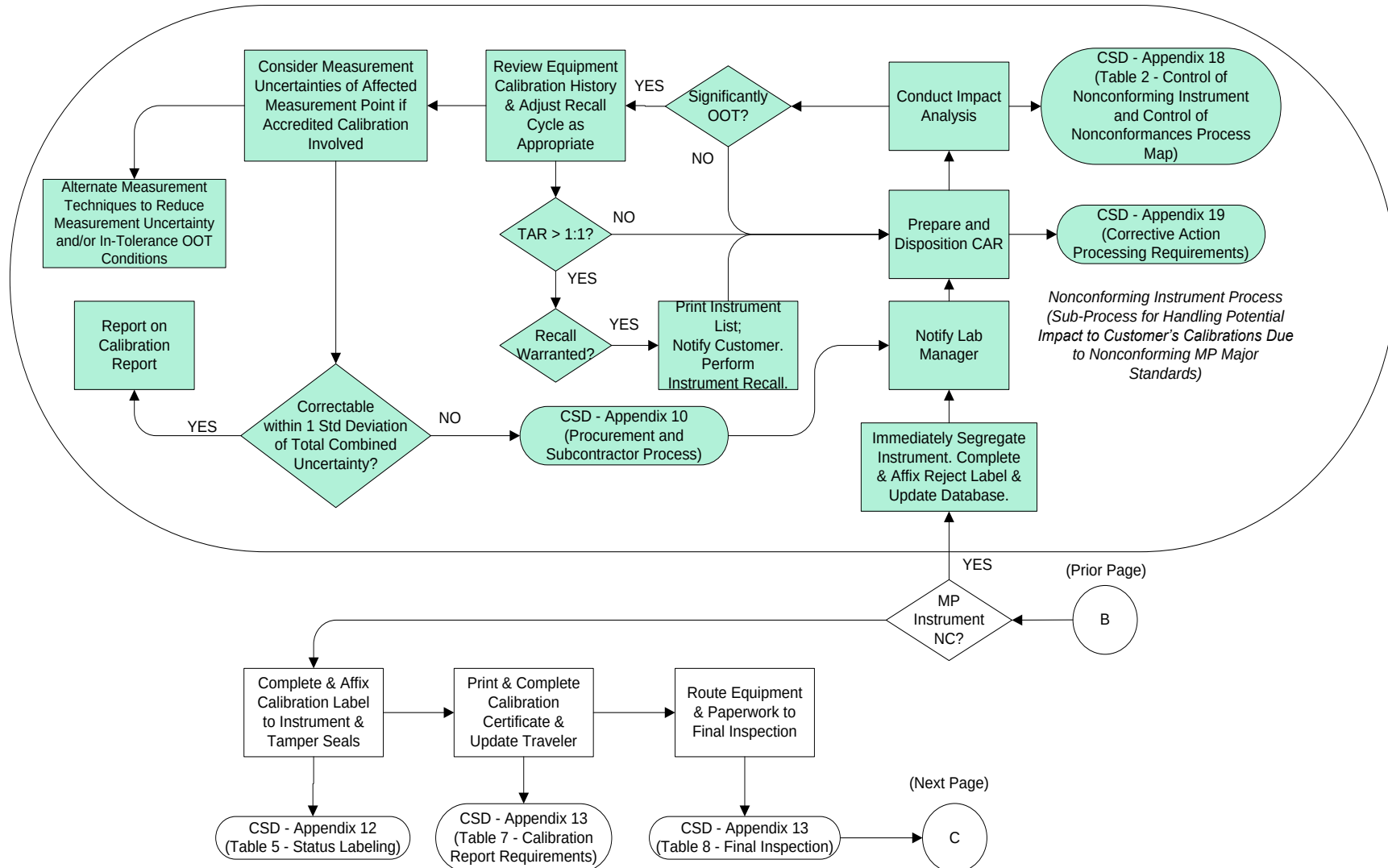


# Calibration System Description

MP CSD

## In-Process Inspection Servicing MP Instruments (Continued)

Ref. ISO/IEC 17025:2017 (Sections 8.7, 7.10,  
8.7, 6.4, 7.8)  
Doc. F10-A R2

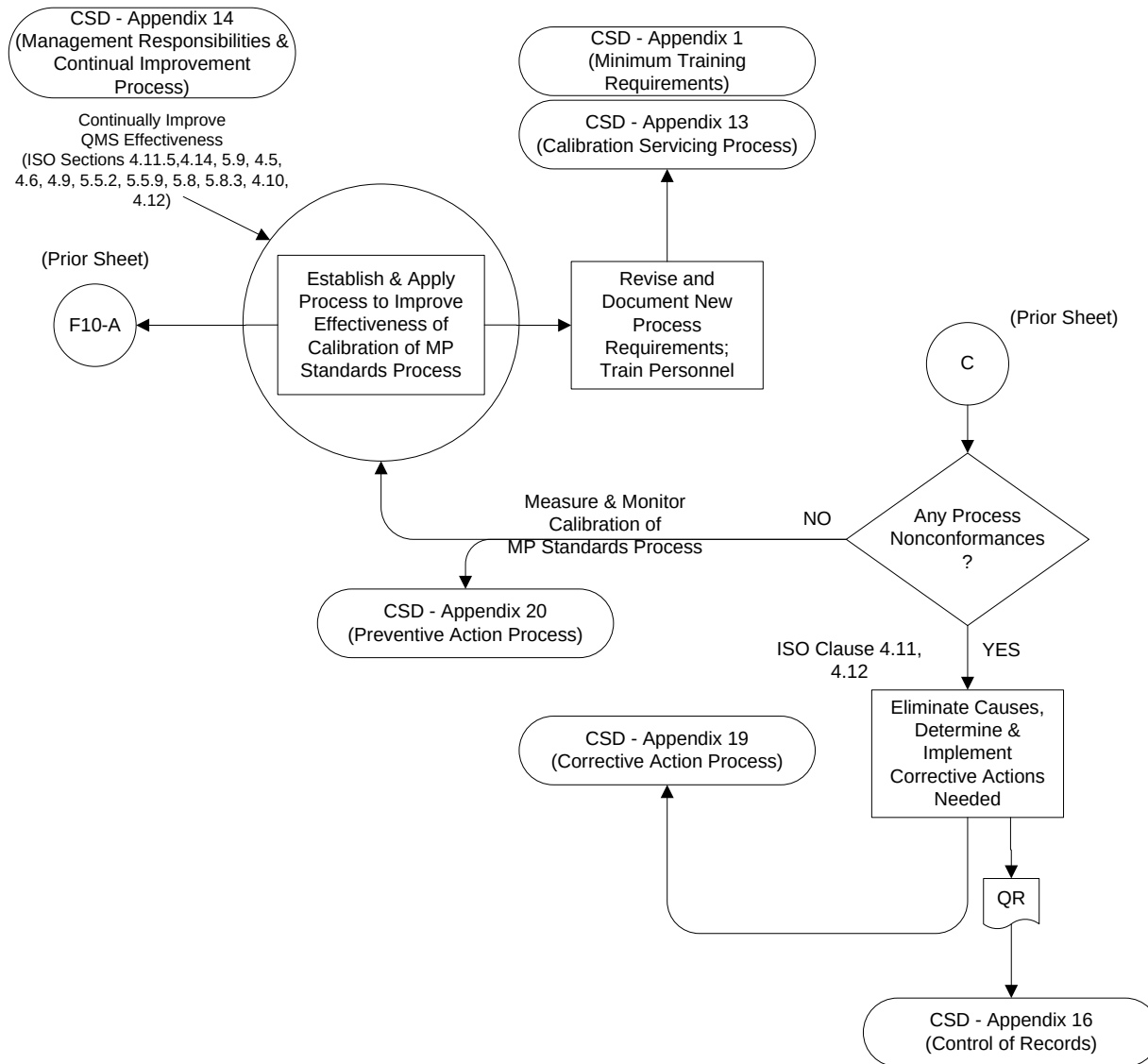


# Calibration System Description

MP CSD

## In-Process Inspection Servicing MP Instruments (Continued)

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.8,  
8.7, 8.6, 7.5)  
Doc. F10-A R2 7-14-03

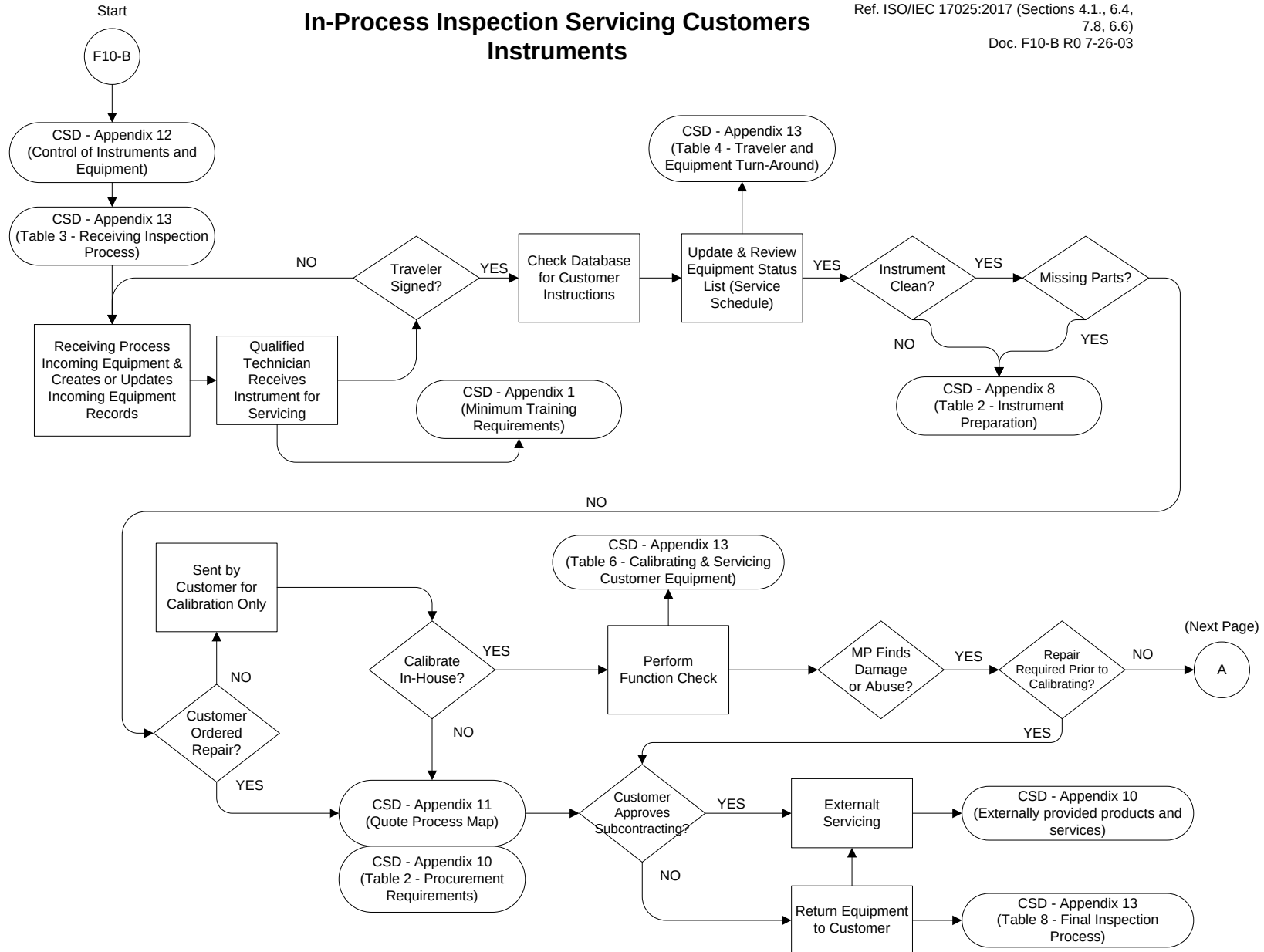


# Calibration System Description

MP CSD

## In-Process Inspection Servicing Customers Instruments

Ref. ISO/IEC 17025:2017 (Sections 4.1., 6.4,  
7.8, 6.6)  
Doc. F10-B R0 7-26-03

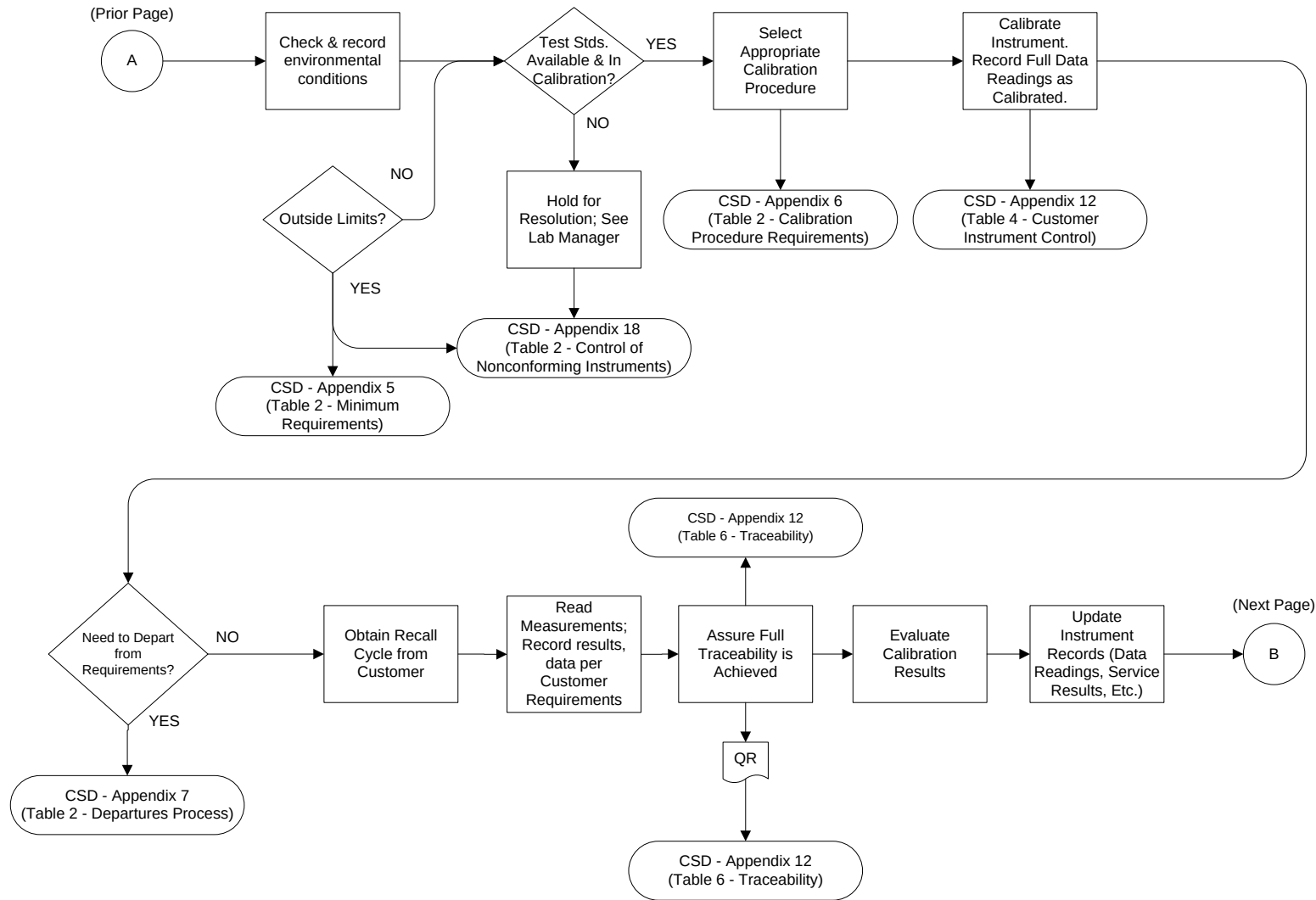


# Calibration System Description

MP CSD

## In-Process Inspection Servicing Customers Instruments (Continued)

Ref. ISO/IEC 17025:2017 (Sections 7.2, 7.10,  
6.4, 7.4)  
Doc. F10-B R0 7-26-03

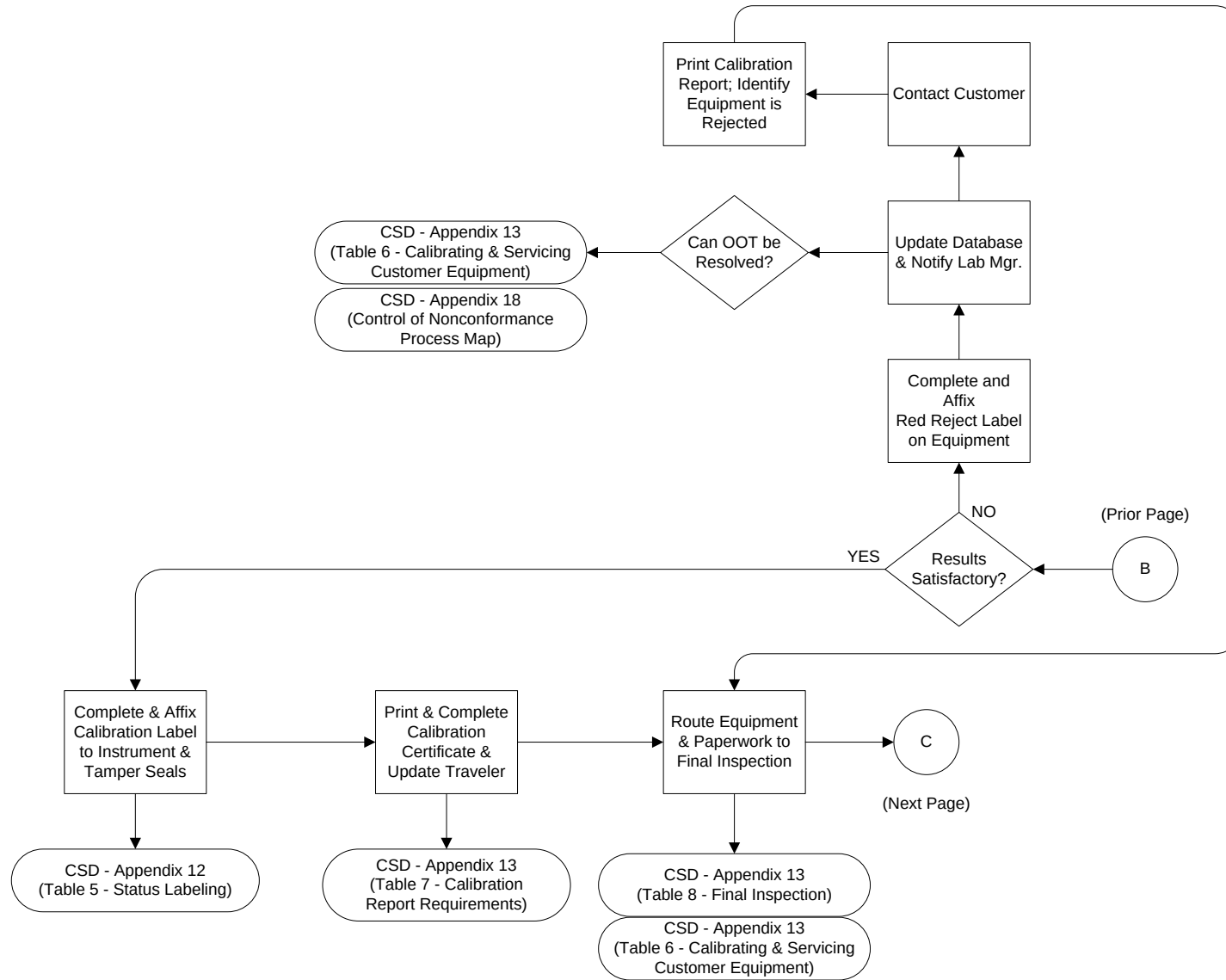


# Calibration System Description

MP CSD

## In-Process Inspection Servicing Customers Instruments (Continued)

Ref. ISO/IEC 17025:2005 (Sections 7.8, 7.10,  
6.4)  
Doc. F10-B R0 7-26-03



## MP CSD

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.8,  
8.7, 8.6, 7.5)  
Doc. F10-B R0 7-26-03

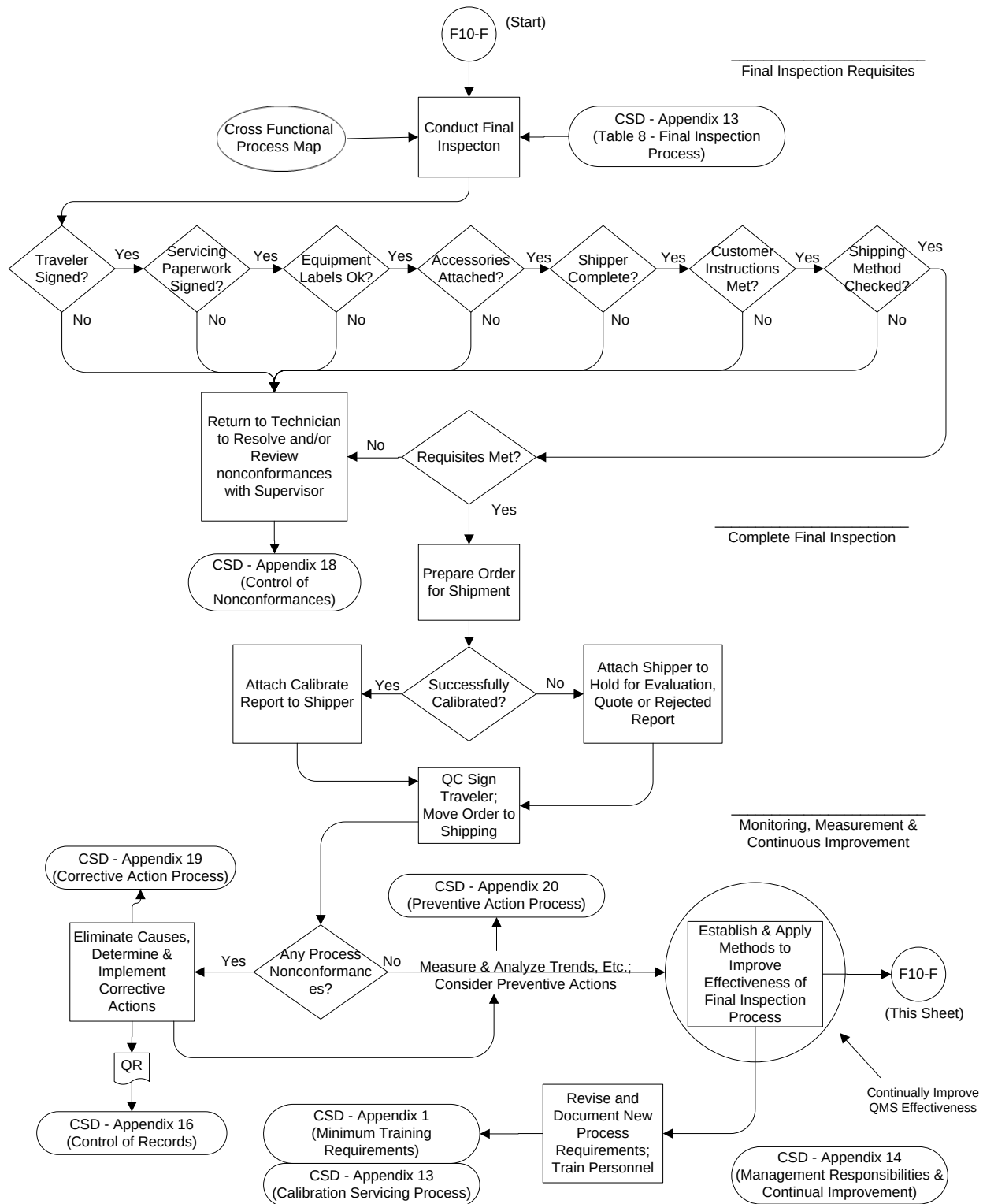


# Calibration System Description

MP CSD

Ref. ISO/IEC 17025:2017 (Sections 7.8, 8.7,  
8.6, 8.9, 7.10, 7.11)  
Doc. F10-F R0 7-26-03

## Final Inspection Process



# Calibration System Description

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## Appendix 14 – Management Responsibilities and Continual Improvement Process

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | All | Resp.<br>Mgr. | Div.<br>Mgr. | QA Mgr.<br>/QC<br>Supv. | Quality<br>Dir. | Pres.      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------------|--------------|-------------------------|-----------------|------------|
| <u>Quality Planning</u> <ul style="list-style-type: none"> <li>Overall responsible for the establishment, implementation and maintenance of the Corporate-wide Quality System, including: <ul style="list-style-type: none"> <li>Ensuring adequate resources for the Quality Director to accomplish requirements of the Quality System.</li> </ul> </li> </ul>                                                                                                                                      |     |               |              |                         |                 | X          |
| <ul style="list-style-type: none"> <li>Ensuring the availability of resources and information necessary to support the operation and monitoring of processes, including monitoring, measuring and analyzing the processes.</li> </ul>                                                                                                                                                                                                                                                               |     |               | X            | X                       | X               | X          |
| <ul style="list-style-type: none"> <li>Monitoring and implementing requirements contained in the Quality Manual and Calibration System Description at the Division.</li> </ul>                                                                                                                                                                                                                                                                                                                      |     |               |              | X                       |                 |            |
| <ul style="list-style-type: none"> <li>Maintaining active Quality Plan for discussion at Management Review meetings.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                     |     | X             | X            | X                       |                 |            |
| <ul style="list-style-type: none"> <li>Reviewing and approving all Corporate-wide plans before they are implemented</li> </ul>                                                                                                                                                                                                                                                                                                                                                                      |     |               |              |                         | X               | X          |
| <ul style="list-style-type: none"> <li>Reviewing and approving all Division level plans before they are submitted to Executive Management for final approval.</li> </ul>                                                                                                                                                                                                                                                                                                                            |     | X             | X            |                         |                 |            |
| <u>Quality Policy:</u> <ul style="list-style-type: none"> <li>Developing and maintaining current, the Corporate MP Quality Policy, including determining the appropriateness of revising the Quality Policy.</li> <li>Communicating to the organization the importance of meeting customer, statutory and regulatory requirements and Corporate Quality Policy.</li> <li>Communicating the Quality Policy to personnel at the Division and ensuring all employees understand the policy.</li> </ul> |     |               | X            | X                       |                 | X<br><br>X |

# Calibration System Description

MP CSD

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | All | Resp.<br>Mgr. | Div.<br>Mgr. | QA Mgr.<br>/QC<br>Supv. | Quality<br>Dir. | Pres. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|---------------|--------------|-------------------------|-----------------|-------|
| <ul style="list-style-type: none"> <li>Examining changes in the Quality Policy and Quality Manual when revised, and interfacing as needed with the Quality Assurance Manager and or QC Supervisor.</li> <li>Issuing the Quality Policy approved by the President, and the Quality Manual, as applicable;</li> </ul> <p><u>Quality Objectives:</u></p> <ul style="list-style-type: none"> <li>Establishing and approving Corporate-wide Quality Objectives.</li> <li>Interfacing with Division Managers in deploying Quality Objectives applicable to their respective areas of responsibility, to facilitate identifying specific goals.</li> <li>Establishing objectives for Division personnel                             <ul style="list-style-type: none"> <li>Considering competitor performance;</li> <li>Considering Best practices;</li> </ul> </li> <li>Reviewing the need for changes to Quality Objectives.</li> </ul> |     |               | x            | x                       | x               |       |
| <p><u>Continual Improvement:</u></p> <ul style="list-style-type: none"> <li>Suggest methods / concepts for performance improvement for timely reaction by top management.</li> <li>Define and implement continual improvement within the Division and support operations</li> <li>Recognizing achievement of improvements</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |     |               | x            |                         |                 |       |
| <p><u>Management Reviews:</u></p> <ul style="list-style-type: none"> <li>Overall responsibility for the implementation of Management Reviews in each respective division.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |     |               | x            | x                       |                 |       |
| <ul style="list-style-type: none"> <li>Conducting management review, including establishing deadlines and implementing timely follow-up for action items.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |     |               | x            | x                       |                 |       |

# Calibration System

## Description

**MP CSD**

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                   | All | Resp. Mgr. | Div. Mgr. | QA Mgr. /QC Supv. | Quality Dir. | Pres. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|------------|-----------|-------------------|--------------|-------|
| <ul style="list-style-type: none"> <li>Reporting on the overall effectiveness of the Quality Program at the Division management review meeting.</li> </ul> |     |            |           | X                 |              |       |
| <ul style="list-style-type: none"> <li>Participating in or supporting management reviews, as notified by division management.</li> </ul>                   | X   |            |           |                   |              |       |
| <ul style="list-style-type: none"> <li>Maintaining the Division management review records and reports, recording findings and actions taken</li> </ul>     |     |            |           | X                 |              |       |

**Table 2 – Quality Policies and Objectives**

| Item                                     | Requirements                                                                                                                                                                                                                                                                                                                                                | Remarks                                |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| <b>Criteria for the Quality Policy</b>   | <p>The Quality Policy will:</p> <ul style="list-style-type: none"> <li>Be appropriate to MP's purpose;</li> <li>Include a commitment for all divisions and locations where MP work is performed to comply with the requirements and continually improve the QMS;</li> <li>Provide a framework for establishing and reviewing quality objectives.</li> </ul> |                                        |
| <b>Periodic Review</b>                   | <ul style="list-style-type: none"> <li>The need to revise the Quality Policy will be assessed at the Management Review meeting. <ul style="list-style-type: none"> <li>The Quality Policy will be reviewed at other times where the need for revision is identified through audits, corrective actions and preventive actions.</li> </ul> </li> </ul>       |                                        |
| <b>Criteria for Quality Objectives</b>   | <ul style="list-style-type: none"> <li>Quality Objectives will: <ul style="list-style-type: none"> <li>Be consistent with the Quality Policy;</li> <li>Be measurable so as to determine the extent to which they have been met.</li> </ul> </li> </ul>                                                                                                      |                                        |
| <b>Publication of Quality Objectives</b> | <ul style="list-style-type: none"> <li>Quality objectives will be issued in a Quality Policy statement in the Quality Manual issued and approved by top management.</li> </ul>                                                                                                                                                                              | See Responsibilities in Table 1 above. |

# Calibration System

## Description

MP CSD

**Table 2 – Quality Policies and Objectives**

| Item                                    | Requirements                                                                                                                                                                                                                                                                                                                                                                                   | Remarks |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Division Quality Objectives</b>      | <ul style="list-style-type: none"> <li>Specific goals to be achieved by the Division will be identified and reported on.</li> <li>Division managers will be proactive in identifying additional areas in their divisions that meet the Quality Objectives.</li> <li>Appropriate guidance will be provided to Division Managers in establishing and implementing Quality Objectives.</li> </ul> |         |
| <b>Communicating the Quality Policy</b> | <ul style="list-style-type: none"> <li>The Quality Policy Manual will be available to all personnel and shall be well communicated and understood.</li> </ul>                                                                                                                                                                                                                                  |         |

**Table 3 – Management Review Requirements**

| Item                                         | Requirements and Descriptions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Process</b>                               | <ul style="list-style-type: none"> <li>Management Review is conducted in each respective division.</li> <li>See the Management Review Process Map in this Appendix 14.</li> <li>Action to address Risk and Opportunities               <ul style="list-style-type: none"> <li>give assurance that the management system achieves its intended results;</li> <li>enhance opportunities to achieve the purpose and objectives of the laboratory;</li> <li>prevent, or reduce, undesired impacts and potential failures in the laboratory activities;</li> <li>achieve improvement.</li> </ul> </li> <li>The inputs to management review shall be recorded and shall include information related to the following:               <ul style="list-style-type: none"> <li>Changes in Internal and external issues,</li> <li>Status of action from previous management reviews,</li> <li>Results of risk identification.</li> </ul> </li> </ul> |         |
| <b>Frequency of Reviews and Participants</b> | <ul style="list-style-type: none"> <li>Division Managers will establish the frequency of the Division-level management reviews for the coming year (e.g., monthly, quarterly, semi-annually, etc.). Attendees for this meeting will be the following:               <ul style="list-style-type: none"> <li>Division Manager</li> <li>Lab Manager</li> <li>QA Manager/ QC Supervisor</li> <li>Sales Manager</li> <li>Admin / Office Manager</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |

## MP CSD

|                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>Review Items</b>                            | <ul style="list-style-type: none"> <li>• See Table 4 in this Appendix 14.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |
| <b>Records</b><br><br><i>Findings Criteria</i> | <ul style="list-style-type: none"> <li>• The outputs from the management review shall record all decisions and actions related to at least:             <ul style="list-style-type: none"> <li>○ The effectiveness of the management system and its processes;</li> <li>○ Improvement of the laboratory activities related to the fulfillment of the requirement of this document;</li> <li>○ provision of required resources;</li> <li>○ any need for change.</li> </ul> </li> <li>• Findings and actions taken as a result of Management Review meetings will be recorded.             <ul style="list-style-type: none"> <li>○ Analyze findings and document any determinations made to change or add procedures (e.g., a Corrective Action Report may be appropriate for tracking purposes).</li> </ul> </li> <li>• Base on impact to quality, including but not limited to:             <ul style="list-style-type: none"> <li>○ Internal audits</li> <li>○ Customer audits and complaints;</li> <li>○ Corrective action analysis;</li> <li>○ Historical and planned business growth;</li> <li>○ Revision to reference standards and/or new reference standards.</li> </ul> </li> </ul> |  |

| Item                                        | Requirements                                                                                                                                                                                                                                                                                                                                     | Remarks                                           |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <i>Reports</i>                              | <ul style="list-style-type: none"> <li>Reports from reviews will be kept on file and readily retrievable.</li> </ul>                                                                                                                                                                                                                             | See Table 1, Responsibilities in this Appendix 14 |
| <b>Action Items</b><br><br><i>Deadlines</i> | <ul style="list-style-type: none"> <li>Action items will be implemented within appropriate and agreed upon time frames.               <ul style="list-style-type: none"> <li>Deadlines and timely follow-up will be established and implemented during reviews.</li> <li>See Action Items in Table 4 of this Appendix 14.</li> </ul> </li> </ul> |                                                   |

| Item                                                     | Requirements                                                                                                                                                                                                                    | Remarks |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Reports</b><br>(Managerial and Supervisory Personnel) | <ul style="list-style-type: none"> <li>Action Items:               <ul style="list-style-type: none"> <li>Matters arising from prior reviews will be discussed and dispositioned during the next review:</li> </ul> </li> </ul> |         |

# Calibration System

## Description

**MP CSD**

**Table 4 – Items to be Reviewed During Management Review**

| Item | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Remarks |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|      | <ul style="list-style-type: none"> <li>○ Specific deadlines will be set for each action item, depending on the nature of each action to be accomplished and to assure that action items are completed according to planned schedules.</li> <li>• Measurement, Analysis and Improvement:               <ul style="list-style-type: none"> <li>○ Corrective Action Reports;</li> <li>○ Preventive Action Proposals;</li> </ul> </li> <li>• Audits:               <ul style="list-style-type: none"> <li>○ Reports from third-party assessments;</li> <li>○ Outcomes of customer and internal audits.</li> </ul> </li> <li>• Customer satisfaction:               <ul style="list-style-type: none"> <li>○ Positive and negative feedback;</li> <li>○ Complaints;</li> <li>○ Customer satisfaction is a key metric in determining the                   <ul style="list-style-type: none"> <li>- overall suitability of the Quality Program, along with</li> <li>- overall profitability of the company and the individual divisions (see Customer Satisfaction Process Map in this Appendix 14).</li> </ul> </li> </ul> </li> <li>• Quality Control:               <ul style="list-style-type: none"> <li>○ Results of in-house quality checks;</li> <li>○ Results of Proficiency Tests;</li> <li>○ Site testing and calibration activities.</li> </ul> </li> <li>• Adequacy of the Quality System:               <ul style="list-style-type: none"> <li>○ Suitability of policies and procedures;</li> <li>○ Revisions or updates to Codes and Standards pertinent to the Quality System.</li> <li>○ The Quality Director will review the Corporate-wide Quality System Program with input from the Divisions.</li> <li>○ The Division Manager will review the Quality System Program at the Division Level.</li> <li>○ Suitability and currency of the Quality Policy (see Table 2 above).</li> <li>○ See the following process maps in this Appendix 14:                   <ul style="list-style-type: none"> <li>- Management Responsibility Process.</li> <li>- Quality Management System Process</li> </ul> </li> </ul> </li> </ul> |         |

# Calibration System Description

MP CSD

**Table 4 – Items to be Reviewed During Management Review**

| Item | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|      | <ul style="list-style-type: none"> <li>• <u>Processes</u> <ul style="list-style-type: none"> <li>○ Deficiencies or improvements in processes.</li> </ul> </li> <li>• <u>Personnel:</u> <ul style="list-style-type: none"> <li>○ Training of new and existing personnel;</li> <li>○ Adequacy of staff.</li> </ul> </li> <li>• <u>Equipment and Facilities:</u> <ul style="list-style-type: none"> <li>○ Adequacy of equipment and facility resources;</li> <li>○ Future plans and projects of changes in type of work, new staff, new equipment;</li> <li>○ Current or planned Quality Policies and Objectives.</li> </ul> </li> </ul> |         |

**Table 5 – Quality Plans**

| Item                            | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Remarks |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Definition</b>               | <ul style="list-style-type: none"> <li>• <i>Quality Planning</i>– The identification and implementation of those attributes which directly affect the quality of services provided.</li> </ul>                                                                                                                                                                                                                                                                                                                      |         |
| <b>Responsibility for Plans</b> | <ul style="list-style-type: none"> <li>• See Table 1 above.</li> <li>• All plans will be coordinated under the direction of the President.</li> </ul>                                                                                                                                                                                                                                                                                                                                                               |         |
| <b>Plan Reporting</b>           | <ul style="list-style-type: none"> <li>• Managers will provide Plans to Executive Management at the Management Review meeting(s) (see Plan Contents below).</li> <li>• The laboratory plan shall include: <ul style="list-style-type: none"> <li>a) actions to address risks and opportunities;</li> <li>b) how to integrate and implement these actions into its management system and;</li> <li>c.) evaluate the effectiveness of these actions.</li> </ul> </li> <li>• See Table 2 and Table 3 above.</li> </ul> |         |
| <b>Plan Duration</b>            | <ul style="list-style-type: none"> <li>• Active plans will cover a minimum of one year.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                  |         |

# Calibration System Description

MP CSD

**Table 5 – Quality Plans**

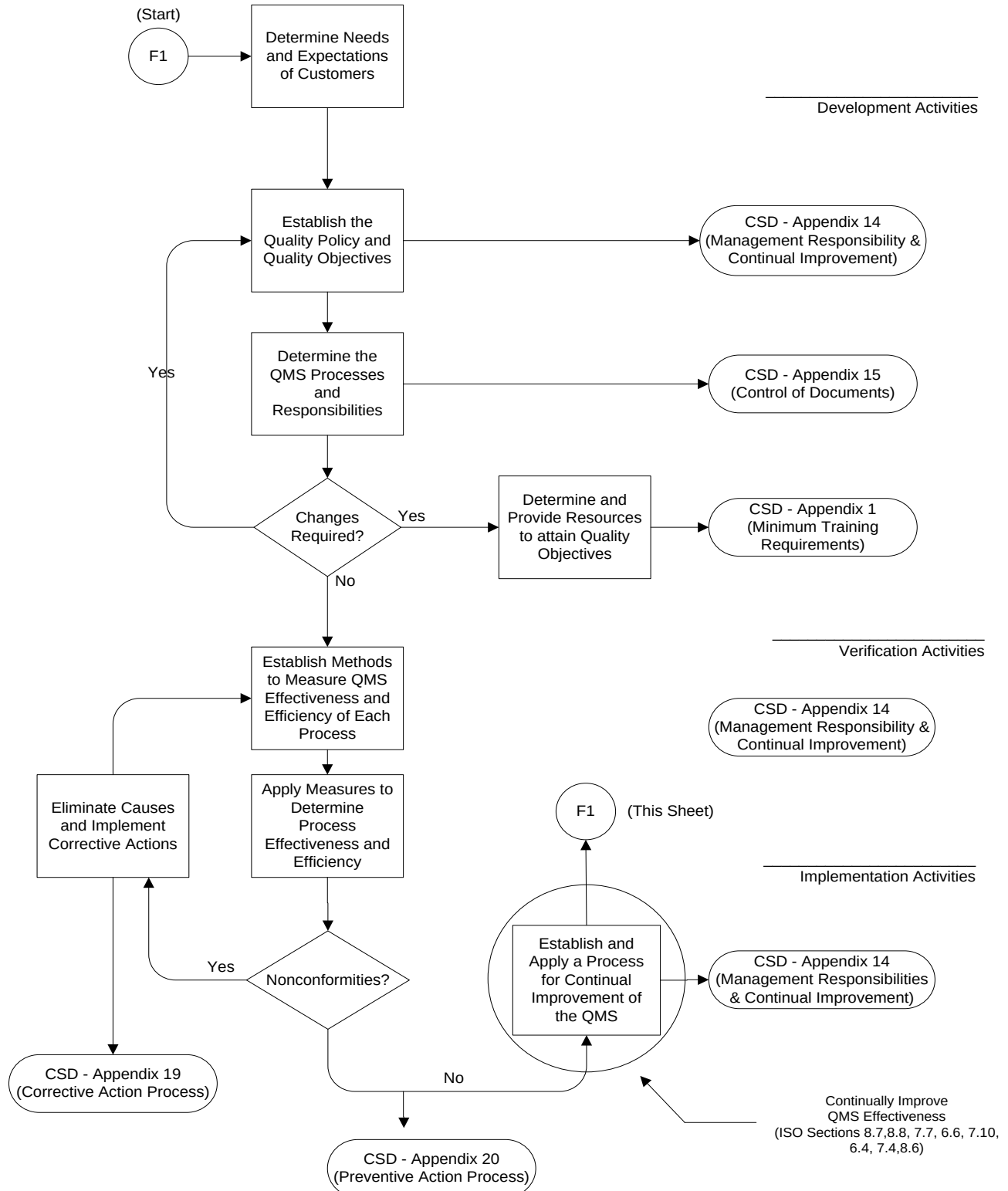
|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>Currency of Plans</b>                   | <ul style="list-style-type: none"> <li>All plans will be kept current (e.g., actively maintained).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |
| <b>Action Items</b><br><br><i>Planning</i> | <p>Management Review Action Plans:</p> <ul style="list-style-type: none"> <li>The progress of each item and its completion will be planned to facilitate monitoring and implementation in the established time frame.</li> <li>Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
| <b>Plan Contents</b>                       | <ul style="list-style-type: none"> <li>Division Manager plans will incorporate plans from the following: <ul style="list-style-type: none"> <li>Sales;</li> <li>Service;</li> <li>Lab Managers.</li> </ul> </li> <li>Department planning Includes: <ul style="list-style-type: none"> <li>Human resource;</li> <li>Training and certification of department personnel, service, facilities and equipment.</li> </ul> </li> <li>Planning activities consider: <ul style="list-style-type: none"> <li>Determine quality objectives;</li> <li>Calibration service requirements;</li> <li>Effective implementation of the Quality Management System;</li> <li>Determination of customer requirements;</li> <li>ISO certification and laboratory accreditation requirements;</li> <li>Adequacy of the calibration service;</li> <li>Verification of the service and completion of repeatability studies;</li> <li>Monitoring, inspection and testing methods;</li> <li>Effectiveness of quality records and documents in the Quality Management System.</li> </ul> </li> </ul> |  |

# Calibration System Description

MP CSD

## Quality Management System Process (Overview)

Ref. ISO/IEC 17025 (4.1, 4.1.5, 4.15, 4.11,  
4.12, 4.3 )  
Doc. F1 R3 6-09-03



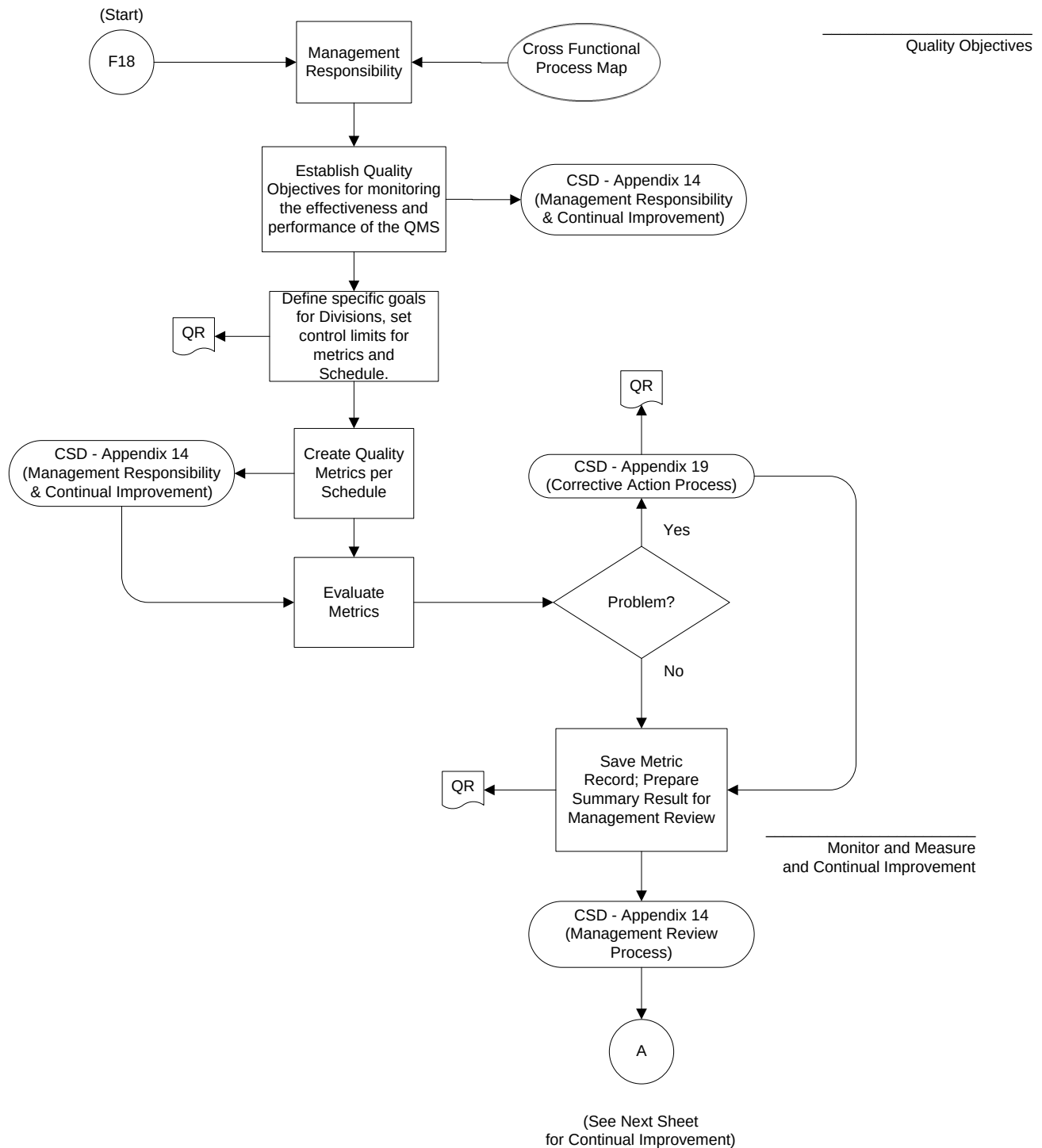
# Calibration System Description

MP CSD

## Management Responsibility Process

(Measurement and Analysis)

Ref. ISO/IEC 17025:2017 (Sections 8.8, 8.7)  
Doc. F18 R1 6-09-03



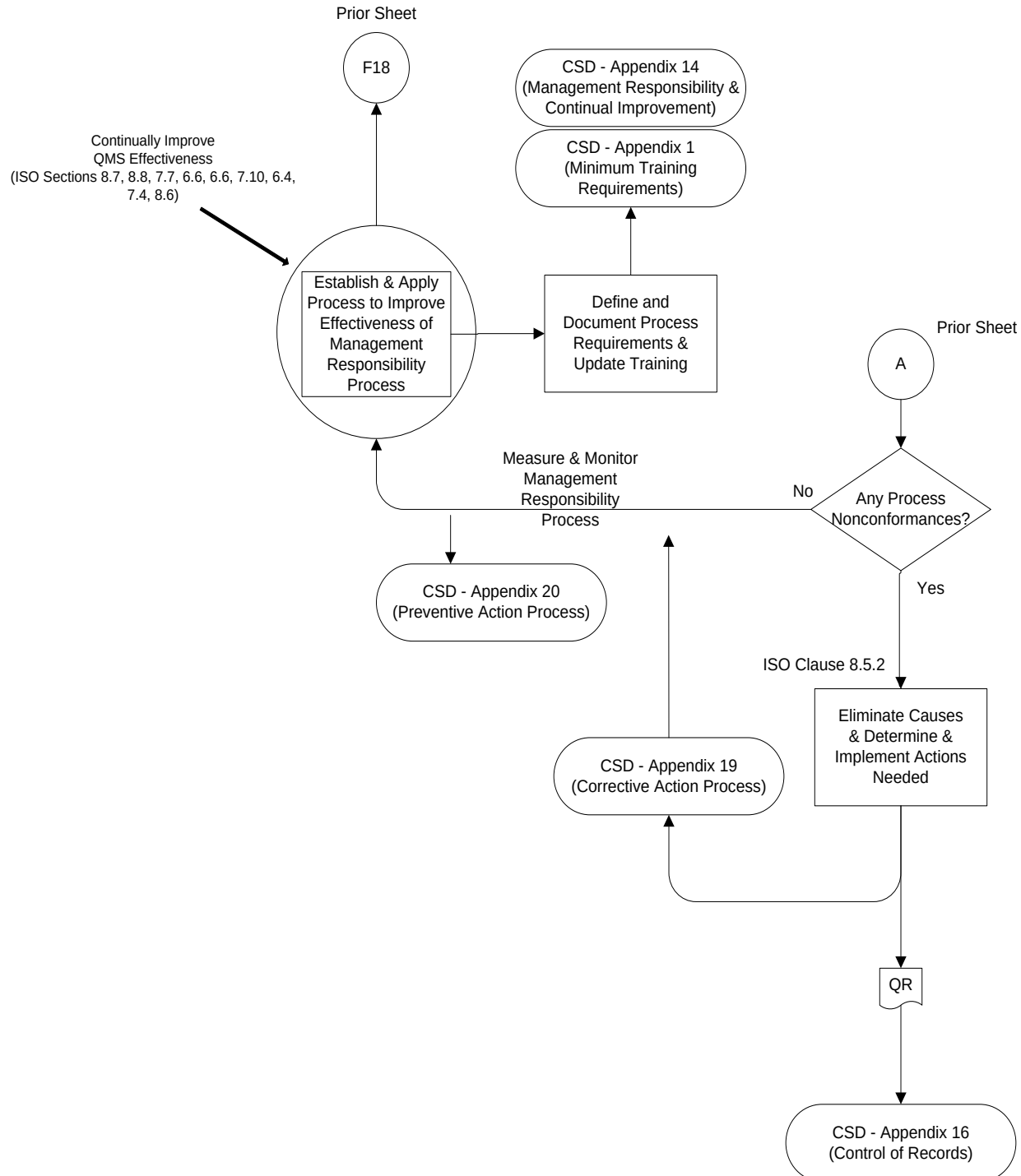
# Calibration System Description

MP CSD

## Management Responsibility Process (Cont)

(Measurement and Analysis)

Ref. ISO/IEC 17025:2017 (Sections 4.1, 8.9,  
8.7, 8.6, 7.5)  
Doc. F18 R1 6-09-03

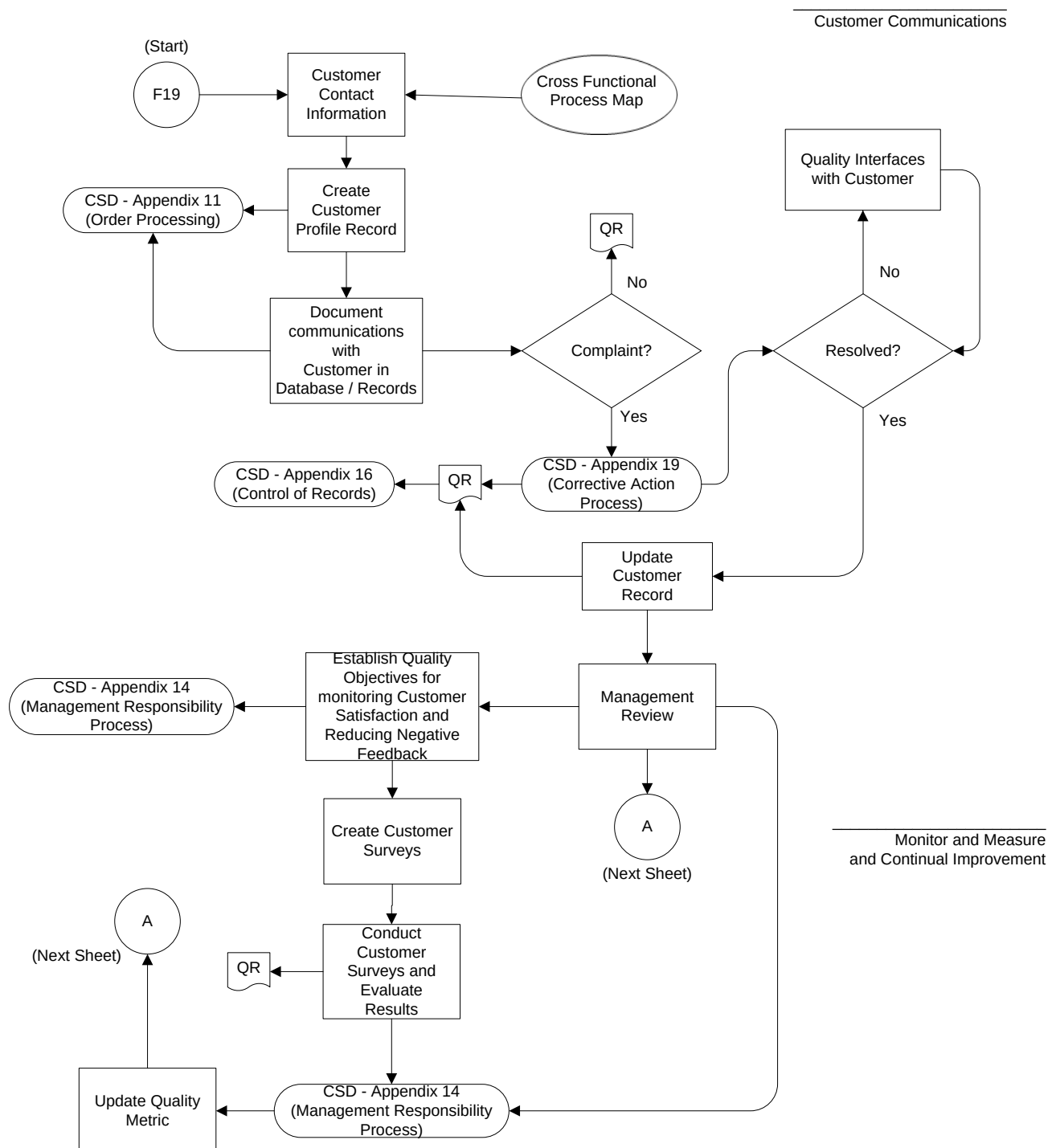


# Calibration System Description

## MP CSD

### Customer Satisfaction Process

Ref. ISO/IEC 17025:2017 (Sections 6.6, 8.7,  
4.1, 7.5)  
Doc. F19 R1 6-09-03

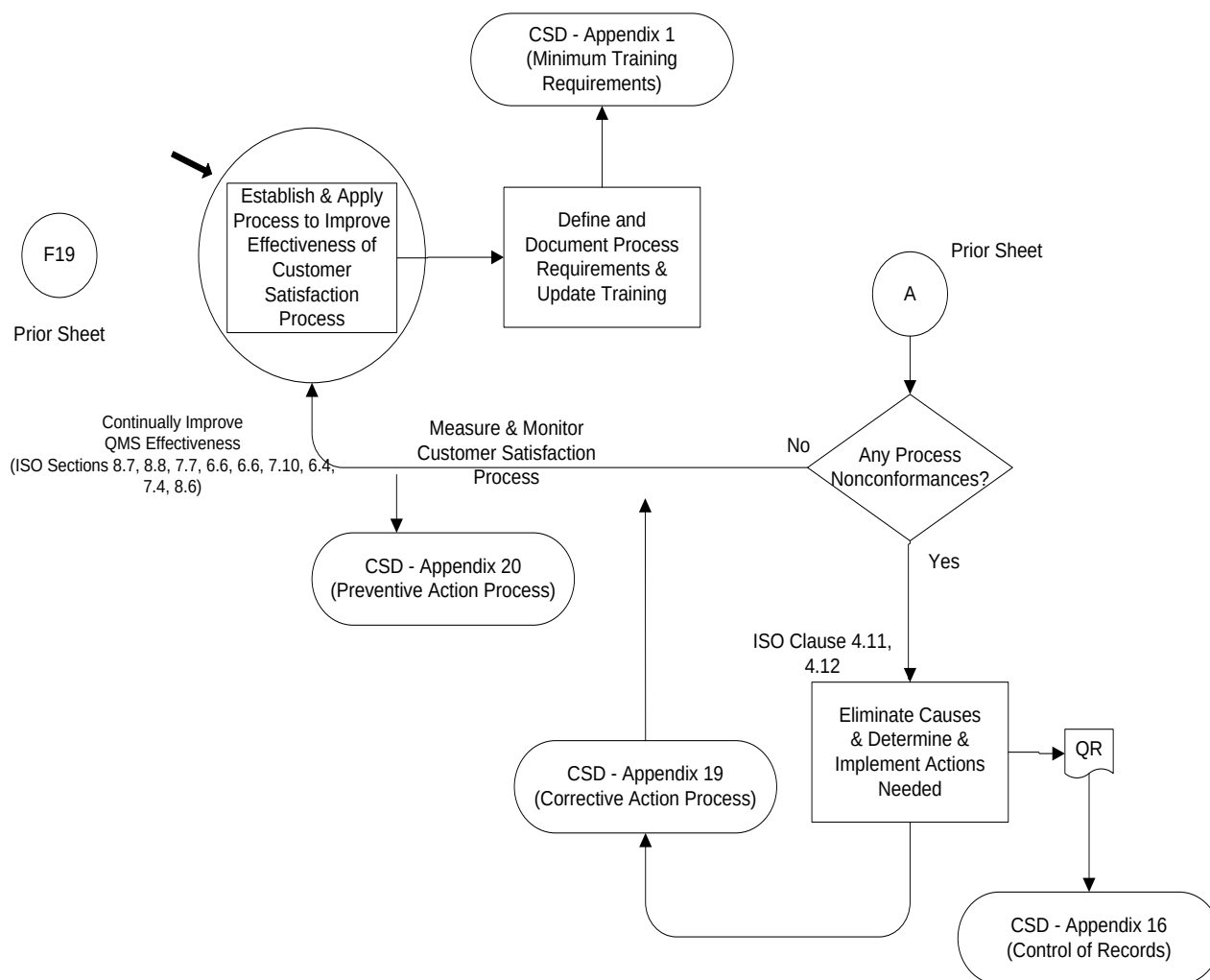


# Calibration System Description

MP CSD

## Customer Satisfaction Process (Cont)

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.11,  
8.7, 8.6)  
Doc. F19 R1 6-09-03

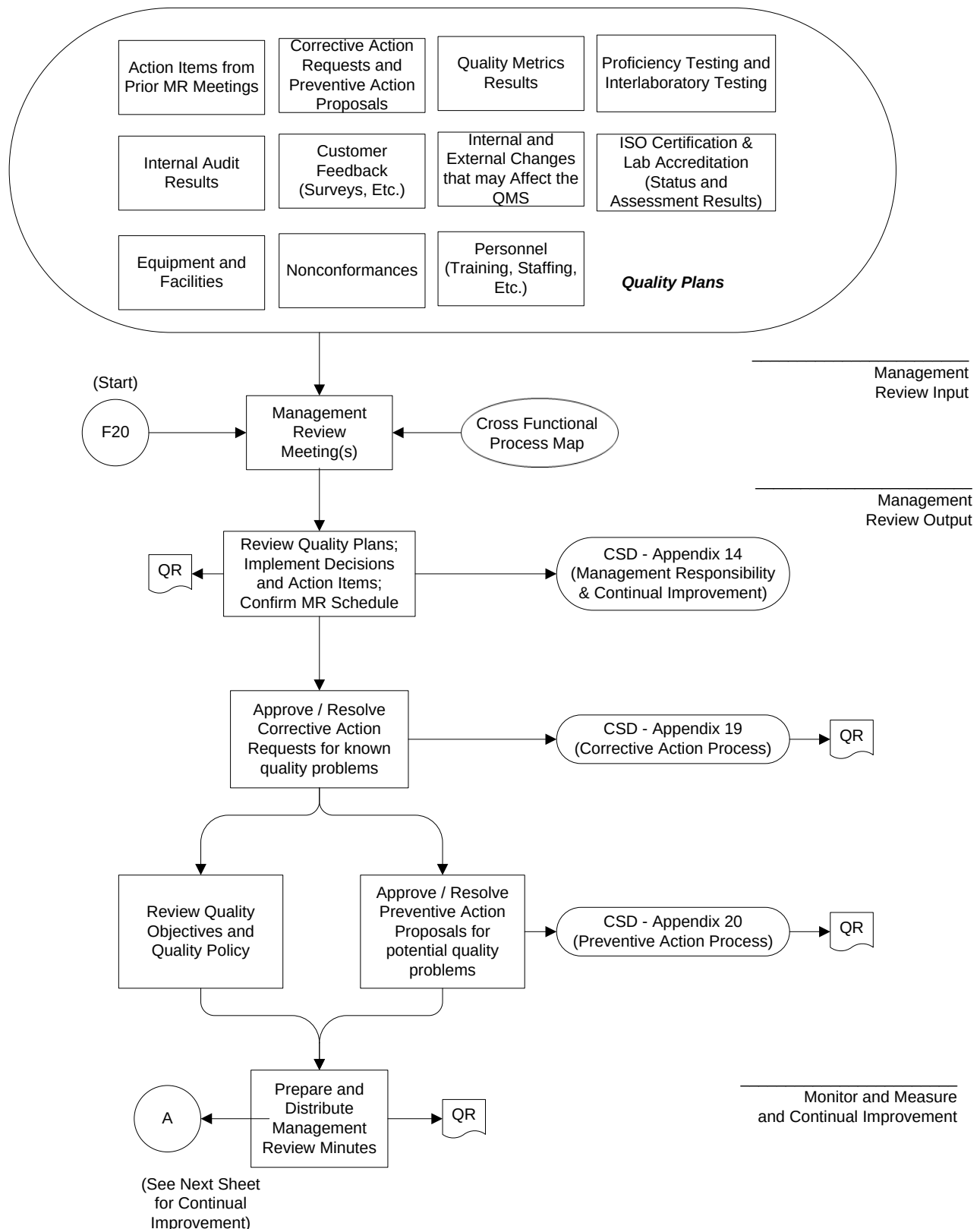


# Calibration System Description

MP CSD

## Management Review Process

Ref. ISO/IEC 17025:2017 (Sections 4.1, 8.7,  
8.6)  
Doc. F20 R1 6-09-03

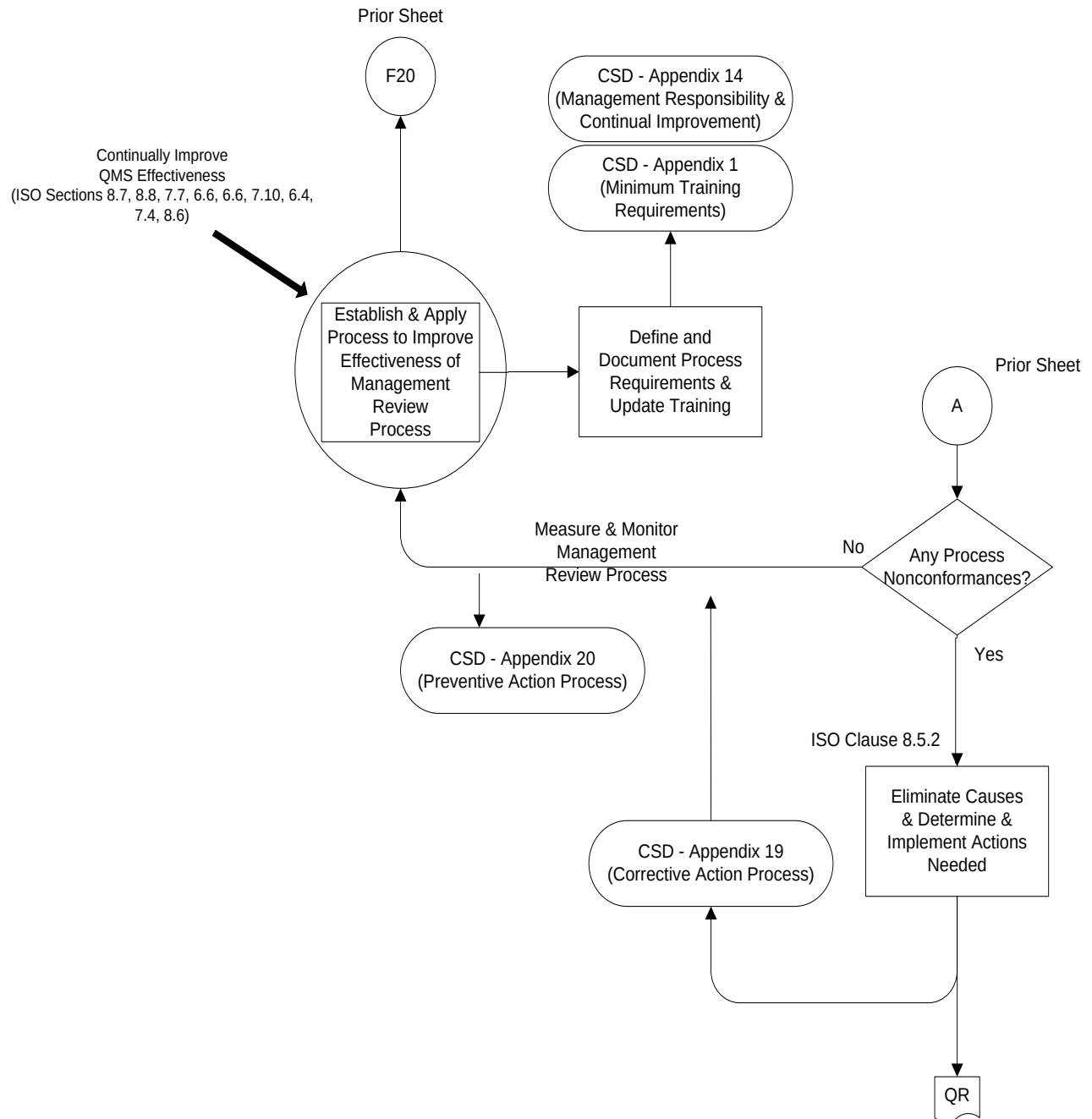


# Calibration System Description

MP CSD

## Management Review Process (Cont.)

Ref. ISO/IEC 17025:2017 (Sections 4.1, 8.7, 8.6)  
Doc. F20 R1 6-09-03



# Calibration System Description

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## Appendix 15 – Control of Documents

Table 1 – Responsibilities

| Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Div.<br>QC<br>Supv | Dept.<br>Mgrs. | Div.<br>Mgr. | QA<br>Dept.        | Lab<br>Mgr. | IT<br>Dept. | Pres. |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----------------|--------------|--------------------|-------------|-------------|-------|
| <ul style="list-style-type: none"> <li>Maintaining a current Master Document List at the Division. (Note: This is the list that identifies the latest revision and issue status of controlled documents in our management system.)</li> <li>Assure that only current on-line and hard copy Quality Manual and CSD documents are available at points of use.</li> <li>Familiar with, know the location of, and ensure that only the latest revision of documents is used.</li> <li>Identifying and periodically reviewing all quality procedures and documents pertinent to their department.</li> <li>Revising, reviewing, and releasing QMS documents (e.g., QM, CSD) for use.</li> <li>Reviewing and approving QMS and CSD prior to release for use.</li> </ul> | X                  | X              | X            | X<br><br><br><br>X |             |             | X     |
| <u>Work Instructions:</u> <ul style="list-style-type: none"> <li>Preparing, revising and reviewing all Work Instructions developed at the Division prior to release for use.</li> <li>Approving all Work Instructions needed for Division operations.</li> <li>Interfacing with the QA Manager during the Work Instruction review process to ensure consistency with CSD and QM requirements; and issuing the Work Instructions as delegated by the QA Manager.</li> <li>Reviewing Work Instructions for company-wide applicability or impact to the QM or CSD.</li> </ul>                                                                                                                                                                                        | X                  | X              | X            | X                  |             |             |       |

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**Table 1 – Responsibilities**

| Requirements                                                                                                                                                                                                                                                                                                                                                                | Div.<br>QC<br>Supv | Dept.<br>Mgrs. | Div.<br>Mgr. | QA<br>Dept. | Lab<br>Mgr. | IT<br>Dept. | Pres. |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|----------------|--------------|-------------|-------------|-------------|-------|
| <ul style="list-style-type: none"> <li>Reviewing and approving all Calibration Procedures at the Division prior to release for use. Also see Appendix 6 – Table 1- Responsibilities</li> <li>Monitor and update Master List of Calibration Procedure used in the Division. Also see Appendix 6 – Table 1- Responsibilities</li> </ul>                                       |                    |                |              |             | X           | X           |       |
| <u>Proprietary Information:</u> <ul style="list-style-type: none"> <li>Taking necessary precautions to ensure that requestor of customer proprietary or confidential information is entitled to receive such information.</li> </ul>                                                                                                                                        | X                  |                |              |             |             |             |       |
| <u>Database:</u> <ul style="list-style-type: none"> <li>Ensuring that only current <u>database files</u> and forms are available for users.</li> <li>Authorizing revisions to database files.</li> <li>Maintaining a current list of computer files and forms.</li> <li>Making minor changes (i.e., header/footer information) to local forms in database files.</li> </ul> |                    |                | X            |             |             | X           | X     |
| <ul style="list-style-type: none"> <li>Retaining archive copies of obsolete Quality Manuals and Procedures to satisfy retention periods established on the Master Document List.</li> </ul>                                                                                                                                                                                 |                    |                |              | X           |             |             |       |
| <ul style="list-style-type: none"> <li>Retaining archive copies of obsolete Calibration Procedures published or approved by Recognized governing Bodies (CDs and DVDs) and destroying (breaking) all other copies. Also see Appendix 6 – Table 1 - Responsibilities</li> </ul>                                                                                              |                    |                |              | X           | X           |             |       |

# Calibration System Description

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**Table 2 – General Requirements**

| Item                        | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks                                                                                                                                          |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Process Maps</b>         | <ul style="list-style-type: none"> <li>Process maps are used to describe key processes. Their primary functions are to: <ul style="list-style-type: none"> <li>Identify and close gaps, exclusions or issues between a process and QMS requirements;</li> <li>Illustrate inter-relationships between key processes;</li> <li>Aid in identifying where process improvements may be made during continual improvement activities or operational changes;</li> <li>Supplement written Work Instructions, where feasible.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | See "Format" requirements in this Table                                                                                                          |
| <b>Master Document List</b> | <ul style="list-style-type: none"> <li>Contains the description, revision level, internal/external designation, source, type, required approval, last review date, location and access group of each document, including all quality documents and work instructions used by the Division (e.g., Calibration Tables, Charts, Text Books and Posters).</li> <li>Include documents of external origin (e.g., Manufacturer Manuals, GIDEP Calibration Procedures, etc.), except do not list documents that are temporarily furnished by and returned to the customer with a job. <ul style="list-style-type: none"> <li>Cross-reference to "See Library" for Manufacturer Manuals.</li> <li>Cross-reference to latest CD/DVD release date for GIDEP Calibration Procedures.</li> </ul> </li> <li>The Master Document List will be updated at least annually or whenever the physical location of a document is changed.</li> </ul>                                                                                                                                                                                                                                                                                                            | See Appendix 15, Table 1, Responsibility                                                                                                         |
| <b>Format</b>               | <ul style="list-style-type: none"> <li>QM and CSD Format – Include title, cover page, table of contents, applicable Standards, requirements, revision level and date, controlled copy statement or restriction, page number on each page and total number of pages, reviewing and approving authorities and authority statement referencing original signature approval page is on file with the Quality Assurance Manager. <ul style="list-style-type: none"> <li>Procedural requirements appear in the CSD, its Appendices and Process Maps.</li> <li>Additional procedure requirements needed are developed by the individual Divisions in the form of Work Instructions.</li> </ul> </li> <li><u>Work Instructions Format</u> – Include Micro Precision company name, title, identified scope, issue date, revision, page number on each page and total number of pages, and review approval and issue by authorities and electronic file reference number. <ul style="list-style-type: none"> <li>Attachments may be included, if applicable.</li> <li>References (higher level QM documents, ISO Standards, etc.) should be listed, where appropriate.</li> <li>Process maps may be included, if appropriate.</li> </ul> </li> </ul> | <p>Global, top level quality system documents</p> <p>Provides detailed instructions, requirements and guidelines for operational activities.</p> |

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**Table 2 – General Requirements**

| Item             | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Remarks                                                                                                                                               |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
|                  | <ul style="list-style-type: none"> <li>○ The style used should follow the higher level QMS documents, but may vary as long as the specified format items are included.</li> <li>• Process Maps Format – Includes title, higher level references (e.g., ISO standard, QM, CSD section, etc.), process map document number, revision level and issue date, and process flowchart. If developed by a Division for its local use, include Division location and approving authority.</li> <li>• Calibration Procedures Format – See Appendix 6</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Used in the global, top level quality system documents; can be created for local processes if desired.                                                |
| <b>Revisions</b> | <ul style="list-style-type: none"> <li>• Database Revisions                             <ul style="list-style-type: none"> <li>○ Requests for changes will be made to the IT Department.</li> <li>○ Only current revision level database menus and forms are made available to users.</li> <li>○ Must be authorized by Executive Management.</li> <li>○ Revisions are identified in the database log files.</li> </ul> </li> <li>• QM and CSD Revisions                             <ul style="list-style-type: none"> <li>○ Requests for changes will be made to the Quality Assurance Department.</li> <li>○ Revision level will be indicated in the lower left corner of the page and manual revision indicated on the cover page (also see Appendix 4).</li> <li>○ Drafts will be identified as such and kept separate from approved releases.</li> <li>○ An <i>Asterisk (*)</i> followed by its Revision Level, will be used to identify revisions made. Summary of revisions will be listed in the History section.</li> <li>○ Revisions will be reviewed and approved prior to implementation; and accepted based on overall impact on operation and quality.</li> </ul> </li> <li>• Work Instructions Revisions                             <ul style="list-style-type: none"> <li>○ Make requests for revisions to the Division Manager.</li> <li>○ Highlight or list revisions in a History section.</li> <li>○ Revisions will be reviewed and approved before implemented; acceptability will be based on overall impact on operation and quality.</li> </ul> </li> <li>• Calibration Procedures Revisions – see Appendix 6</li> </ul> | <p>See Appendix 15, Table 1, Responsibilities</p> <p>See Appendix 15, Table 1, Responsibilities</p> <p>See Appendix 15, Table 1, Responsibilities</p> |

# Calibration System Description

**MP CSD**

**Table 2 – General Requirements**

| Item                                                           | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Remarks                                                                                                                           |
|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| <b>Review and Issue</b>                                        | <ul style="list-style-type: none"> <li>Quality procedures are validated and uploaded to CMS database</li> <li>A thorough review of quality procedures for details (i.e. formatting, Page numbers, etc.) shall be done by QA Corporate prior to release. Revised quality procedures may be issued either by mail, by hand Or by e-mail</li> <li>Calibration procedure review and issue requirements are discussed in Appendix 6.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | See Appendix 15, Table 1, Responsibilities                                                                                        |
| <b>Departing from Established Procedures</b>                   | <ul style="list-style-type: none"> <li>Requirements are described in Appendix 7.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                   |
| <b>Suggestions for Improvements in Processes or Procedures</b> | <ul style="list-style-type: none"> <li>Notify the Quality Assurance Manager.</li> <li>The QA Manager and Executive Management will review and revise quality procedures and documents to ensure continuing suitability and compliance with the Quality Policy.</li> <li>Direct suggestions for improvement to department supervisors and managers (e.g., individuals contact department managers; Division Manager for local process improvements; QA Manager for global process improvements, etc.)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                         | See Appendix 15, Table 1, Responsibilities<br>See Appendix 20, Preventive Action Process                                          |
| <b>Security</b><br>(Hard Copy and Electronic Files)            | <ul style="list-style-type: none"> <li>Documents will be controlled and protected using appropriate security measures, such as limiting access and safeguarding or locking a document against unauthorized changes.                             <ul style="list-style-type: none"> <li>Electronic media is controlled by password protection.</li> <li>Operating systems shall have a root password with a separate password for day-to-day operations access</li> <li>Changes to the global database system require authorization and clearance from Executive Management.</li> <li>Protecting or locking a document (e.g., use Adobe Acrobat or other similar)</li> </ul> </li> <li>Computer calibration report databases will be downloaded to an off-site server on a daily basis.                             <ul style="list-style-type: none"> <li>A current list of computer files and forms will be maintained by Executive Management.</li> </ul> </li> </ul> | See Appendix 15, Table 1, Responsibilities<br>Also see Customer Confidentiality and Proprietary Rights in this Appendix, Table 3. |
| <b>Disposition of Documents</b>                                | <ul style="list-style-type: none"> <li>Promptly remove and destroy superseded and/or obsolete documents from all points of use.</li> <li>Obsolete electronic database files will be archived on the computer with limited access.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Also see Appendix 15, Table 1, Responsibilities                                                                                   |

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**Table 2 – General Requirements**

| Item | Requirements                                                                                                                                                                                                                                                                                                                                   | Remarks |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|      | <ul style="list-style-type: none"><li>• Obsolete on-line (e.g., local) documents used at the Division will be stored in a directory identified as “Obsolete” or “Retired”.<ul style="list-style-type: none"><li>○ Hard copies of obsolete document will be stamped “Obsolete” and will identify the revision replacing it.</li></ul></li></ul> |         |

**Table 3 – Documents of External Origin**

| Item                                                       | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Remarks |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Customer-supplied Manuals /Technical Ref. Materials</b> | <ul style="list-style-type: none"><li>• Log into computer for automatic listing in shipping documents.</li><li>• When appropriate, make copies and file for future reference.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |
| <b>Confidentiality and Proprietary Right</b>               | <ul style="list-style-type: none"><li>• Customer documents are considered proprietary and confidential.</li><li>• No customer information (including Calibration Certificates) will be transmitted electronically or by other means, (whether by the permanent lab or during field services) without the express approval of the Quality Control Supervisor for the Division or Division Manager.<ul style="list-style-type: none"><li>○ Precautions during transmittal include: obtaining caller's name, phone number, looking up the customer's number and file information, and then returning the call to verify the identity of the caller; or obtaining a fax request from the caller to verify customer letterhead, etc.</li><li>○ See the team site for the Agreement Regarding Confidential Information Trade Secrets.</li></ul></li><li>• Obtain written approval from the customer's QA Manager prior to transmitting customer confidential or proprietary information to third parties. File the written approval so that it is readily retrievable (e.g., in the customer's file, etc.)</li><li>• Use a Micro Precision fax letterhead or e-mail header for transmittals, that contain the following or equivalent:<ul style="list-style-type: none"><li>○ “All transmitted documents are for the owner's eyes only; customer's confidentiality will be protected through all practical means.”</li></ul></li><li>• Customers will be provided controlled access to their Calibration Certificates on the MP web site through log-in and password.<ul style="list-style-type: none"><li>○ Reports will be in HTML format.</li><li>○ Reports will be protected against changes by customers with the exception of the customer control information (e.g.,</li></ul></li></ul> |         |

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**Table 3 – Documents of External Origin**

| Item                                | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks                                    |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
|                                     | customer control number, department and instrument location).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |
| <b>GIDEP Calibration Procedures</b> | <ul style="list-style-type: none"> <li>Archive copies of all obsolete CDs/DVDs will be kept in a secure location where they cannot be misused.</li> <li>If a hard copy of the GIDEP Calibration Procedure is printed, the following will be implemented: <ul style="list-style-type: none"> <li>The technician printing the Procedure will date and initial the first page.</li> <li>No hard copy will be used with a log date exceeding one year.</li> <li>Verify the hard copy against the latest electronic GIDEP Procedure to verify the currency of the hard copy, and initial and date the verification.</li> <li>Destroy any hard copy that is not the latest revision.</li> </ul> </li> </ul> | See Appendix 15, Table 1, Responsibilities |

**Table 4 – Documents of Internal Origin**

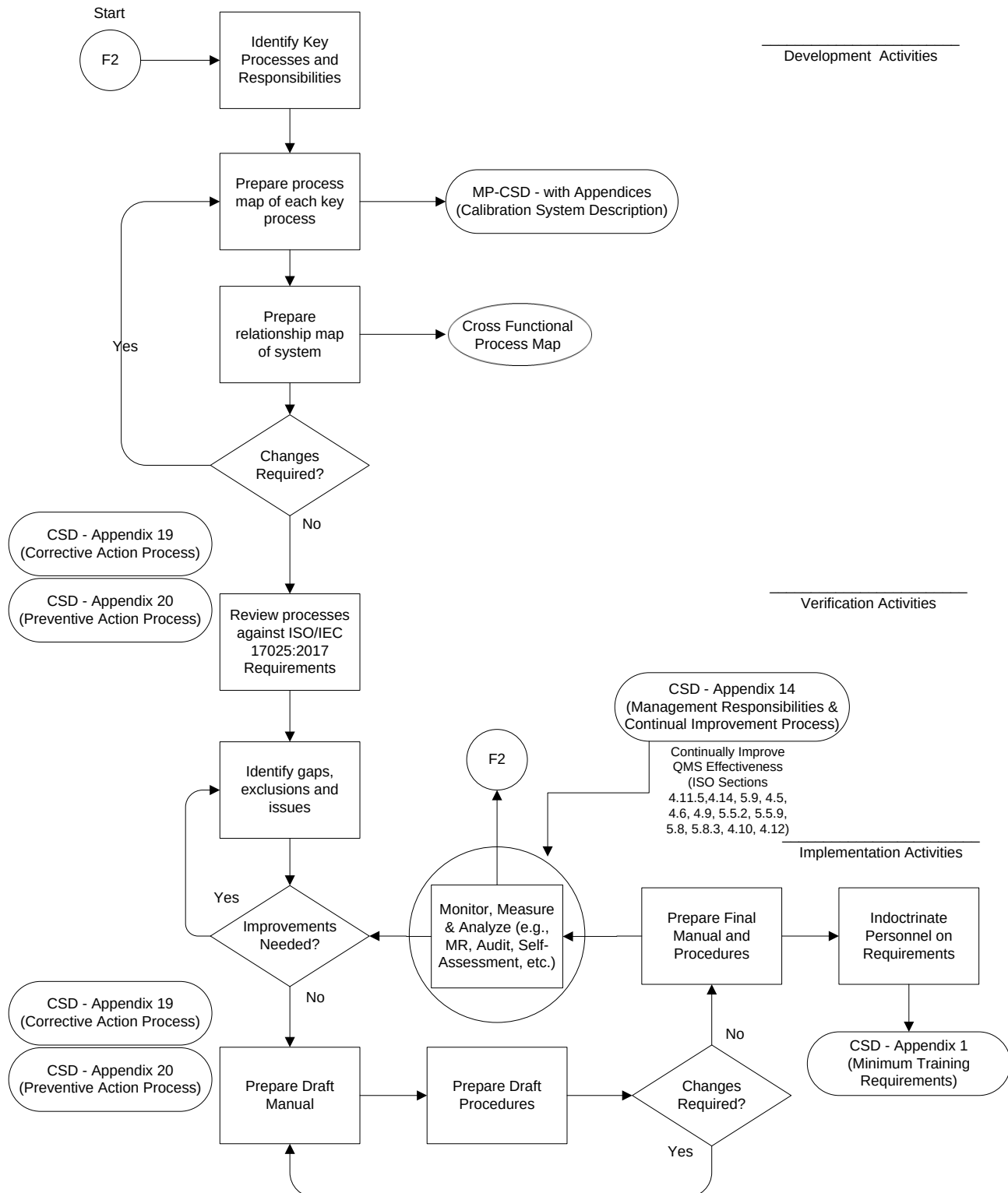
| Item                                                     | Requirements                                                                                                                                                                                                                                                                                                                  | Remarks                                    |
|----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Quality Manual and Calibration System Description</b> | <ul style="list-style-type: none"> <li>The electronic on-line copies will be controlled and safeguarded in a format that prevents changes to the document.</li> <li>May be accessed on-line or in hard copy form, as deemed appropriate by the Division for its points of use.</li> </ul>                                     |                                            |
| <b>Transmittal to Customers</b>                          | <ul style="list-style-type: none"> <li>If transmitting the Quality Manual electronically to the customer, notify the customer that: <ul style="list-style-type: none"> <li>The document is not controlled.</li> <li>The document should be deleted after one year or when a newer version is received.</li> </ul> </li> </ul> |                                            |
| <b>Local Documents</b>                                   | <ul style="list-style-type: none"> <li>Work instructions will be created, controlled and dispositioned, the same as any other quality document.</li> </ul>                                                                                                                                                                    | See Appendix 15, Table 1, Responsibilities |

# Calibration System Description

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## QMS Documentation Development and Improvement Process

Ref. ISO/IEC 17025:2017 (Sections  
4.1, 8.7, 8.6)  
Doc. F2 R2 6-20-03



# Calibration System Description

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## Appendix 16 – Control of Records

Table 1 – Responsibilities

| Requirements or Activity                                                                                                                                                       | IT Dept. | Division Mgr. | QC Supv. | Quality Director |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------------|----------|------------------|
| <ul style="list-style-type: none"> <li>Identification, development and specification of control activities for Quality Records.</li> </ul>                                     |          |               |          | X                |
| <ul style="list-style-type: none"> <li>Storage of Quality Records at Division.</li> </ul>                                                                                      |          | X             |          |                  |
| <ul style="list-style-type: none"> <li>Implementing adequate controls for Quality Records at Division and keeping an updated Quality Record list.</li> </ul>                   |          |               | X        |                  |
| <ul style="list-style-type: none"> <li>Responsible for integrity of MP proprietary database system of computer Records, including backup, updates, and maintenance.</li> </ul> | X        |               |          |                  |
| <ul style="list-style-type: none"> <li>Interface with Quality Director regarding disposal of electronic records on database.</li> </ul>                                        | X        |               |          | X                |

Table 2 – Quality Record Control Requirements <sup>\*R01</sup>

| Item                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks |
|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>General</b><br><br><i>Definition of Quality Record</i> | <ul style="list-style-type: none"> <li>A completed document which provides evidence of conformity to requirements and of the effective operation of the Quality Management System.                             <ul style="list-style-type: none"> <li>A list of Quality Records appears in Table 3 of this Appendix 16.</li> </ul> </li> </ul>                                                                                                                                                                                                                               |         |
| <i>Retrievability</i>                                     | <ul style="list-style-type: none"> <li>Retrievable within the prescribed retention period with reasonable effort.</li> <li>Retrieving archived files are allowed upon customer request.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                           |         |
| <i>Legibility</i>                                         | <ul style="list-style-type: none"> <li>Legible when prepared and maintained.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |
| <i>Storage and Preservation</i>                           | <ul style="list-style-type: none"> <li>Records of observations, calculations, data transfers and checks will be identifiable to the specific task they pertain to and will be stored for future reference</li> <li>Stored in a suitable environment (e.g., file cabinets). Electronic files stored on specified file servers.</li> <li>Regular back-up and maintenance of electronic files stored on servers.</li> <li>Stored / maintained as hard copies and/or computer files.</li> <li>Stored / maintained as active, on-going records or as archived records.</li> </ul> |         |

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**Table 2 – Quality Record Control Requirements** \*R01

| Item                                          | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Mistakes in Records</i>                    | <ul style="list-style-type: none"> <li>Corrected in hard copies by drawing a line through the incorrect entry and initialing, dating and noting the change alongside the existing entry.</li> <li>Corrected in computer files by generating a new record and referencing the corrected record in the new record.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |
| <i>Controls for Identification of Records</i> | <ul style="list-style-type: none"> <li>MP generated Quality Records will be documented on appropriate forms designed for this purpose (either hard copy or generated within the MP database).                             <ul style="list-style-type: none"> <li>Forms used corporate-wide will be approved by the Quality Assurance Manager.</li> <li>Division-specific forms will be approved by the Division Manager.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |
| <i>Controls for Storage of Records</i>        | <ul style="list-style-type: none"> <li>Quality Records to be maintained, storage method / location, retention period, and entity with primary and secondary responsibility appears in Table 3 of this Appendix 16.</li> <li>Customer and other external inputs (correspondence, orders, audits and surveillances, proficiency tests, etc.) will be retained as Quality Records.</li> <li>Electronic Quality Records are identified by title, unique number and/or date within the MP database.</li> <li>Hard copies of Quality Records will contain the above information (if generated from the MP database), or will be otherwise evident as a record (e.g., provided by the customer, approved by authorized MP management (e.g., pertinent memo, correspondence, etc.) and dated.</li> <li>Active and archived electronic Quality Records are stored in the MP database which is controlled by the Corporate Information Systems Manager.</li> <li>Hard copies of active and archived Quality Records located at each Division will be indexed, locked or otherwise prevented from unauthorized access and stored in the Division Manager's office or other designated area in the laboratory.</li> <li>The Division Manager may elect to have the Quality Control Supervisor maintain the Quality Records but only if the records can be locked up and secured from unauthorized access.</li> </ul> |         |

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**Table 2 – Quality Record Control Requirements** \*R01

| Item                                                       | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Remarks |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Controls for Protection of Records</i>                  | <ul style="list-style-type: none"> <li>Access to electronic Quality Records in the MP database is controlled by passwords assigned to individuals according to area of responsibility. Passwords are controlled and issued by the Information System Manager.</li> <li>The MP database is backed up by the Corporate Information System Manager on a daily basis. The back-up schedule and records are kept by corporate management.</li> <li>The Information Systems Manager is responsible for the integrity of backups for specified retention periods (e.g., Table 3 of this Appendix 16), and assuring that the database is being properly maintained and protected.</li> <li>In general, employees have access to Customer records according to their areas of responsibility. <ul style="list-style-type: none"> <li>Access to all other Quality Records is limited to the Division Manager, the Quality Assurance Manager, the Quality Control Supervisor and Internal Auditors.</li> </ul> </li> <li>Customer records will not be forwarded to a third party without the written approval of the customer.</li> <li>MP specific Quality Records will not be sent to a third party without the approval of the Quality Assurance Manager.</li> <li>Whenever a Quality Record is forwarded electronically, care will be taken to assure that the transmittal does not change or degrade the record content.</li> </ul> |         |
| <i>Controls for Replacement of Lost or Damaged Records</i> | <ul style="list-style-type: none"> <li>On-line records will be reprinted (utilizing backup information) and will include a statement as to the reason it was reprinted.</li> <li>The Division Manager will be contacted to notify appropriate persons regarding lost or damaged records.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |
| <i>Controls for Retrieval of Records</i>                   | <ul style="list-style-type: none"> <li>The responsible Manager will provide for the timely retrieval of records in accordance with customer, regulatory, administrative or industry needs. <ul style="list-style-type: none"> <li>Unless the record is needed for revision or other specific purposes, uncontrolled copies will be provided to satisfy retrieval requests.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |
| <i>Controls for Superseding Records</i>                    | <ul style="list-style-type: none"> <li>Quality Records will be appropriately identified so as to distinguish archive copies from current copies. <ul style="list-style-type: none"> <li>Example: Add an identification statement that the Certificate supersedes the old Calibration Report number. A unique Calibration Report Number is generated by the MP database when a Calibration Report replaces an existing Report.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |

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**Table 2 – Quality Record Control Requirements** <sup>\*R01</sup>

| Item                                                  | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                                              |
|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| <i>Retention Period for Records</i>                   | <ul style="list-style-type: none"> <li>Retention periods for types of Quality Records are generally identified in Table 3 below.</li> <li>The retention status of Quality Records will be reviewed annually.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                      |
| <i>Disposition of Records</i>                         | <ul style="list-style-type: none"> <li>Prior to disposition, verify the following conditions: <ul style="list-style-type: none"> <li>Regulatory requirements are satisfied;</li> <li>Customer-specified requirements are satisfied (e.g., is MP retaining Calibration Reports for customers, in which case customer-specified retention periods govern);</li> <li>MP specified requirements are satisfied.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                            |                                                                      |
| <i>Disposal of Records</i>                            | <ul style="list-style-type: none"> <li>Annual reviews are conducted to determine records for disposal. <ul style="list-style-type: none"> <li>Hard copies of Quality Records will be shredded by the Division when retention periods have lapsed.</li> <li>Electronic copies of Quality Records stored on database shall be permanently deleted after it has reached the maximum retention period.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                    | Refer to Appendix 16, Table 3, Quality Records and Retention Periods |
| <b>Records Required for Establishing Traceability</b> | <ul style="list-style-type: none"> <li>The following records will be maintained to establish traceability: <ul style="list-style-type: none"> <li>Calibration Certificates for MP instruments and reference standards and data;</li> <li>Calibration Certificates from NIST, external provider and OEMs that calibrate MP instruments and reference standards;</li> <li>Measurement uncertainty programs and associated documents and data;</li> <li>Procedures, methods and work instructions used to perform the calibrations;</li> <li>Evidence of technical competence (e.g., personnel records, the laboratory's accreditation records, etc.);</li> <li>Evidence of periodic recalibrations to preserve traceability; Equipment Service Reports.</li> </ul> </li> </ul> | Ref. Appendix 13, Table 5, Traceability                              |
| <b>MP Equipment Records</b>                           | <ul style="list-style-type: none"> <li>MP equipment records will include the following: <ul style="list-style-type: none"> <li>Traceability records (see above);</li> <li>Manufacturer manuals;</li> <li>Verifications and checks of compliance with calibrations;</li> <li>Records of preventive maintenance activities;</li> <li>Records of intermediate checks;</li> <li>Records of proficiency testing activities;</li> <li>Records of repairs and/or service reports</li> <li>Procurement documents (purchase orders, servicing, etc., as applicable);</li> <li>Equipment software (e.g., for ATE), uniquely identified when practical.</li> </ul> </li> </ul>                                                                                                          |                                                                      |

# Calibration System

## Description

MP CSD

**Table 3 – Quality Records and Retention Periods** <sup>\*R01</sup>

| Record Type or Description                                                                            | Primary / Secondary Control                |                                      | Storage Methods / Locations               | Retention Period (Yrs.) | Remarks                                                                    |
|-------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------------------------|-------------------------------------------|-------------------------|----------------------------------------------------------------------------|
|                                                                                                       | Corporate                                  | Division                             | Electronic                                |                         |                                                                            |
| Quality Policy                                                                                        | Primary                                    |                                      | MP-QM and MP-CSD viewable on MP Teamsite  | 3                       |                                                                            |
| Management Review Minutes                                                                             | Primary for Corporate-Wide                 | Primary for Division Specific        | MP Teamsite                               | 3                       |                                                                            |
| Goals and Objectives                                                                                  | Primary for Corporate-Wide                 | Primary for Division Specific        | MP Teamsite                               | 3                       |                                                                            |
| Purchase Orders, Contracts and Contract Review Records                                                |                                            | Primary                              | MP Database                               | 3                       |                                                                            |
| Externally Provided Qualification Records                                                             | Primary for Traceability Vendors           | Primary for non-Traceability Vendors | MP Database                               | 3                       |                                                                            |
| Records of External Provider Performance Monitoring                                                   | Primary for Traceability Vendors           | Primary for non-Traceability Vendors | MP Teamsite                               | 3                       |                                                                            |
| Records of Loss or Damage of Customer Products (i.e. Damage Reports)                                  |                                            | Primary                              | MP Database<br>Damage Reports             | 3                       |                                                                            |
| Customer Satisfaction Records (Complaints, Surveys, audits, metrics)                                  | Secondary through Management Review inputs | Primary for Division                 | MP Teamsite                               | 3                       |                                                                            |
| Nonconformance and Corrective Action Reports (resulting from QC inspections, CARs, audits, customers) | Primary for Corporate-Wide                 | Primary for Division Specific        | MP Database / Teamsite.<br>Automated CARs | 3                       | Division should facilitate retrieving all complaints for a given customer. |

# Calibration System

## Description

MP CSD

**Table 3 – Quality Records and Retention Periods** <sup>\*R01</sup>

| Record Type or Description                                                                                                                                                                                                                                                                                                   | Primary / Secondary Control                                 |                                                                                                | Storage Methods / Locations                                                                  | Retention Period (Yrs.) | Remarks                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-------------------------|--------------------------------------|
|                                                                                                                                                                                                                                                                                                                              | Corporate                                                   | Division                                                                                       | Electronic                                                                                   |                         |                                      |
| <b>Continual Improvement</b><br>(Metrics / Statistical Techniques, PAPs)                                                                                                                                                                                                                                                     | Primary for Corporate-Wide                                  | Primary for Division Specific                                                                  | Metrics in Spreadsheets, Correspondence through MP database / Networked Computers / Desktops | 3                       |                                      |
| <b>Training and Qualification of Personnel</b><br>(includes Quizzes, Certs, and Proficiency Testing)                                                                                                                                                                                                                         | Primary for Quality Personnel and Division Mgmt.            | Primary for Division Specific Personnel                                                        | MP Teamsite                                                                                  | 7                       | See Appendix 1 Training Requirements |
| <b>Audit Records</b><br>(Plans, Reports, CARs, including third-party audits / surveillances)                                                                                                                                                                                                                                 | Primary for Corporate-Wide;                                 | Primary for Registrar or Accrediting Body's Assessments and Division Specific Internal Audits; | MP Teamsite                                                                                  | 3                       |                                      |
| <b>MP Equipment and Reference Standards</b><br><br><ul style="list-style-type: none"> <li>• Calibration Reports</li> <li>• Equipment History and Service Records</li> <li>• QC Inspection Traveler / Shipping Records</li> <li>• Environmental Records</li> <li>• Interlaboratory Comparisons / Proficiency Tests</li> </ul> | Primary for Procurement Approval and Intra-laboratory Tests | Primary for Division Procurement and Division Intra-laboratory tests;                          | MP database by unique Equipment Control Number, and Unique Calibration Report Number         | 15                      |                                      |
|                                                                                                                                                                                                                                                                                                                              |                                                             |                                                                                                |                                                                                              | 15                      |                                      |
|                                                                                                                                                                                                                                                                                                                              |                                                             |                                                                                                |                                                                                              | 3                       |                                      |
|                                                                                                                                                                                                                                                                                                                              |                                                             |                                                                                                | MP Teamsite                                                                                  | 3                       |                                      |
|                                                                                                                                                                                                                                                                                                                              |                                                             |                                                                                                | MP Teamsite                                                                                  | 4                       |                                      |

## MP CSD

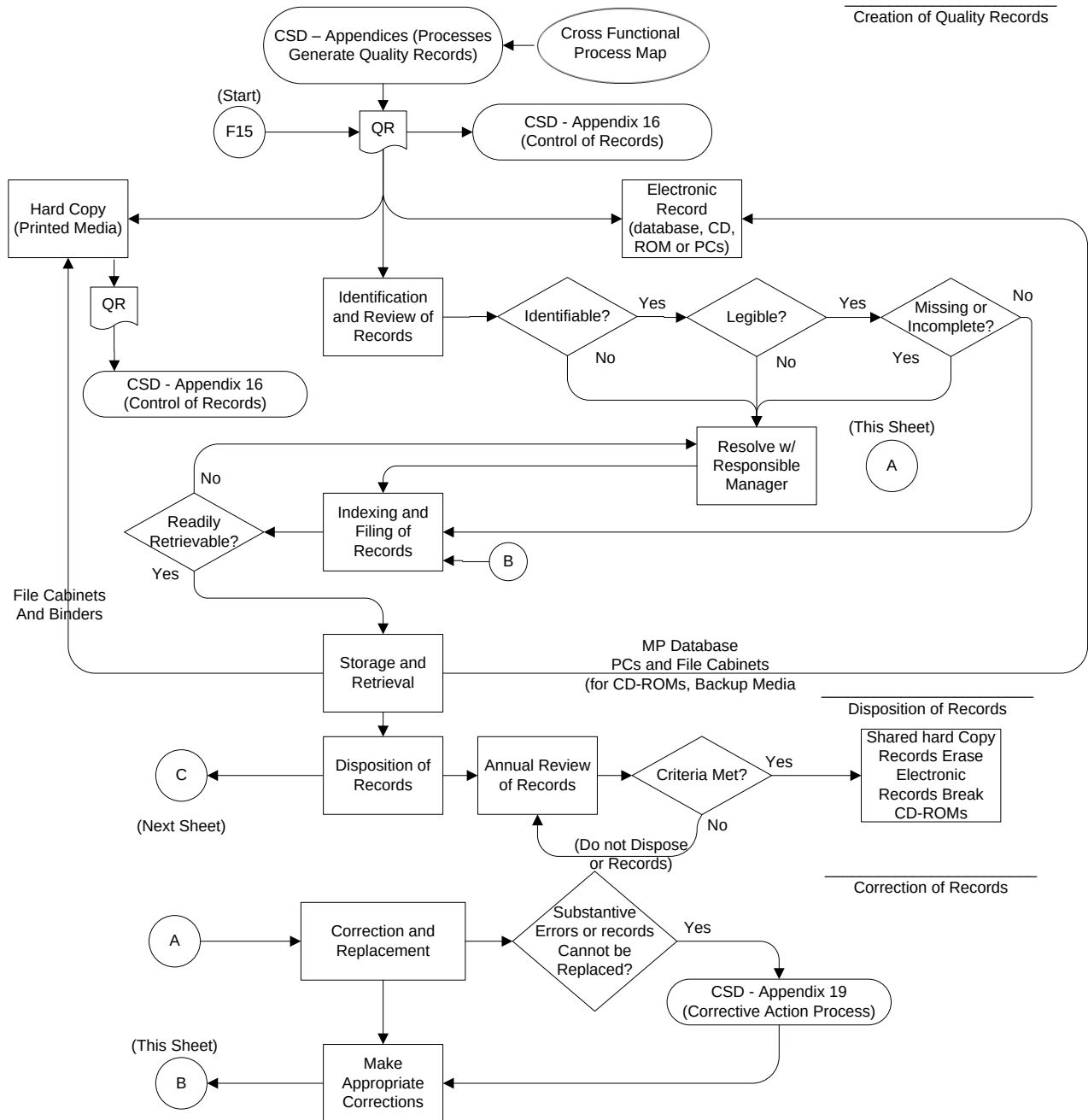
| Record Type or Description                                                                                                                                                                                                                         | Primary / Secondary Control |          | Storage Methods / Locations                                                                            | Retention Period (Yrs.) | Remarks                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------|--------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                    | Corporate                   | Division | Electronic                                                                                             |                         |                                                                            |
| <b>Customer Calibration and Repair Service Records</b> <ul style="list-style-type: none"> <li>Calibration Reports</li> <li>Accounting, Receipt, Inspection, Data, Correspondences, CARs and QC Inspection / Traveler / Shipping records</li> </ul> |                             | Primary  | MP database by Customer Account Number, Equipment Control Number, and Unique Calibration Report Number | 15<br><br>3             | Record is retrievable within the retention period upon request by customer |

# Calibration System Description

## MP CSD

### Record Control Process

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.5,  
8.7, 8.6)  
Doc. F15 R1 6-20-03

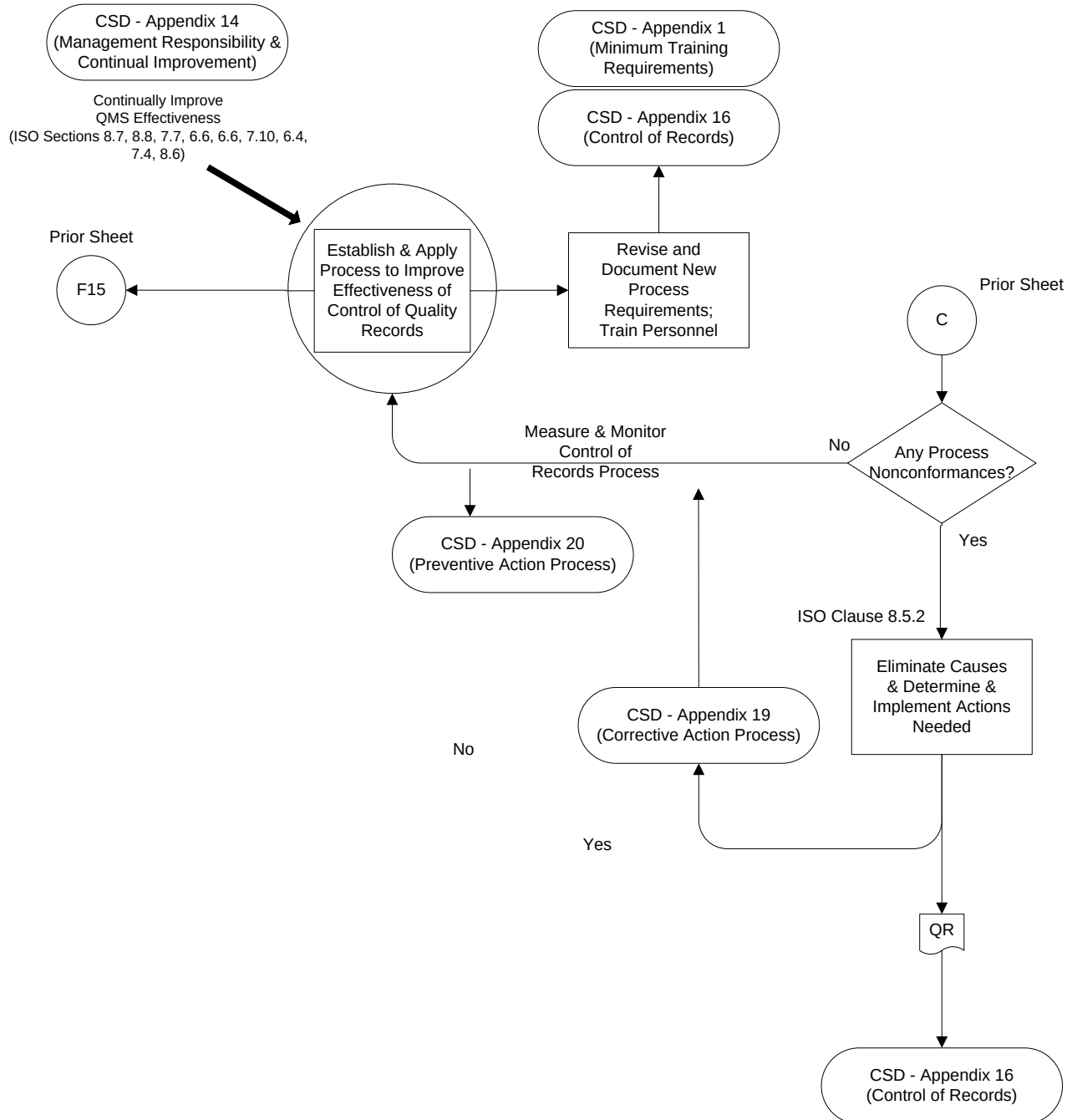


# Calibration System Description

MP CSD

## Record Control Process (Cont.)

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.5,  
8.7, 8.6)  
Doc. F15 R1 6-20-03



# Calibration System Description

MP CSD

## Appendix 17 – Internal Audit Process

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Lead Auditor | Internal Auditor | Mgr. Auditee | QA Mgr. /QC Supv. | Quality Dir | Div. Mgr. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------|--------------|-------------------|-------------|-----------|
| <ul style="list-style-type: none"> <li>Conducts periodic audits of specified QMS and CSD processes.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                         | X            | X                |              |                   | x           |           |
| <ul style="list-style-type: none"> <li>Participates in audits and responds to deficiencies, monitors corrective actions taken, verifies effectiveness of corrective actions taken.</li> </ul>                                                                                                                                                                                                                                                                                          |              |                  |              | X                 |             |           |
| <ul style="list-style-type: none"> <li>Approves Audit Schedules, Plans and Reports conducted on the Quality Assurance Department.</li> </ul>                                                                                                                                                                                                                                                                                                                                           |              |                  |              |                   | X           |           |
| <ul style="list-style-type: none"> <li>Interfaces as necessary with the QA Manager concerning Observations and Findings and related concerns.</li> </ul>                                                                                                                                                                                                                                                                                                                               |              |                  | X            |                   |             |           |
| <ul style="list-style-type: none"> <li>Interface with the Auditor regarding the verification of effectiveness of corrective actions.</li> </ul>                                                                                                                                                                                                                                                                                                                                        |              |                  | X            | X                 |             |           |
| <ul style="list-style-type: none"> <li>Determine the needs for follow-up audits in the event that corrective action was found ineffective.</li> </ul>                                                                                                                                                                                                                                                                                                                                  | X            | X                |              |                   |             |           |
| <u>Quality Control</u> <ul style="list-style-type: none"> <li>Ensuring that corrective actions are implemented and CARs processed per requirements.</li> <li>Overall responsibility for implementation of audits per requirements.</li> <li>Retaining copies of all Audit Plans and Audit Reports.</li> <li>Retaining copies of Audit Plans and Audit Records pertaining to the Division, and CARs pertaining to Audit Findings and observations addressed to the Division.</li> </ul> |              |                  |              | X                 | X           | X         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |              |                  |              | X                 | X           |           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |              |                  |              | X                 |             | X         |

# Calibration System Description

**MP CSD**

**Table 2 – Audit Requirements**

| Item                                              | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks |
|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Auditors</b>                                   | <ul style="list-style-type: none"> <li>Audits will be conducted by trained and qualified Auditors (see Training Requirements in Appendix 1, Table 3, Quality Personnel).</li> <li>Auditors will not audit their own work.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |         |
| <b>Inputs to Audits</b><br><br><i>Definitions</i> | <ul style="list-style-type: none"> <li>Management Reviews</li> <li>Calibration Service</li> <li>Purchasing</li> <li>Nonconformance</li> <li>Continual Improvement</li> <li>Metrics</li> <li>QMS Documents</li> <li>Lead Auditor – Prepares Audit Plan, organizes and leads audit and prepares Audit Report.</li> <li>Internal Auditor – Perform internal audits, participate in audits as part of Audit Team, or are assigned to Audit Team to provide technical expertise in area being audited.</li> <li>Checklist – a document used during the audit that contains information on the questions to be asked, topics to be covered, requirements, etc. and facilitates the recording of responses and observations. As feasible, a procedure, table, process map, or custom-developed list of questions, or any combination thereof, may be used as a Checklist.</li> <li>Finding – Noncompliance of a stated Quality System or its referenced Standard requirement, based on significant objective evidence that corrective action is required, which if left uncorrected, would render a portion of the Quality System ineffective or would result in the complete breakdown of the Quality System.</li> <li>Observation – Statements that reflect the state of operations, procedures or activities discovered during the audit. Deficiencies that is of a lesser offense than Findings. May include recommendations for improvements.</li> <li>Objective Evidence – Qualitative and quantitative information, records, data and statements made during interviews that pertain to the quality of an item or service, its existence or implementation, which support the Finding or Observation. Objective evidence is evidence that is based upon observation, measurement or test and can be verified.</li> </ul> |         |

# Calibration System Description

**MP CSD**

**Table 2 – Audit Requirements**

| Item                                                                                                                                                 | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Overview of Audit Process</i>                                                                                                                     | <ul style="list-style-type: none"> <li>See the Audit Process Map in this Appendix 17.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |
| <i>Criteria for Audits</i><br><br><i>Frequency of Audits</i><br><br><br><br><br><br><br><br><i>Planning and Scheduling</i><br><br><i>Audit Plans</i> | <ul style="list-style-type: none"> <li>Compliance with the QMS and CSD (including Lab Accreditation requirements, where applicable).</li> <li>All QMS and CSD processes (including administration and continual improvement activities) will be audited periodically.</li> <li>The following processes may be audited more frequently (e.g., annually, or as established during Management Review meetings): <ul style="list-style-type: none"> <li>Control of Instruments and Equipment (Appendix 12);</li> <li>Calibration Servicing Process (Appendix 13)</li> <li>Related processes to the extent applicable to the above (e.g., Order Processing, Corrective Action, Training, Environmental Control, etc.)</li> </ul> </li> <li>Consider the status and importance of the processes and areas to be audited as well as results of prior audits.</li> <li>Plans will be prepared prior to performing each audit and will contain, as a minimum, the following information: <ul style="list-style-type: none"> <li>Division, department or area being audited;</li> <li>Audit Plan Number;</li> <li>Purpose and Scope;</li> <li>Associated material (reference documents pertinent to the Audit);</li> <li>History (pertinent information concerning the prior audit(s) being considered during the current audit, etc.);</li> <li>Audit method (e.g., inputs used as the Checklist, etc.)</li> </ul> </li> <li>The Audit method approved in the Audit Plan will be used to conduct the specific audit.</li> <li>Audits will be thorough and specific enough to determine compliance with the referenced QMS and/or CSD requirement.</li> <li>The Quality Director and the Auditor responsible for the Audit will sign the Audit Plan. <ul style="list-style-type: none"> <li>A copy of the signed Audit Plan will be sent to the Auditee.</li> </ul> </li> </ul> |         |
| <i>Signatures and Distribution</i>                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |         |

# Calibration System Description

**MP CSD**

**Table 2 – Audit Requirements**

| Item                                                                                                                                                                                                                             | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Remarks |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Audit Reports</i>                                                                                                                                                                                                             | <ul style="list-style-type: none"> <li>A formal Audit Report will be prepared and signed by the Auditor responsible for the audit.</li> <li>The Quality Director will approve and sign the Audit Report. After approval, the Audit Report will be distributed to the Auditee and Executive Management.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |
| <i>Conducting the Audit</i><br><br><i>Attendance Record</i><br><br><i>Items Examined</i><br><i>Checklist Notations</i><br><br><i>Verification of Prior Audits</i><br><br><i>Objective Evidence</i><br><br><i>Closing Meeting</i> | <ul style="list-style-type: none"> <li>Personnel interviewed and conducting the audit will sign and date the Audit Attendance Record.</li> <li>Identify the items examined during the audit on the Audit Checklist.</li> <li>Identify Findings, Observations or Satisfactory on the Audit Checklist. Other notations, as appropriate, should also be entered, such as: <ul style="list-style-type: none"> <li>N/A – Not applicable;</li> <li>N/R – Not reviewed</li> <li>Comments (e.g., conclusions, summaries, etc.) where applicable.</li> </ul> </li> <li>Review prior audit deficiencies and associated Corrective Action Reports (CARs): <ul style="list-style-type: none"> <li>Determine processing and/or implementation status.</li> <li>See Appendix 19, Corrective Action Process</li> </ul> </li> <li>Attach any objective evidence collected during the audit to the Audit Checklist</li> <li>Discuss deficiencies and non-conformances with the Auditee at the conclusion of the audit. <ul style="list-style-type: none"> <li>Clarify and confirm the Findings and Observations.</li> </ul> </li> </ul> |         |
| <b>Preparing the Audit Report</b>                                                                                                                                                                                                | <ul style="list-style-type: none"> <li>Summarize the items and areas examined. Complete the Audit Report within thirty (30) days of the audit. Include the following in the Audit Report: <ul style="list-style-type: none"> <li>Division, department or area audited;</li> <li>Audit Report Number;</li> <li>Audit Date and Report Date;</li> <li>Purpose and Scope;</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |

# Calibration System Description

**MP CSD**

**Table 2 – Audit Requirements**

| Item | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Remarks |
|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|      | <ul style="list-style-type: none"> <li>○ Associated Material (list documents pertinent to the audit);</li> <li>○ History (pertinent information concerning prior audit(s) considered for the current audit, etc.)</li> <li>○ Summary;</li> <li>○ Observations and Findings</li> <li>○ Implementation and effectiveness of corrective actions.</li> <li>• Use the following guidelines in defining Findings and Observations:</li> <li>• <u>Observations:</u> <ul style="list-style-type: none"> <li>○ Areas where improvements are recommended, or for preventive action;</li> <li>○ Non-compliances which are “minor” in nature. Examples: <ul style="list-style-type: none"> <li>• Procedures require clarifications;</li> <li>• Noncompliance is an isolated occurrence;</li> <li>• Noncompliance, if not corrected immediately, will not result in a total breakdown of the Quality System, etc.</li> </ul> </li> <li>○ Non-compliances currently being tracked under an open CAR.</li> </ul> </li> <li>• <u>Findings:</u> <ul style="list-style-type: none"> <li>○ Noncompliance in implementing the QMS or CSD requirements;</li> <li>○ Inconsistencies between Quality System documents and Code and Standard requirements upon which the QMS or CSD are based;</li> <li>○ Other types of non-compliances (e.g., misapplication of a requirement, etc.)</li> </ul> </li> <li>• When possible, reference the requirement statement along with the noncompliance in the Audit Report.</li> <li>• The Auditor and QA Manager each sign the Report: <ul style="list-style-type: none"> <li>○ Review the report for content and compliance with the Audit Plan, prior to signature;</li> <li>○ The Auditor and QA Manager resolve any changes required;</li> <li>○ The Quality Assurance Manager signs the Report.</li> </ul> </li> <li>• Send a copy of the signed Audit Report to the Auditee (e.g., Manager of the audited Division or area for disposition of non-compliances.)</li> </ul> |         |

# Calibration System

## Description

**MP CSD**

**Table 2 – Audit Requirements**

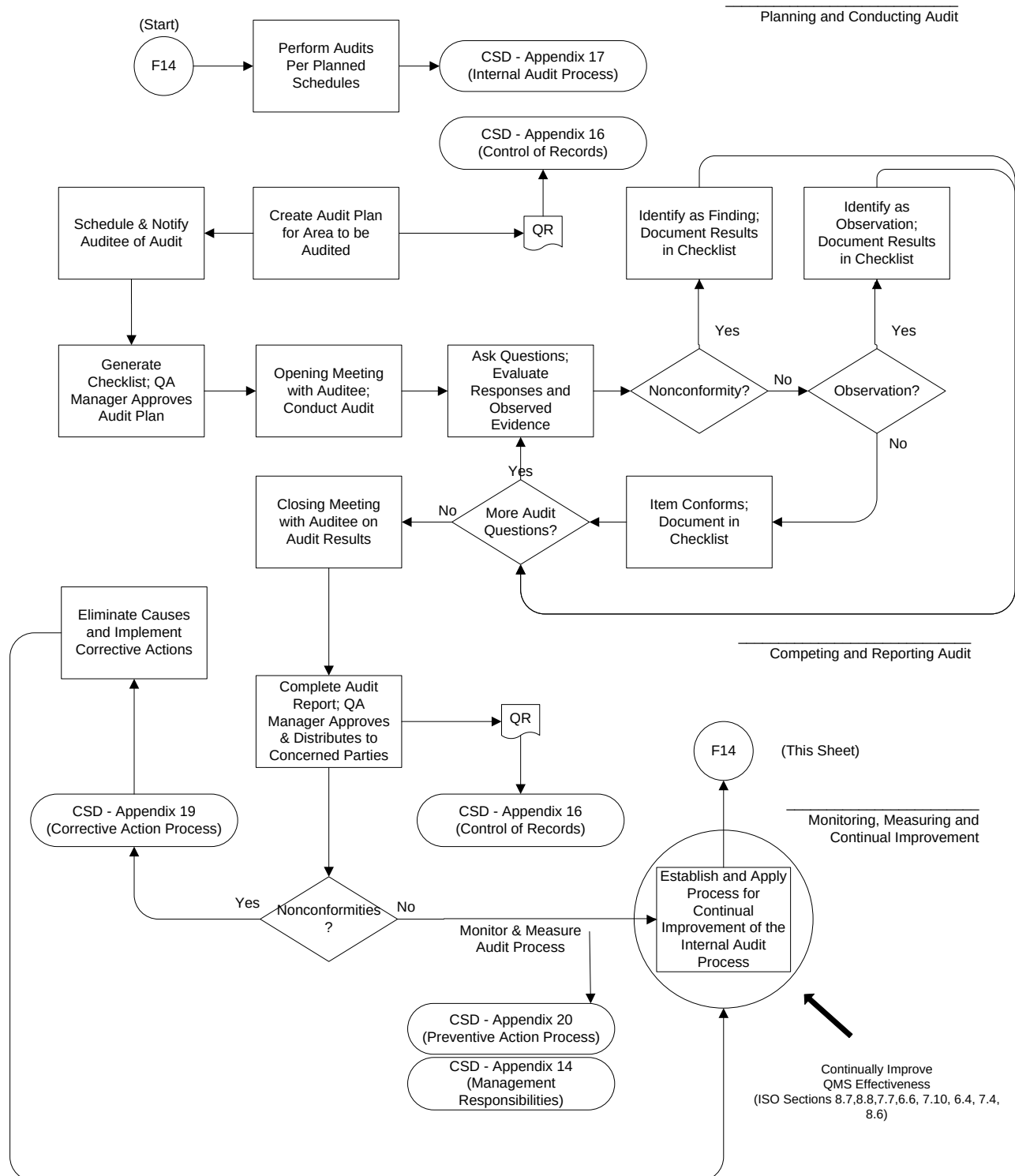
| Item                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                           | <ul style="list-style-type: none"> <li>Maintain file copies of the Audit Plan, Audit Report and associated Corrective Action Reports (see Responsibilities in Table 1 above).</li> </ul>                                                                                                                                                                                                                                                                     |         |
| <b>Follow-Up Verifications</b>                            | <ul style="list-style-type: none"> <li>Interface as necessary with the Quality Director and/or Auditor regarding the identified Observations and Findings, and related concerns, such as:                             <ul style="list-style-type: none"> <li>Resources;</li> <li>Time frames to complete corrective action, etc.</li> </ul> </li> <li>Track Findings using Corrective Action Reports (see Appendix 19, Corrective Action Process)</li> </ul> |         |
| <b>Quality Control</b>                                    | <ul style="list-style-type: none"> <li>See Responsibilities in Table 1 above.</li> <li>The Quality Assurance Department is audited periodically to ensure its compliance with requirements of the QMS and CSD.</li> <li>Audit Reports are readily available for review and verification purposes during subsequent audits.</li> </ul>                                                                                                                        |         |
| <b>Outputs from Audit</b>                                 | <ul style="list-style-type: none"> <li>Audit Documents (Audit Plan, Report, Objective Evidence, etc.)</li> <li>Identified non-conformances and Suggestions for Improvement;</li> <li>Means for Measuring Status and Effectiveness of QMS and CSD.</li> </ul>                                                                                                                                                                                                 |         |
| <b>Verification of Effectiveness of corrective action</b> | <ul style="list-style-type: none"> <li>Implemented corrective action shall be observed and monitored within 3 to 6 months, to verify its effectiveness.</li> <li>Corrective action that was found ineffective shall subject to follow-up audits.</li> <li>Records and evidences of effectiveness will be attached to next audit report.</li> </ul>                                                                                                           |         |

# Calibration System Description

MP CSD

## Audit Process

Ref. ISO/IEC 17025:2017 (8.8, 7.5, 8.7, 8.6)  
Doc. F14 R1 6-09-03



## MP CSD

| Requirements                                                                                                                                                                                                                                                                                                                                                                                   | All | Service Mgr. | Lab Mgr.   | QA Mgr./ QC Supv. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|--------------|------------|-------------------|
| <ul style="list-style-type: none"> <li>Responsible for identifying nonconforming sources either instruments or in the management system.</li> <li>Alerting the QC Supervisor and Lab Manager on nonconforming instruments.</li> </ul>                                                                                                                                                          | X   |              |            |                   |
| <ul style="list-style-type: none"> <li>Assures that nonconforming instruments are promptly red tagged and segregated and locked out in the computer.</li> </ul>                                                                                                                                                                                                                                |     |              |            | X                 |
| <ul style="list-style-type: none"> <li>Initiating Corrective Action Reports for any MP nonconforming Instruments</li> </ul>                                                                                                                                                                                                                                                                    |     |              | X          |                   |
| <ul style="list-style-type: none"> <li>Overall responsibility for maintaining and ensuring the ongoing control of nonconforming instruments at the Division.</li> <li>Reviewing nonconforming instruments history, determining whether to shorten the recall cycle, determining customer recall for nonconforming instruments.</li> </ul>                                                      |     |              | X<br><br>X |                   |
| <ul style="list-style-type: none"> <li>Reviewing rejected instruments prior to return to customer; assuring service options have been addressed, and initialing Calibration Reports for rejected instruments.               <ul style="list-style-type: none"> <li>Note: The Service Manager may appoint a designee to initial rejected instrument Calibration Reports.</li> </ul> </li> </ul> |     | X            |            |                   |
| <ul style="list-style-type: none"> <li>Responsible for authorizing the resumption of work after non-conforming issues were validated and/or corrective actions was applied and verified.</li> </ul>                                                                                                                                                                                            |     |              | X          | X                 |

| Item               | Requirements                                                                                                                                                                                                                                                                                                                                               | Remarks |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>General</b>     | <ul style="list-style-type: none"> <li>Non-conformances are detected as early as possible through:               <ul style="list-style-type: none"> <li>Receiving Inspection (see Appendix 13, Table 3);</li> <li>In-Process Servicing (see Appendix 13, Table 5 and Table 6);</li> <li>Final Inspection (see Appendix 13, Table 8)</li> </ul> </li> </ul> |         |
| <i>Sources</i>     | <ul style="list-style-type: none"> <li>Nonconforming instruments may be identified internally by MP or externally through customer returns or notification.</li> </ul>                                                                                                                                                                                     |         |
| <i>Definitions</i> | <ul style="list-style-type: none"> <li><u>Significantly Out-of-Tolerance</u> – An instrument or measurement standard, with an error, which is more than twice its allowable tolerance.</li> </ul>                                                                                                                                                          |         |

# Calibration System

## Description

MP CSD

**Table 2 – Control of Nonconforming Instruments**

| Item                    | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| MP Instruments or Items | <ul style="list-style-type: none"> <li>Nonconforming Instrument – An instrument that does not conform to specified requirements. Examples: <ul style="list-style-type: none"> <li>Overdue calibration;</li> <li>Out-of-tolerance conditions;</li> <li>Outside specified limits;</li> <li>Improper status and control labeling;</li> <li>Physical impairments that affect accuracy;</li> <li>Physical impairments that degrade value;</li> <li>Traceability documentation, including trace numbers and calibration data.</li> </ul> </li> <li>Will be taken out of service, clearly identified and (whenever possible) stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily, whenever the instruments or items: <ul style="list-style-type: none"> <li>Have been found to be out-of-tolerance, either during a cycled calibration or if between cycled calibrations;</li> <li>Have been subjected to overloading or mishandling;</li> <li>Gives suspect results;</li> <li>Have been shown by verification or otherwise to be defective or outside limits.</li> </ul> </li> </ul>                                                                                                                                                                                                                                                   |         |
| Customer Instruments    | <ul style="list-style-type: none"> <li>The effect or departure from standard limits on calibration results will be examined.</li> <li>Notify the customer and recall the customer's instrument if it has been calibrated by an MP instrument or measuring standard found to be significantly out-of-tolerance (see definition above).</li> <li>If the customer's equipment is found out of tolerance its expected accuracy at the time of calibration: * R02 <ul style="list-style-type: none"> <li>Notify As-Found out-of-tolerance result including sufficient calibration data in a timely manner as applicable; before proceeding with calibration.</li> <li>Written notification must be made to the customer for disposition. Request the customer decision (in writing) on changing the Recall Cycle as applicable.</li> </ul> </li> <li>If the customer's instrument is found out-of-tolerance, status labeling requirements will be followed (see Appendix 12, Table 5). <ul style="list-style-type: none"> <li>Clearly indicate the instrument's condition on return to the customer in both the instrument labeling and the Calibration Report.</li> </ul> </li> <li>Rejected instruments will be reviewed prior to return to assure that all practical service options have been addressed. <ul style="list-style-type: none"> <li>See Responsibilities in Table 1 above.</li> </ul> </li> </ul> |         |

# Calibration System

## Description

MP CSD

**Table 2 – Control of Nonconforming Instruments**

| Item                                                                                      | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks                                                                                                   |
|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| <p><i>Any Nonconforming Instrument</i></p> <p><i>Impact Analysis</i></p>                  | <ul style="list-style-type: none"> <li>• Notify the Lab Manager directly (or through the Computer Message File) when a nonconforming instrument is identified.</li> <li>• Create a job record to capture all service notes for the nonconforming instrument if the instrument cannot be serviced immediately to correct the nonconformance.</li> <li>• Perform an analysis of the impact on calibration when an MP instrument or measuring standard is found to be out-of-tolerance.</li> <li>• The impact analysis will consist of the following: <ul style="list-style-type: none"> <li>○ Review all instruments calibrated with the nonconforming instrument between the nonconforming instrument's last "in tolerance" calibration and current "out-of-tolerance" calibration;</li> </ul> <p>If the total accumulated accuracy and/or uncertainty is found to be <u>significantly out-of-tolerance</u> (see definition above), then:</p> <ul style="list-style-type: none"> <li>• The instrument's calibration history will be reviewed;</li> <li>• The instrument's recall cycle will be shortened, if required (see Reliability Target in Appendix 12, Table 3, Control of MP Instruments)</li> </ul> </li> <li>• Determine if a recall is warranted, if an out-of-tolerance condition causes a test to be performed that falls below the accuracy ratio of 1:1, then: <ul style="list-style-type: none"> <li>○ Determine if a recall is warranted;</li> <li>○ If yes, generate an instrument listing of all customers who have had instruments calibrated by the out-of-tolerance instrument; and</li> <li>○ Notify affected customers.</li> </ul> </li> </ul> | <p>See Table 1 of this Appendix 18 for Responsibilities.</p> <p>See Responsibilities in Table 1 above</p> |
| <p><i>Corrective Action Report (CAR)</i></p> <p><i>Segregation and Identification</i></p> | <ul style="list-style-type: none"> <li>• Issue a CAR for any MP nonconforming instrument, and <ul style="list-style-type: none"> <li>○ Record both the impact analysis and</li> <li>○ The action(s) taken to address the nonconformance.</li> </ul> </li> <li>• Nonconforming instruments which cannot be brought into tolerance will immediately be: <ul style="list-style-type: none"> <li>○ Red tagged;</li> <li>○ Segregated physically from other instruments, where Possible</li> </ul> </li> <li>• Locked out through the computer to prevent its use.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <p>See Appendix 19, Corrective Action Process</p>                                                         |

# Calibration System

## Description

MP CSD

**Table 2 – Control of Nonconforming Instruments**

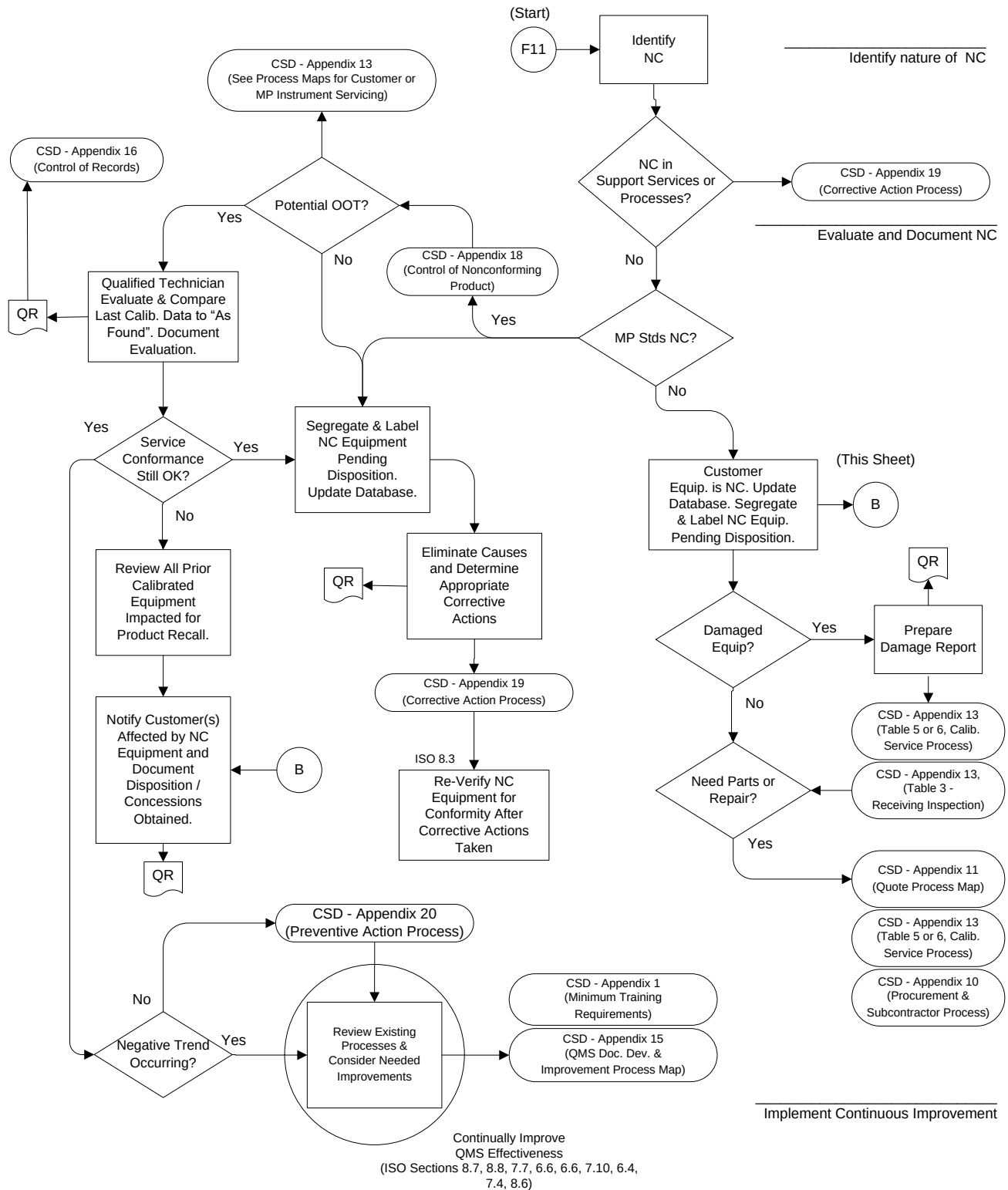
| Item                             | Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Remarks |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Records</b>                   | <ul style="list-style-type: none"><li>• Issue a Nonconformance/Rejected Report for all nonconforming instruments at the time of test.<ul style="list-style-type: none"><li>○ No instrument will undergo further service or will be subcontracted without a Nonconformance/Rejected Report on file, unless the instrument will be immediately adjusted or repaired and before condition has been captured on worksheets or computer.</li><li>○ If the instrument is inoperative, then state this fact in the Report; no other data is required.</li><li>○ If the instrument is to be repaired by an external provider, but calibrated by MP:<ul style="list-style-type: none"><li>- Issue a Rejected Report before sending the instrument to the external provider;</li><li>- Complete a final Calibration Report after the instrument is serviced by the external provider.</li></ul></li><li>○ The initial Rejected Report is not required if the customer sends in an instrument specifically for repair and has authorized the subcontract work to be performed.<ul style="list-style-type: none"><li>- If no “before data” is recorded, then the final Calibration Report will list “N/A” in the before column of the Report.</li></ul></li></ul></li><li>• The significance of the nonconformance will be reviewed and documented in the Nonconformance/Rejected Report.</li></ul> |         |
| <b>Damage Report</b>             | <ul style="list-style-type: none"><li>• See Damage Report requirements in Receiving Inspection, Appendix 13, Table 3.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |
| <b>Improvement Opportunities</b> | <ul style="list-style-type: none"><li>• When improvement opportunities are identified or preventive action is required, action plan shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |

# Calibration System Description

## MP CSD

Ref. ISO/IEC 17025:2017 (Sections 7.8, 7.10,  
8.7, 8.6, 7.5, 8.3, 4.1, 6.6)  
Doc. F11

### Control of Nonconformances Process



# Calibration System Description

MP CSD

## Appendix 19 – Corrective Action Process

**Table 1 - Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Resp.<br>Individual | Div.<br>Mgr. | QA Mgr.<br>/QC Supv.         | Internal<br>Auditor | Quality<br>Dir. |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------|------------------------------|---------------------|-----------------|
| <ul style="list-style-type: none"> <li>Initiation of Corrective Action Reports (CAR).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | X                   |              |                              |                     |                 |
| <ul style="list-style-type: none"> <li>Evaluate if initiated CAR is valid and requires further action; also reviews valid CARs.</li> <li>Addresses CARs and complaints submitted by customers; supervises / assures implementation of all required processing.</li> <li>Ensure Division CARs are handled within specified time frames (see CAR Processing Requirements in Table 2 below).</li> <li>Retains copies of correspondence received which might indicate a nonconformance (e.g., Internal and Internet Email, Faxes, written notes / letters, etc.)</li> </ul> |                     |              | X<br><br>X<br><br>X<br><br>X |                     |                 |
| <ul style="list-style-type: none"> <li>Takes necessary action and investigates root cause.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | X                   |              |                              |                     |                 |
| <ul style="list-style-type: none"> <li>Closes CARs; provides needed oversight for CAR review and verification to prevent recurrence.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                         |                     |              | X                            |                     |                 |
| <ul style="list-style-type: none"> <li>Reviews/monitors on-going CAR process; interfaces w/ Div. Manager for implementation of CAR process.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |              | X                            |                     | X               |
| <ul style="list-style-type: none"> <li>Reviews and approves request for CAR due date extension.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |              | X                            |                     | X               |
| <ul style="list-style-type: none"> <li>Verification of closed CARs and proper processing of CARs (QC or other qualified individual, as designated by the Division Manager)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                   |                     |              | X                            |                     |                 |

# Calibration System

## Description

MP CSD

**Table 2 – CAR Processing Requirements**

| Item                                                                  | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks                                            |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Authorities and Responsibilities                                      | <ul style="list-style-type: none"> <li>See Table 1 above.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                    |
| <i>Initiate CAR</i><br><br><i>Using CARs</i>                          | <ul style="list-style-type: none"> <li>TIME FRAME: Initiate promptly upon discovering a nonconformance or receipt of audit deficiency, etc.</li> <li>Actions taken to eliminate the recurrence of non-conformances already detected are reactive and as such are handled under the corrective action process.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                    |
| <i>Processing Customer Complaints / CARs – Special Considerations</i> | <ul style="list-style-type: none"> <li>Customer complaints received by MP that involves quality of servicing shall be immediately addressed and communicated to respective concern department, in example:               <ul style="list-style-type: none"> <li>Specific customer requirements agreed prior calibration servicing was not met.</li> <li>Errors are identified in calibration reports (e.g., traceability references, etc.)</li> </ul> </li> <li>Customer complaints will be logged and monitored using customer Complaint log online application found in team site</li> <li>Customer complaints will be logged upon receipt of the complaint via Incoming correspondence (e.g. Email, telephone conversation, etc.)</li> <li>QA personnel shall address the complaints and ensure that the concerns were communicated clearly to respective department involved and appropriate actions were taken               <ul style="list-style-type: none"> <li>Customer complaint will be addressed using CAR process once the customer requires MP to issue corresponding CAR or requires 8D report.</li> </ul> </li> <li>Customer complaint shall be monitored in a timely manner and make sure all issues were addressed and adequately closed.</li> <li>Customer complaint summary shall be presented and discuss during management review meeting.</li> <li>Requirement of Complaint               <ol style="list-style-type: none"> <li>Process to receive, evaluate and make decision</li> <li>Description of handling process</li> <li>Process shall include a)-c)</li> <li>Gather and verify all information to validate</li> <li>Acknowledge receipt of complaint</li> <li>Outcomes communicated</li> <li>Give formula notice of complaint to complaint</li> </ol> </li> </ul> | See Responsibilities ii Appendix 19. Table 1 above |
| <i>Methods</i>                                                        | <ul style="list-style-type: none"> <li>CARs must be communicated using MP Teamsite CAR system.</li> <li>CAR number will be automatically generated.</li> <li>Identify the responsible individual for correcting the problem and select from the drop-down menu in the online CAR system.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                    |

## MP CSD

| Item                       | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                            | <ul style="list-style-type: none"> <li>Response due date:               <ul style="list-style-type: none"> <li>30 days from date of detection (CAR initiation date) except:</li> <li>10 days from date of customer-initiated complaint or customer issued CAR</li> <li>If completion of identified corrective action is greater than 30 days, CAR due date extension may be requested. However reasons or concerns (e.g., new process development, Management Review required, etc.) will be subject for evaluation and approval of Quality Director and/or Quality Manager.</li> </ul> </li> <li>Complete all information required for traceability of the CAR (e.g., Reference Number, etc.).</li> <li>CARs generated as a result of customer inputs, complaints, etc. will include sufficient information to satisfy customer CAR processing requirements (see Table 1 above for Responsibilities.)</li> </ul> |         |
| <i>Problem Description</i> | <ul style="list-style-type: none"> <li>Clearly describe the nonconformity / significant quality-related problem on the CAR.               <ul style="list-style-type: none"> <li>Nonconformities / significant quality-related problems may arise from:</li> <li>Internal or external audits;</li> <li>Process nonconformities / process measurements;</li> <li>Management reviews;</li> <li>Market feedback;</li> <li>Customer complaints.</li> </ul> </li> <li>Initiator signs and dates CAR (automatically generated upon closure in online CAR system on the MP team site).</li> <li>CAR process continues with CAR Log Update / Reporting and Response by responsible individual identified in CAR (below).</li> </ul>                                                                                                                                                                                       |         |
| <b>Response</b>            | <ul style="list-style-type: none"> <li>TIME FRAME: Respond on or before Response Due Date stated in CAR.</li> <li>Person identified in CAR as responsible completes Root Cause and Corrective Action Taken / To Be Taken sections of CAR.</li> <li>Interface as necessary with personnel from appropriate disciplines (e.g., operations, quality, etc.) when completing response.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |
| <i>Root Cause Analysis</i> | <ul style="list-style-type: none"> <li>Identify the underlying root cause in the Root Cause section of the</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |

# Calibration System

## Description

MP CSD

**Table 2 – CAR Processing Requirements**

| Item                                                      | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Remarks |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <i>Identify and Implement Corrective Action(s)</i>        | <p>CAR. Examples:</p> <ul style="list-style-type: none"> <li>○ Established goals / objectives integration with processes</li> <li>○ Monitoring methods</li> <li>○ Effectiveness and efficiency of processes</li> <li>○ Indoctrination and training</li> <li>○ Software effectiveness / adequacy</li> </ul> <ul style="list-style-type: none"> <li>• TIME FRAME: Within the Response Due Date as identified above. <ul style="list-style-type: none"> <li>○ Corrective action should be promptly implemented whenever possible.</li> <li>○ If implementation depends on long-term planning requirements (e.g., computer system, new or revised process, etc.), a longer period may be established for implementing the corrective action, except:</li> </ul> </li> <li>• Identify and document in CAR all required actions (to be taken or promptly taken) to correct the stated nonconformance. <ul style="list-style-type: none"> <li>○ Evaluate the need for action to assure nonconformities will not recur.</li> </ul> </li> <li>• Provide traceable references when completing the Root Cause and Corrective Action sections (e.g., names, procedure numbers with revision levels, etc.) for follow-up verification activities.</li> <li>• Person completing response signs and dates CAR (automatically generated upon closure in online CAR system on the MP team site).</li> <li>• CAR Process continues with CAR Log Update / Reporting, and CAR Closure.</li> </ul> |         |
| <b>Verification of Effectiveness of Corrective Action</b> | <ul style="list-style-type: none"> <li>• TIME FRAME: 3 to 6 months</li> <li>• After corrective actions have been implemented and have had some time to be effective, check that actions taken: <ul style="list-style-type: none"> <li>○ Were effective in and solved the nonconformity problem, and</li> <li>○ Continue to be effective in preventing recurrence of the nonconformity</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |

# Calibration System

## Description

**MP CSD**

**Table 2 – CAR Processing Requirements**

| Item                                            | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Remarks |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                 | <ul style="list-style-type: none"> <li>Identify action(s) taken to verify effectiveness of corrective action(s) implemented (or to be implemented yet) in the follow-up section of the CAR.</li> <li>Sign and date the follow-up section as follow-up verification is performed (repeat as needed until CAR is fully verified to satisfaction of person conducting verification).</li> <li>CAR Process continues with CAR Log Update and CAR Closure (below).</li> </ul>                                                                                                                                                                                                                                                                            |         |
| <b>Close CAR</b><br><br><i>Actions Required</i> | <ul style="list-style-type: none"> <li>TIME FRAME: the Response Due Date as identified above, OR</li> <li>CAR is considered closed after corrective action has been verified and found to effectively prevent recurrence of the identified nonconformance.</li> <li>Check that all associated corrective actions identified in the CAR are adequate, sufficiently addressed and are effectively being implemented.</li> <li>Sign and date CAR when closed (see Table 1 above for Responsibilities) (date and signature automatically generated upon closure of CAR in MP Teamsite CAR system).</li> <li>CAR Process continues with CAR Log Update / Reporting.</li> <li>Actions based upon risk.</li> <li>Update Risk and Opportunities.</li> </ul> |         |
| <b>Records</b>                                  | <ul style="list-style-type: none"> <li>CAR form and associated inputs (i.e., customer CAR, and internal / external forms of communication, etc.) and implementation evidence (if applicable) are available online using the CAR system.</li> <li>See Appendix 16 for Control of Records</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <b>CAR Log and Reporting</b>                    | <ul style="list-style-type: none"> <li>See Table 1 above for Responsibilities.</li> <li>Complete CAR Log is available online for monitoring and follow-up report processing.               <ul style="list-style-type: none"> <li>CAR Number</li> <li>Reference (source)</li> <li>Date Issued</li> <li>Issued By</li> <li>Issued To</li> <li>Respond by (date)</li> <li>Date Closed</li> <li>Date Verified</li> </ul> </li> <li>Maintain correspondence pertaining to CARs or potential CARs (e.g. inputs) using online CAR system on MP Teamsite.</li> </ul>                                                                                                                                                                                       |         |

# Calibration System Description

MP CSD

**Table 2 – CAR Processing Requirements**

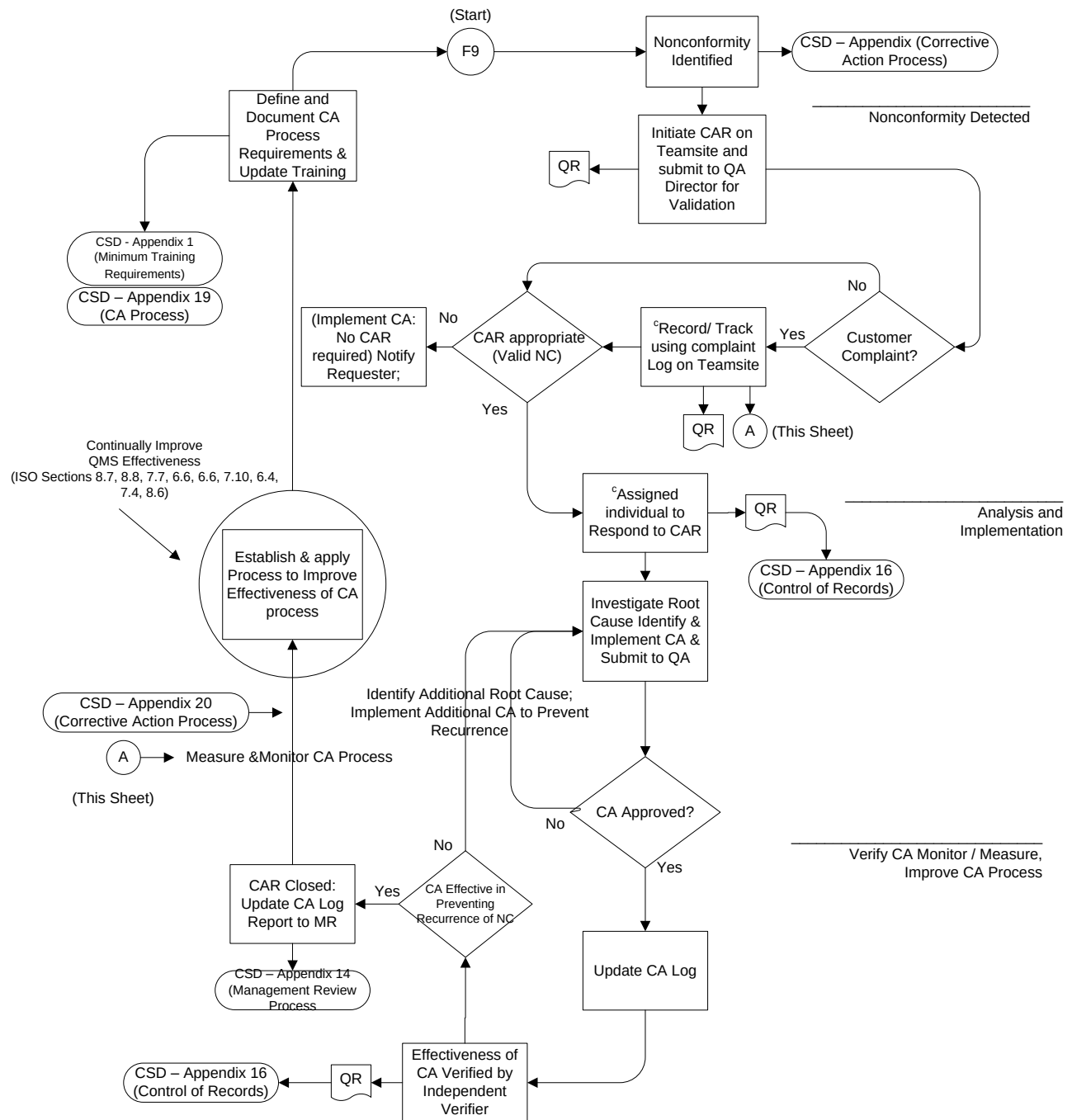
| Item                         | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remarks |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Continual Improvement</b> | <ul style="list-style-type: none"><li>• Implemented corrective action shall be observed and monitored within 3 to 6 months, to verify its effectiveness.</li><li>• Corrective action that was found ineffective shall subject to follow- up audits.</li><li>• Evaluate trends and areas for continual improvement (see Appendix 20, Preventive Action and Continual Improvement.</li></ul>                                                                                                                                                                                                                                                      |         |
| <b>Follow-up Audits</b>      | <ul style="list-style-type: none"><li>• Where the identification of non-conformances or departures cast doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with International Standards, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with monitoring of corrective actions as soon as possible.</li><li>• Records and documentation of audited areas of activity shall be referenced on the succeeding audit report, where evidence/report of the implementation and effectiveness of the corrective action shall be readily available</li></ul> |         |

# Calibration System Description

MP CSD

## Corrective Action Process

Ref. ISO/IEC 17025:2017 (Sections 4.1, 8.7,  
8.6, 8.4, 8.9)  
Doc. F9 R2 2-03-12



# Calibration System Description

MP CSD

## Appendix 20 – Preventive Action Process

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | All Pers. | Assigned Individual | Div. Mgr. | QA Mgr. /QC Supv                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Quality Dir.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Initiation of Preventive Action Proposals (PAPs).</li> <li>Overall corporate-wide responsibility for effective implementation of preventive action process.</li> <li>Reviews/monitors on-going PAP process; interfaces w/Div. QC for implementation of PAP process.</li> <li>Interface on PAPs that involve expenditures not covered by Divisional budget.</li> <li>Overall responsibility for PAP process at the Division, including maintaining and ensuring ongoing suitability of the working preventive actions at the Division.</li> <li>Performs initial evaluation of PAP to determine if it should proceed for action or be denied (withdrawn);</li> <li>Assigns PAP to responsible individual to determine / implement needed actions and sets action dates;</li> <li>Reviews and approves solutions proposed by assigned individual for Division implementation within limits of authority established by QA Manager and Executive Management.</li> <li>Notifying other Division / department managers of PAPs requiring their review input and follow-up activities.</li> <li>Maintains file copy of PAPs at the Division (or received from other Divisions for review approval comments).</li> <li>Selects person(s) responsible to implement the approved preventive action solution (either of these individuals have this responsibility).</li> <li>Selects individual to perform independent follow-up verification of effectiveness of preventive actions taken (either of these individuals have this responsibility).</li> <li>Retains copies of correspondence (email, faxes, written notes/ letters, etc.) pertaining to suggested improvements, PAPs, etc.</li> <li>Assures Division PAPs are handled within specified time frames.</li> </ul> | X         |                     |           | <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> | <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> <div style="text-align: center;">X</div> |

# Calibration System Description

MP CSD

**Table 1 – Responsibilities**

| Requirements or Activity                                                                                                                                                                                                                                                | All Pers. | Assigned Individual | Div. Mgr. | QA Mgr. /QC Supv | Quality Dir. |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------------|-----------|------------------|--------------|
| <ul style="list-style-type: none"> <li>Completes and maintains PAP log.</li> </ul>                                                                                                                                                                                      |           |                     |           | X                |              |
| <ul style="list-style-type: none"> <li>Responsible for determining needed actions (performing root cause analysis) and implementing needed actions (proposing solutions).</li> </ul>                                                                                    |           | X                   |           |                  |              |
| <ul style="list-style-type: none"> <li>Responsible for verification of implemented preventive actions and ensuring that the implemented solution is effective and meets the specifications of the solution as approved; closes PAP.</li> </ul>                          |           | X                   |           |                  | X            |
| <ul style="list-style-type: none"> <li>Provides needed oversight for PAP review and verification for effectiveness of solution in preventing occurrence of non-conformances or of meeting suggested improvement (both individuals participate in this step).</li> </ul> |           |                     | X         | X                |              |

**Table 2 – Preventive Action Proposal Process**

| Item                                        | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Authorities and Responsibilities</b>     | <ul style="list-style-type: none"> <li>See Table 1 above.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |
| Initiate PAP<br><br><i>When to Use PAPs</i> | <ul style="list-style-type: none"> <li>TIME FRAME: Initiate at least annually; and whenever potential non-conformances are being evaluated.</li> <li>Actions taken to eliminate the cause of a potential nonconformance (e.g., taken to prevent occurrence) are proactive and as such are handled under the preventive action process.</li> <li>Use Preventive Action Proposals (PAP) to:               <ul style="list-style-type: none"> <li>Identify and document potential calibration servicing quality or QMS problems before a nonconformance occurs;</li> <li>Investigate the problem to determine the likelihood of an occurrence;</li> <li>Propose solutions to eliminate a cause in order to prevent an occurrence;</li> <li>Verify that a solution was effective in preventing a problem.</li> </ul> </li> </ul> |         |

# Calibration System

## Description

MP CSD

**Table 2 – Preventive Action Proposal Process**

| Item                                                                                                           | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Remarks |
|----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <p><i>Communications</i></p> <p><i>Describing Potential non-conformances</i></p> <p><i>Supporting Data</i></p> | <ul style="list-style-type: none"> <li>PAPs will be communicated using MP Teamsite PAP system.</li> <li>PAP number will be automatically generated.</li> <li>Completes the name of originating division, department/division to use the PAP and the name of the person submitting the PAP.</li> <li>Consider the following when describing potential non-conformances and their causes: <ul style="list-style-type: none"> <li>What can go wrong in an existing (or new) process (e.g., receiving inspection process, calibration service process, quality control process, shipping / delivery process, etc.)?</li> <li>What items / processes have a potential to fail?</li> <li>How likely is it for these potential failures to reach a customer (e.g., errors in Calibration Certificates, labeling equipment, calibration method used, impact of environmental control failure on calibration results, etc.)?</li> <li>What is the probability that these failures will actually occur?</li> <li>How serious would these failures be if they did occur?</li> <li>Can this information be used by other departments or Divisions?</li> <li>Is the potential problem a global one? (e.g., hardware / software related, etc.)</li> <li>Is the process effectively meeting the quality objectives (e.g., method used to track turn-around processing times, process for responding timely and adequately to customer complaints, etc. helping or hindering meeting goals)?</li> </ul> </li> <li>Where appropriate or helpful in describing the PAP, create charts, graphs, etc. to pictorially convey the information. Consider all viable input sources such as: <ul style="list-style-type: none"> <li>CARs (selecting high rollers of a given problem; reviewing nature of customer complaints);</li> <li>Management Review minutes (forecasts, issues raised, possible action items);</li> <li>Benchmark studies (before/after a process was changed or an improvement made, etc.)</li> <li>Employee suggestions (prior PAPs that were possibly not acted upon, ideas that save time or effort or help eliminate errors, etc.).</li> </ul> </li> </ul> |         |

# Calibration System

## Description

**MP CSD**

**Table 2 – Preventive Action Proposal Process**

| Item                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Process Description | Remarks                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------------------------------------|
| <p><i>Making Suggestions</i></p> <ul style="list-style-type: none"> <li>○ Statistical analysis;</li> <li>○ Audit reports (internal and external);</li> <li>• When using a PAP to suggest improvements, identify: <ul style="list-style-type: none"> <li>○ Basis for request, such as: <ul style="list-style-type: none"> <li>• Production goals cannot be met effectively;</li> <li>• Customer complaints/feedback are increasing;</li> <li>• Results of analysis of data;</li> <li>• Self-assessment / internal audit results;</li> <li>• Customer survey results;</li> <li>• Financial data / quarterly reports, etc.;</li> <li>• Service delivery data, etc.</li> </ul> </li> <li>○ Include the improvement suggestion in the Potential NC/Problem section of the PAP.</li> </ul> </li> </ul> <p><i>Getting Help</i></p> <ul style="list-style-type: none"> <li>• Interface as necessary with appropriate management (e.g., quality, executive, etc.) when developing the PAP.</li> </ul> <p><i>Evaluation Date</i></p> <ul style="list-style-type: none"> <li>• Enter a desired reply date for assessing the validity of the PAP to assist management in performing its evaluation of the need to take action on the PAP.</li> </ul> <p><i>Traceability</i></p> <ul style="list-style-type: none"> <li>• Identify sources or references that help provide traceability to the potential nonconformance or suggestion raised in the PAP.</li> </ul> <p><i>Submit PAP</i></p> <ul style="list-style-type: none"> <li>• Sign (or enter name if submitting electronically) and date the PAP and submit to responsible management for initial evaluation.</li> <li>• PAP process continues with PAP Log Update / Reporting and Initial Evaluation of PAP (below).</li> </ul> |                     |                                                    |
| <p><i>Initial Evaluation of PAP</i></p> <ul style="list-style-type: none"> <li>• TIME FRAME: Reply to originator by requested evaluation date (e.g., PAP is either approved or declined (and reason)).</li> <li>• Perform an initial assessment of the validity, likelihood and severity of the potential nonconformance in order to determine whether any action should be pursued.</li> </ul> <p><i>Setting Priorities</i></p> <ul style="list-style-type: none"> <li>• Decisions as to which PAPs to act upon and establishing priorities will be based on:</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     | See Table 1, in this Appendix for Responsibilities |

# Calibration System

## Description

MP CSD

**Table 2 – Preventive Action Proposal Process**

| Item                                                                                 | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Remarks |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                                      | <ul style="list-style-type: none"> <li>○ Severity of the problem that would result from inaction;</li> <li>○ Likelihood that the problem would occur;</li> <li>○ Cost of implementation.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |
| <p><i>PAP Declined</i></p> <p><i>PAP Approved</i></p> <p><i>Action Due Dates</i></p> | <ul style="list-style-type: none"> <li>• If appropriate, route PAPs to Executive Management for evaluation. <ul style="list-style-type: none"> <li>○ PAPs not routed to Executive Management should be included in PAP reporting during periodic corporate Management Reviews.</li> </ul> </li> <li>• State the reason and enter disposition status in PAP log.</li> <li>• If further investigation is required, a qualified, responsible individual will be assigned to analyze the problem, determine the underlying root cause(s) and identify the actions needed to prevent the condition.</li> <li>• Enter a date by which the responsible individual is to have determined <u>what preventive action(s)</u> are necessary to address the potential problem; <u>and/or</u> <ul style="list-style-type: none"> <li>○ Enter a date by which the responsible individual is <u>to have implemented</u> the necessary preventive action(s).</li> </ul> </li> <li>• Sign (or enter name if electronically processed) and date the PAP indicating evaluation has been completed.</li> <li>• PAP process continues with PAP Log Update / Reporting and Determining / Implementing Actions Needed (below).</li> </ul> |         |
| <p><b>Determine / Implement Action(s) Needed</b></p> <p><i>Analysis</i></p>          | <ul style="list-style-type: none"> <li>• TIME FRAME: Identify / implement actions as indicated in PAP.</li> <li>• As appropriate or applicable, the responsible individual assigned to address the PAP will: <ul style="list-style-type: none"> <li>○ Analyze the potential problem identified;</li> <li>○ Determine the underlying root cause(s);</li> <li>○ Identify action(s) needed to prevent the potential problem (condition).</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |

# Calibration System

## Description

MP CSD

**Table 2 – Preventive Action Proposal Process**

| Item                                                                                                                      | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Remarks |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <p><i>Benefits Realized through (Root Cause) Analysis</i></p> <p><i>Review the Effectiveness of Proposed Solution</i></p> | <ul style="list-style-type: none"> <li>• Root cause analysis should result in the following: <ul style="list-style-type: none"> <li>○ Identifying quality practices;</li> <li>○ Documenting suggested changes;</li> <li>○ Proposing controls to ensure that the approved preventive action is taken and that it is effective.</li> </ul> </li> <li>• Assess the proposed solution to determine: <ul style="list-style-type: none"> <li>○ Will it correct the cause of the potential problem?</li> <li>○ Will it adversely affect the process or product?</li> <li>○ Will it provide an important quality gain relative to the time or cost of implementation?</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
| <p><i>Extending Due Dates</i></p> <p><i>Supporting Records</i></p>                                                        | <ul style="list-style-type: none"> <li>• If applicable, other Divisions / departments should also review the proposed solution to determine: <ul style="list-style-type: none"> <li>○ Are proposed actions practical?</li> <li>○ Are there any unintended effects?</li> <li>○ Can unintended effects be minimized?</li> </ul> <p>Record (email, memo, minutes, etc.) the review approval / comments of other affected Division / department management reviewing the PAP.</p> </li> <li>• If the needed actions will take some time to determine and/or implement, then: <ul style="list-style-type: none"> <li>○ Identify the nature of the action(s) needed and estimated completion date(s).</li> <li>○ <u>Example:</u> Develop a new process for integrating customer complaints received via the Internet and verbal or written correspondence by (date) to allow sufficient time for database redesign and programming.</li> <li>○ Interface with management if required time frames need to be adjusted.</li> </ul> </li> <li>• If the needed action(s) can be readily determined and implemented, then: <ul style="list-style-type: none"> <li>○ State the action to be implemented and date;</li> <li>○ Obtain responsible management's approval for the proposed action (signature and date) on the PAP;</li> <li>○ Implement the approved preventive action.</li> </ul> </li> <li>• Identify and/or attach records created or used as input in determining and implementing the preventive action(s).</li> </ul> |         |

# Calibration System

## Description

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**Table 2 – Preventive Action Proposal Process**

| Item                                                                                                                                    | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Remarks |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                                                                                                                         | <p>Examples:</p> <ul style="list-style-type: none"> <li>○ Analysis charts, graphs;</li> <li>○ Meeting minutes;</li> <li>○ PAP;</li> <li>○ Other pertinent inputs / outputs</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |
|                                                                                                                                         | <ul style="list-style-type: none"> <li>• PAP process continues with PAP Log Update / Reporting and management Approval of Proposed Actions (below).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| <b>Approval of Proposed Actions</b>                                                                                                     | <ul style="list-style-type: none"> <li>• TIME FRAME: Within 7 days of due date(s) identified for determining actions needed or implementing actions needed.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
|                                                                                                                                         | <ul style="list-style-type: none"> <li>• Responsible management will approved PAP through MP Teamsite PAP system.</li> <li>• PAP process continues with PAP Log Update / Reporting and Follow-up Verification by responsible individual (below).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |
| <p><b>Follow-Up Verification and PAP Closure</b></p> <p><i>Independence</i></p> <p><i>Actions Required</i></p> <p><i>PAP Closed</i></p> | <ul style="list-style-type: none"> <li>• TIME FRAME: After 90 days (min.) with monthly monitoring.</li> <li>• An individual other than the originator of the PAP will verify the effectiveness of the PAP solution.</li> <li>• Review records identified in and/or attached to the PAP and evaluate that the solution is effective and adequate for the potential nonconformance, problem, or improvement suggestion made. Examples: <ul style="list-style-type: none"> <li>○ Update charts, graphs, etc. with data since the PAP was initiated;</li> <li>○ Examine relevant records made since the PAP;</li> <li>○ Observe and/or take measurements in processes, etc.</li> </ul> </li> <li>• If the solution is found inadequate (unsatisfactory), the PAP process will be started over at the point of analysis of the potential root cause and to determine other solutions. <ul style="list-style-type: none"> <li>○ Also see “PAP” closed below.</li> </ul> </li> <li>• If the solution is found to be effective (satisfactory) when verified, the PAP considered closed. <ul style="list-style-type: none"> <li>○ Effectiveness may be determined by checking that no CARs have been logged since implementation of the PAP (for the type of problem being averted in the PAP).</li> <li>○ If the implemented preventive action did not prevent</li> </ul> </li> </ul> |         |

# Calibration System

## Description

MP CSD

**Table 2 – Preventive Action Proposal Process**

| Item                                | Process Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Remarks |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                     | <p>occurrence of the potential problem, then an investigation should be made to determine if in fact the PAP was sufficiently developed and/or implemented to meet its intended objectives.</p> <ul style="list-style-type: none"> <li>Once a PAP is closed, if the problem being averted does occur, it will be addressed through the Corrective Action Process, Appendix 19.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                               |         |
|                                     | <ul style="list-style-type: none"> <li>Sign (or enter name if processing PAP electronically) and date the follow-up section as follow-up verification is performed (see Table 1 above for Responsibilities).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |         |
| <b>Records</b>                      | <ul style="list-style-type: none"> <li>PAP form and its associated inputs and outputs (i.e., listed in the body of the PAP and/or attached to it) and implementation verification record(s).</li> <li>See Appendix 16 for Control of Records.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |
| <b>PAP Log Update and Reporting</b> | <ul style="list-style-type: none"> <li>See Table 1 above for Responsibilities.</li> <li>Complete and maintain PAP Log and monthly (min) monitoring and follow-up verification processing.                             <ul style="list-style-type: none"> <li>PAP Number</li> <li>Reference (source)</li> <li>Date Issued</li> <li>Originator</li> <li>Initial Evaluation Complete and PAP Disposition</li> <li>Assigned to and date</li> <li>Root Cause and Solution Analysis Complete</li> <li>Actions Implemented and Date</li> <li>Follow-Up Verification Adequate</li> <li>PAP Closed Date</li> </ul> </li> <li>Maintain PAPs and associated records/correspondence in a MP Teamsite.</li> <li>The records should readily identify PAPs which were declined and those that was approved and implemented.</li> </ul> |         |
| <b>Continual Improvement</b>        | <ul style="list-style-type: none"> <li>Use PAPs to drive continual improvement.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |

# Calibration System Description

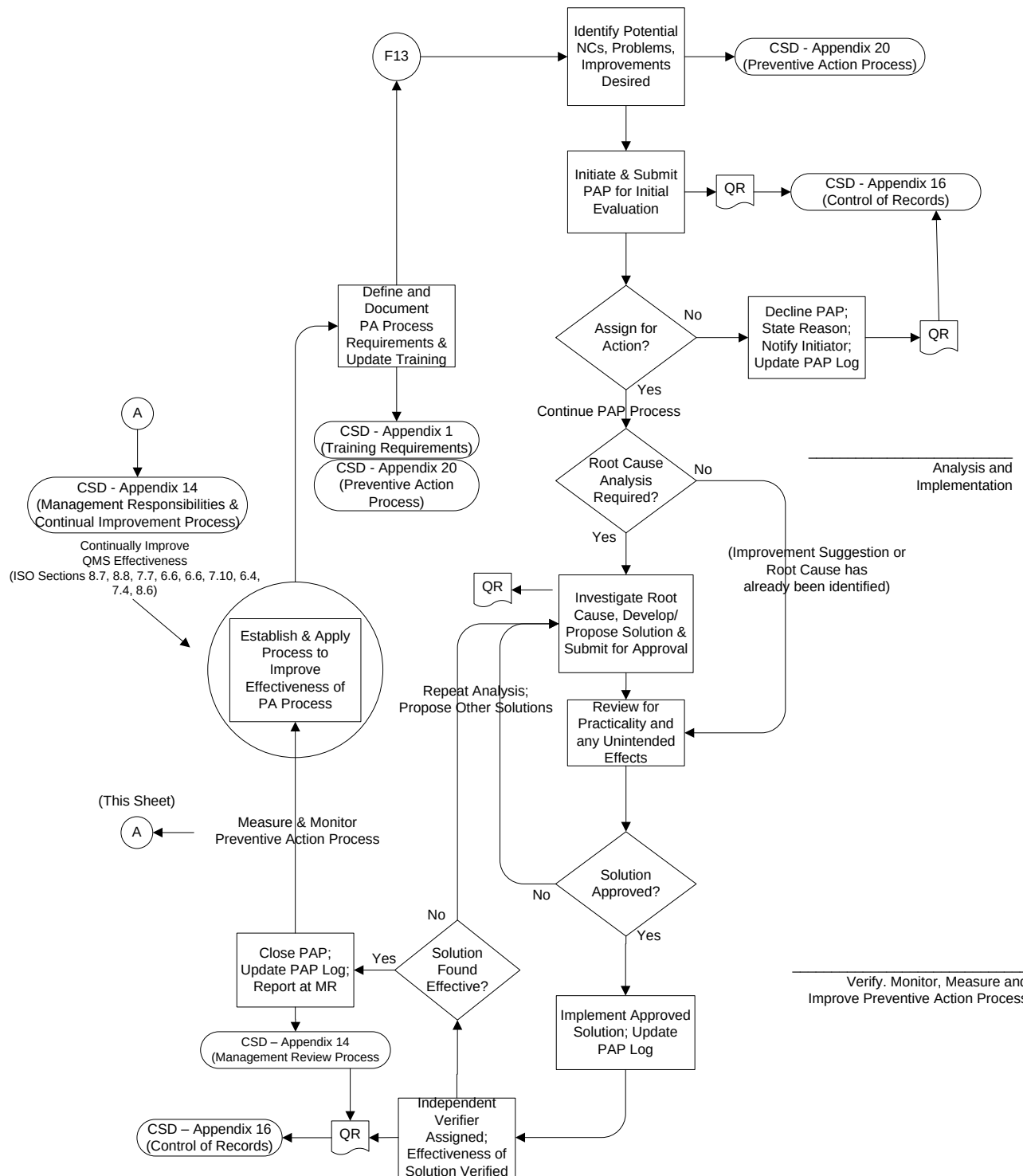
MP CSD

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.5, 8.6, 8.9)

Doc. F13 R1 6-20-03

## Preventive Action Process

Identify Need for  
Preventive Action



# Calibration System Description

MP CSD

## Appendix 21 – System/Software Development Process

**Table 1 – Responsibilities**

| Activity                                                                                                                                                                                                                                                                                                                                                                                         | System User | IT Director | IT Personnel | QA Corporate | Division Manager |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|--------------|--------------|------------------|
| <u>Request for :</u> <ul style="list-style-type: none"> <li>System/Software Development</li> <li>System/ Software Modification.</li> </ul>                                                                                                                                                                                                                                                       | X<br>X      |             |              |              |                  |
| <u>System Development:</u> <ul style="list-style-type: none"> <li>Discussion of proposed development and/or system modification.</li> <li>Evaluation and approval of the project.</li> <li>Software design, development, integration and testing.</li> </ul>                                                                                                                                     | X           | X<br>X<br>X | X            | X            |                  |
| <u>System Implementation:</u> <ul style="list-style-type: none"> <li>System Implementation planning and approval.</li> <li>System Training</li> <li>Customer Notification / Orientation/ Training</li> </ul>                                                                                                                                                                                     | X           |             | X<br>X       | X            | X                |
| <u>System Maintenance:</u> <ul style="list-style-type: none"> <li>Operate and maintains information systems, including data back-up and archiving</li> <li>Notify users for concerns such as database offline; site addresses changes; system fixes and upgrades.</li> <li>Notify customers for concerns such as database offline; site addresses changes; system fixes and upgrades.</li> </ul> |             | X<br>X<br>X | X<br>X<br>X  |              |                  |

# Calibration System

## Description

MP CSD

**Table 2 – System/ Software Development Process**

| Item                                                       | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Remarks |
|------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>System/<br/>Software<br/>Development</b>                | <ul style="list-style-type: none"> <li>The systems development process describes the stages involved in an information system development project, from an initial feasibility study through maintenance of the completed application.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |
| <b>System/<br/>Software<br/>Modifications</b>              | <ul style="list-style-type: none"> <li>The correction of errors in software systems and the remedying of inadequacies of the existing application.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |
| <b>System<br/>Development /<br/>Modification<br/>Phase</b> | <ul style="list-style-type: none"> <li>Requirements Analysis – identifying the needs for creation of the new system or modification of the existing application. It is the process of analyzing the information needed by the end users from any system presently being used or developing the functional requirements of a system that can meet the needs of the users.</li> <li>Design – transforms detailed requirements into complete, detailed system design focusing on how to deliver the required functionality of the new system to develop or to be modified. System designs must be reviewed with the users to ensure that it meets users' needs.</li> <li>Development –converts the design into a complete information system including acquisition and installing systems environment, creating system and testing databases, preparing test procedures and test files, coding, compiling, and refining programs.</li> <li>Integration and Test – demonstrate that the developed system or modified application conforms to the functional requirements of the user. Includes coding and debugging process to achieve the final system requirements. The system must be tested to evaluate its actual functionality in relation to expected or intended functionality. Interface with the end users will be the key in determining whether the developed system meets the intended requirements and the extent to which the system is actually used.               <ul style="list-style-type: none"> <li>User Testing - user-centered interaction design to evaluate software by testing it on users. Using the user's(requestor) account the programmer may view the exact occurrence of the problem.</li> <li>Loading Testing - putting demand on a system or device and measuring its response.</li> <li>Functional Testing - testing conducted on a complete, integrated system to evaluate the system's compliance with its specified requirements.</li> <li>Stress Testing - testing beyond normal operational capacity, often to a breaking point, in order to observe the results.</li> </ul> </li> </ul> |         |

# Calibration System Description

MP CSD

**Table 2 – System/ Software Development Process**

| Item                                            | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Remarks |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Software Quality Assurance (SQA) Testing</b> | <ul style="list-style-type: none"> <li>Software Quality Assurance Testing evaluates the degree to which the software satisfies stated and implied requirement; i.e. absence of system crashes; correspondence between the software/application and the user's expectations; performance to specified requirements.</li> <li><b>Quality Assurance Plan</b> <ul style="list-style-type: none"> <li>Defect tracking – keeps track of each defect found, its source, when it was detected, when it was resolved, how it was resolved, etc.</li> <li>Module testing – each individual module is tested</li> <li>Source code tracing – step through source code line by line</li> <li>Technical reviews – completed work is reviewed by peers</li> <li>Integration testing -- exercise new code in combination with code that is already in use</li> <li>System testing – execution of the software for the purpose of finding defects</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| <b>System Implementation Plan</b>               | <ul style="list-style-type: none"> <li>Includes implementation preparation, implementation of the system into actual environment, and resolution of the problems identified in the integration, test phases and SQA testing.</li> <li>The Implementation Plan describes how the information system will be deployed, installed and transitioned into an operational system. The plan contains: <ul style="list-style-type: none"> <li>An overview of the system.</li> <li>A brief description of the major tasks involved in the implementation.</li> <li>The overall resources needed to support the implementation effort such as hardware, software, facilities, materials, and personnel.</li> <li>Any site-specific implementation requirements.</li> <li>User Training / Customer Training</li> <li>Customer Notification –shall be carried out on the division level of authority.</li> <li>Live system Implementation Date <ul style="list-style-type: none"> <li><i>The plan is developed during the Design Phase and is updated during the Development Phase; the final version is provided in the Integration and Test Phase and is used for guidance during the Implementation Phase. The outline shows the structure of the Implementation Plan.</i></li> </ul> </li> </ul> </li> <li>Implementation activities shall be carried out based on the approved plan.</li> </ul> |         |

# Calibration System Description

MP CSD

**Table 2 – System/ Software Development Process**

| Item                                        | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Remarks                                                                                                                                    |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| <b>System/<br/>Software<br/>Maintenance</b> | <ul style="list-style-type: none"><li>• The maintenance phase keeps the system/ software up to date with the environment, after it has been released to the users.</li><li>• System/Software Maintenance consists of the following:<ul style="list-style-type: none"><li>○ Corrective maintenance - deals with eliminating weaknesses in the code.</li><li>○ Adaptive maintenance - deals with adapting the software to new environments.</li><li>○ Perfective maintenance - deals with updating the software according to changes in user requirements.</li><li>○ Preventive maintenance - deals with updating documentation and making the software more maintainable.</li></ul></li><li>• Electronic records periodic back-up and database achieving</li></ul> | <p>Changes and updates shall be immediately communicated to MP Users and Customers.</p> <p>Also see Responsibilities in Table 1 above.</p> |

# Calibration System Description

MP CSD

## System/Software Development Process

