

Calibration System Description

MP CSD

Appendix 16 – Control of Records

Table 1 – Responsibilities

Requirements or Activity	IT Dept.	Division Mgr.	QC Supv.	Quality Director
Identification, development and specification of control activities for Quality Records.				X
Storage of Quality Records at Division.		X		
Implementing adequate controls for Quality Records at Division and keeping an updated Quality Record list.			X	
Responsible for integrity of MP proprietary database system of computer Records, including backup, updates, and maintenance.	X			
Interface with Quality Director regarding disposal of electronic records on database.	X			X

Table 2 – Quality Record Control Requirements ^{*R01}

Item	Requirements	Remarks
General <i>Definition of Quality Record</i>	- A completed document which provides evidence of conformity to requirements and of the effective operation of the Quality Management System. - A list of Quality Records appears in Table 3 of this Appendix 16.	
<i>Retrievability</i>	- Retrievable within the prescribed retention period with reasonable effort. - Retrieving archived files are allowed upon customer request.	
<i>Legibility</i>	Legible when prepared and maintained.	
<i>Storage and Preservation</i>	- 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 - Stored in a suitable environment (e.g., file cabinets). Electronic files stored on specified file servers. - Regular back-up and maintenance of electronic files stored on servers. - Stored / maintained as hard copies and/or computer files. - Stored / maintained as active, on-going records or as archived records.	

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Table 2 – Quality Record Control Requirements *R01

Item	Requirements	Remarks
<i>Mistakes in Records</i>	- Corrected in hard copies by drawing a line through the incorrect entry and initialing, dating and noting the change alongside the existing entry. - Corrected in computer files by generating a new record and referencing the corrected record in the new record.	
<i>Controls for Identification of Records</i>	- MP generated Quality Records will be documented on Appropriate forms designed for this purpose (either hard copy or generated within the MP database). - Forms used corporate-wide will be approved by the Quality Assurance Manager. - Division-specific forms will be approved by the Division Manager.	
<i>Controls for Storage of Records</i>	- 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. - Customer and other external inputs (correspondence, orders, audits and surveillances, proficiency tests, etc.) will be retained as Quality Records. - Electronic Quality Records are identified by title, unique number and/or date within the MP database. - 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. - Active and archived electronic Quality Records are stored in the MP database which is controlled by the Corporate Information Systems Manager. - 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. - 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.	

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Table 2 – Quality Record Control Requirements *R01

Item	Requirements	Remarks
<i>Controls for Protection of Records</i>	- 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. - 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. - 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. - In general, employees have access to Customer records according to their areas of responsibility. - Access to all other Quality Records is limited to the Division Manager, the Quality Assurance Manager, the Quality Control Supervisor and Internal Auditors. - Customer records will not be forwarded to a third party without the written approval of the customer. - MP specific Quality Records will not be sent to a third party without the approval of the Quality Assurance Manager. - Whenever a Quality Record is forwarded electronically, care will be taken to assure that the transmittal does not change or degrade the record content.	
<i>Controls for Replacement of Lost or Damaged Records</i>	- On-line records will be reprinted (utilizing backup information) and will include a statement as to the reason it was reprinted. - The Division Manager will be contacted to notify appropriate persons regarding lost or damaged records.	
<i>Controls for Retrieval of Records</i>	- The responsible Manager will provide for the timely retrieval of records in accordance with customer, regulatory, administrative or industry needs. - Unless the record is needed for revision or other specific purposes, uncontrolled copies will be provided to satisfy retrieval requests.	
<i>Controls for Superseding Records</i>	- Quality Records will be appropriately identified so as to distinguish archive copies from current copies. - 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.	

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Table 2 – Quality Record Control Requirements ^{*R01}

Item	Requirements	Remarks
<i>Retention Period for Records</i>	- Retention periods for types of Quality Records are generally identified in Table 3 below. - The retention status of Quality Records will be reviewed annually.	
<i>Disposition of Records</i>	- Prior to disposition, verify the following conditions: - Regulatory requirements are satisfied; - Customer-specified requirements are satisfied (e.g., is MP retaining Calibration Reports for customers, in which case customer-specified retention periods govern); - MP specified requirements are satisfied.	
<i>Disposal of Records</i>	- Annual reviews are conducted to determine records for disposal. - Hard copies of Quality Records will be shredded by the Division when retention periods have lapsed. - Electronic copies of Quality Records stored on database shall be permanently deleted after it has reached the maximum retention period.	Refer to Appendix 16, Table 3, Quality Records and Retention Periods
Records Required for Establishing Traceability	- The following records will be maintained to establish traceability: - Calibration Certificates for MP instruments and reference standards and data; - Calibration Certificates from NIST, external provider and OEMs that calibrate MP instruments and reference standards; - Measurement uncertainty programs and associated documents and data; - Procedures, methods and work instructions used to perform the calibrations; - Evidence of technical competence (e.g., personnel records, the laboratory's accreditation records, etc.); - Evidence of periodic recalibrations to preserve traceability; Equipment Service Reports.	Ref. Appendix 13, Table 5, Traceability
MP Equipment Records	- MP equipment records will include the following: - Traceability records (see above); - Manufacturer manuals; - Verifications and checks of compliance with calibrations; - Records of preventive maintenance activities; - Records of intermediate checks; - Records of proficiency testing activities; - Records of repairs and/or service reports - Procurement documents (purchase orders, servicing, etc., as applicable); - Equipment software (e.g., for ATE), uniquely identified when practical.	

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Table 3 – Quality Records and Retention Periods ^{*R01}

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 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. Automated CARs	3	Division should facilitate retrieving all complaints for a given customer.

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Table 3 – Quality Records and Retention Periods ^{*R01}

Record Type or Description	Primary / Secondary Control		Storage Methods / Locations	Retention Period (Yrs.)	Remarks
	Corporate	Division	Electronic		
Continual Improvement (Metrics / Statistical Techniques, PAPs)	Primary for Corporate-Wide	Primary for Division Specific	Metrics in Spreadsheets, Correspondence through MP database / Networked Computers / Desktops	3	
Training and Qualification of Personnel (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
Audit Records (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	
MP Equipment and Reference Standards • Calibration Reports • Equipment History and Service Records • QC Inspection Traveler / Shipping Records • Environmental Records • Interlaboratory Comparisons / Proficiency Tests	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 MP Teamsite MP Teamsite	15 15 3 3 4	

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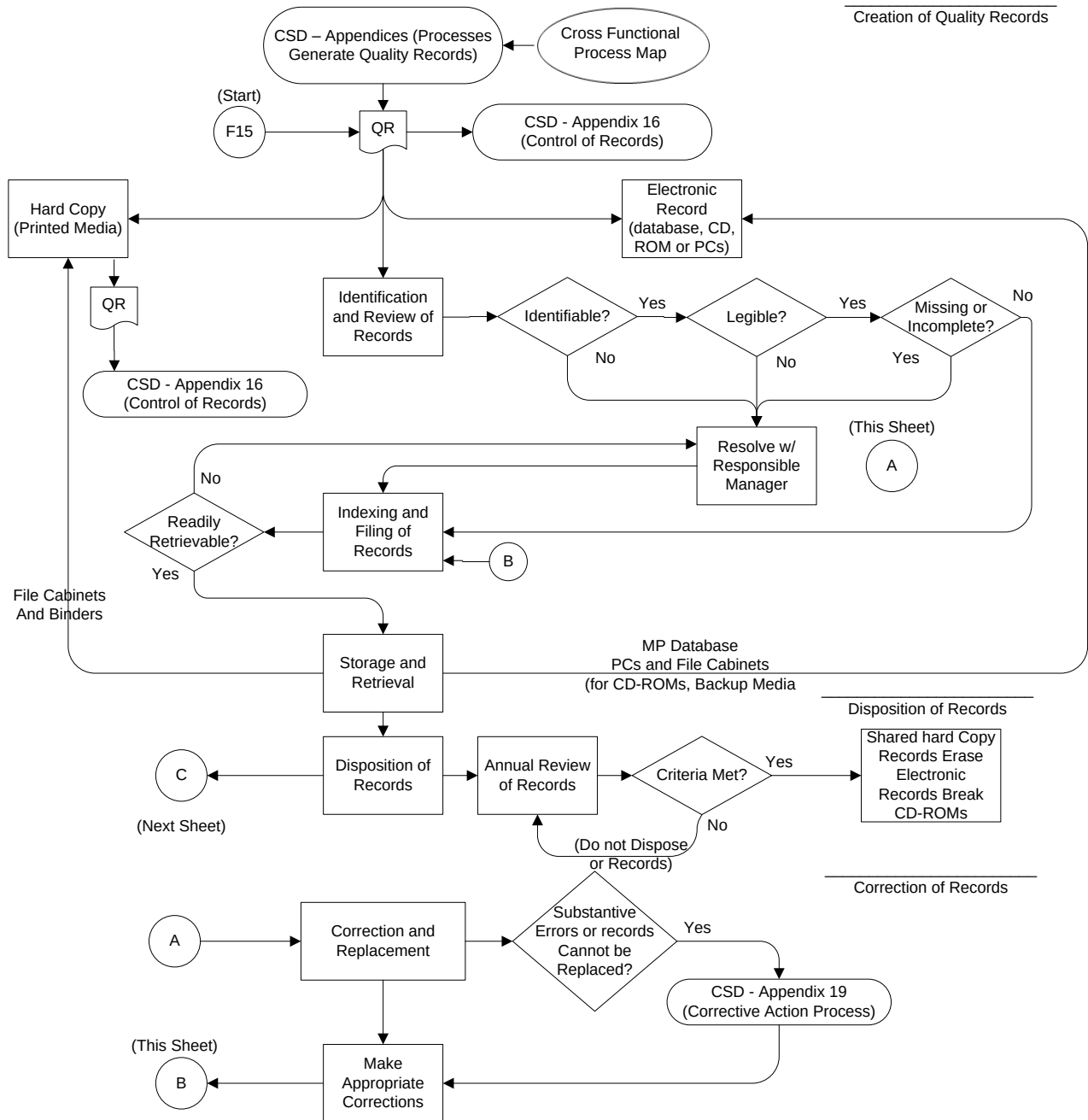
Record Type or Description	Primary / Secondary Control		Storage Methods / Locations	Retention Period (Yrs.)	Remarks
	Corporate	Division	Electronic		
Customer Calibration and Repair Service Records - Calibration Reports - Accounting, Receipt, Inspection, Data, Correspondences, CARs and QC Inspection / Traveler / Shipping records		Primary	MP database by Customer Account Number, Equipment Control Number, and Unique Calibration Report Number	15 3	Record is retrievable within the retention period upon request by customer

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Record Control Process

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



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Record Control Process (Cont.)

Ref. ISO/IEC 17025:2017 (Sections 4.1, 7.5,
8.7, 8.6)
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