Semiconductor and Dimensional Metrology Division Quality Manual

Revision 7.2

Approved: David L. Seiler **Date:** 9/26/2014

David Seiler, Division Chief

Table of Contents

1 Introduction

This Manual includes extensions to the NIST level Quality Manual describing the specific quality practices of the Semiconductor and Dimensional Metrology Division (SDMD). The SDMD level language generally follows the NIST level manual, but some material may be in slightly different numbered sections to line up with the section numbering in ISO 17025.

1.1 Commitment to Quality

The Semiconductor and Dimensional Metrology Division (***Division*** 683) is part of the NIST Physical Measurement Laboratory (PML). Calibration of industry dimensional standards, participation in the development of consensus standards, development of measurement methods and test structures, and provision of ***Standard Reference Materials (SRMs)*** are essential elements of the work of the ***Division*** in fulfillment of its mission. In the conduct of this vital work, as in all its efforts, the ***Division*** is committed to excellence characteristic of a global leader in measurements and standards. Our GOAL is to meet the needs of our customers and, through continuous improvement, to seek to anticipate their needs, exceed their expectations, and deliver outstanding value to the Nation.

All staff members whose activities affect the quality of our services are to be familiar with the ***Quality System*** (***QS***) described herein, and to implement it in their work. The Semiconductor and Dimensional Metrology Division commits that its Quality System be, to the extent allowed by statute and regulation, in conformity with the international standard ISO/IEC 17025 and the relevant requirements of ISO Guide 34 as they apply to the Standard Reference Materials and related services that NIST delivers.

David G. Seiler
Division Chief

1.2 Scope

1.1.1 SP-250 Calibrations

The scope of the SDMD Quality System is all SDMD measurements carried out under the NIST Calibration Program listed in the NIST SP-250 and provision of and value-assignment to its Standard Reference Materials listed in the NIST SP-260.

Other measurement services may be proposed for inclusion within this Scope at the discretion of the Division 683 Groups. Proposed services may be submitted by any Division 683 staff member to the Division Quality Manager. The Quality Manager will review the proposal and submit it to the Division Chief and Group Leaders for approval in order to add the service to the List described above and, if needed, will make modifications of this document to include the suggested service as described in Section 4.3.3 of this document.

1.1.2 Reference Materials

The Semiconductor and Dimensional Metrology Division typically prepares an annual program of work and funding to produce Reference Materials. Many, if not most, of the materials require considerable research, and then multi-year production efforts. The research effort does not fall under the scope of the SDMD Quality System. Once the research has developed a material, and a verified measurement procedure, the production and documentation of the Reference Material (RM) or Standard Reference Material (SRM) is required to follow the policies and procedures of this Quality Manual.

All Reference Material work is governed by the “Guide to NIST SRM Development and Production” and the NIST Administrative Manual Subchapter 5.19 Standard Reference Materials for production flowcharts and control processes. The current versions of these two documents are considered part of the SDMD Quality System.

2 Normative References

Policies and procedures specifically developed and approved for the NIST Quality System for Measurement Services as documented in the NIST-QM-I are controlling.

Links to the NIST Quality Manual, the NIST Administrative Manual, and "Guide to NIST SRM Development and Production" in the following URLs:
https://share.nist.gov/sites/qs/SitePages/Home.aspx
http://inet.nist.gov/mando/directives/adman-contents.cfm, and
http://msd-i.nist.gov/labpartners/srmguide1.pdf

3 Definitions

Special Test: In this manual we mean any measurement that is not performed on a regular basis, and does not have an existing procedure and uncertainty budget.

NOTE: The terminology "Special Test" is used in this manual in a different sense that it is used in the NIST SP250. Many of the SDMD "Special Tests" of the SP250 are indistinguishable from calibrations, and the term is a historical artifact.

Collaborator – (In the context of NIST use of this term for activities covered in the scope of this Quality Manual) one who provides services to NIST in support of a NIST measurement service or one who provides a NIST measurement service to a NIST customer, for NIST, under the terms of a prearranged agreement. For example, a collaborator might conduct analyses of samples for NIST in support of the provision of a NIST SRM. In all cases of a collaborative agreement, NIST is responsible for the final product delivered to the customer.

Measurement services: A NIST measurement service is any activity that results in NIST providing an identifiable customer with a measurement result (or measurement results. Such activities may or may not involve artifacts. The measurement services covered by this Quality Manual encompasses all services listed in the Semiconductor and Dimensional Metrology Divistions section of NIST Special Publication (SP) 250, NIST Calibration Services Users Guide and the NIST Special Publication (SP) 260, Standard Reference Materials Catalog.

Reference Material. In this Quality Manual we use the capitalized "Reference Material" for all materials characterized for the NIST Measurement Services Division for release through their Standard Reference Material program. In the Semiconductor and Dimensional Metrology Division this includes both Standard Reference Materials (SRM) and Reference Materials (RM).

NIST Certified Value – An assigned value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been fully investigated or accounted for by NIST.

NIST Reference Value – A non-certified value that is the best estimate of the true value based on available data; however, the value does not meet the NIST criteria for certification and is provided with associated uncertainties that may reflect only measurement reproducibility, may not include all sources of uncertainty, or may reflect a lack of sufficient statistical agreement among multiple analytical methods.

SDMD Quality Event System – The Quality Event System is used to record any facet of the quality system, good or bad. Typical entries are complaints, report changes, interlaboratory test results, poor customer response cards, great customer response cards, recognition of positive impacts on companies, thank you emails from customers, awards, in short anything that might be of interest when preparing the yearly management review.

SDMD Quality Event System Log – The log is a spread sheet used to record all quality events and details of the event deemed useful to record. Events that are negative and require follow up by the Quality Manager are marked in color to denote an incomplete entry.

Reference Material (RM) – Material or substance one or more of whose property values are sufficiently homogeneous, stable, and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

SRM Certificate – Document stating the intended purpose and application of an SRM, its certified property value(s) with associated uncertainty (ies), and any other technical information deemed necessary for its proper use. In accordance with ISO Guide 31:2000, an NIST SRM certificate bears the logo of the U.S. Department of Commerce, the name of NIST as the certifying body, and the name and title of the NIST officer authorized to accept responsibility for its contents. NOTE 1: An SRM certified for one or more specific physical or engineering performance properties is issued with a Certificate; an SRM certified for one or more specific chemical properties is issued with a Certificate of Analysis. NOTE 2: An SRM certificate may contain NIST reference and/or information values in addition to certified values.

SRM Leader – A technical person appointed to be responsible for the development and production of an SRM or RM. This person is appointed by the Group Leader in charge of the project.

Standard Reference Material (SRM) – A reference material, one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other document which is issued by NIST.

Traceability – The property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

4.1 Management Requirements

4.1.1 The Semiconductor and Dimensional Metrology Division

The Semiconductor and Dimensional Metrology Division is part of the Physical Measurement Laboratory, and has four groups, each led by a Group Leader. Each group has primary technical interest in a particular range of sizes. The groups are:

683.01 Dimensional Metrology Group
683.02 Surface and Nanostructure Metrology Group
683.03 Nanoscale Metrology Group
683.05 Microelectronics Device Integration Group
683.06 CMOS Reliability & Advanced Devices Group

All SDMD measurements are conducted at the NIST Gaithersburg site.

The SDMD Division Chief, acting through his leadership staff, is responsible for the technical and scientific work involved in the development, maintenance and provision of national standards of measurement and the associated measurement services. This work shall be done in a way that meets the needs of our clients and the requirements of ISO 17025. Resource allocations (personnel, fiscal, equipment, and space) specifically for these efforts are authorized by the Division Chief.

The institutional competency in provision of a measurement service is the responsibility of the Division Chief. Division Chiefs, or their designates, sign reports of calibration and test, RM and SRM certificates in the name of the NIST Director. In the SDMD, each Group Leader or their designate is authorized to sign certificates and reports of calibration and test.

4.2 Quality System for Measurement Services

4.2.1 Organizational Structure of SDMD-QS: Responsibilities and Authorities

The organizational hierarchy of the SDMD-QS is shown below.

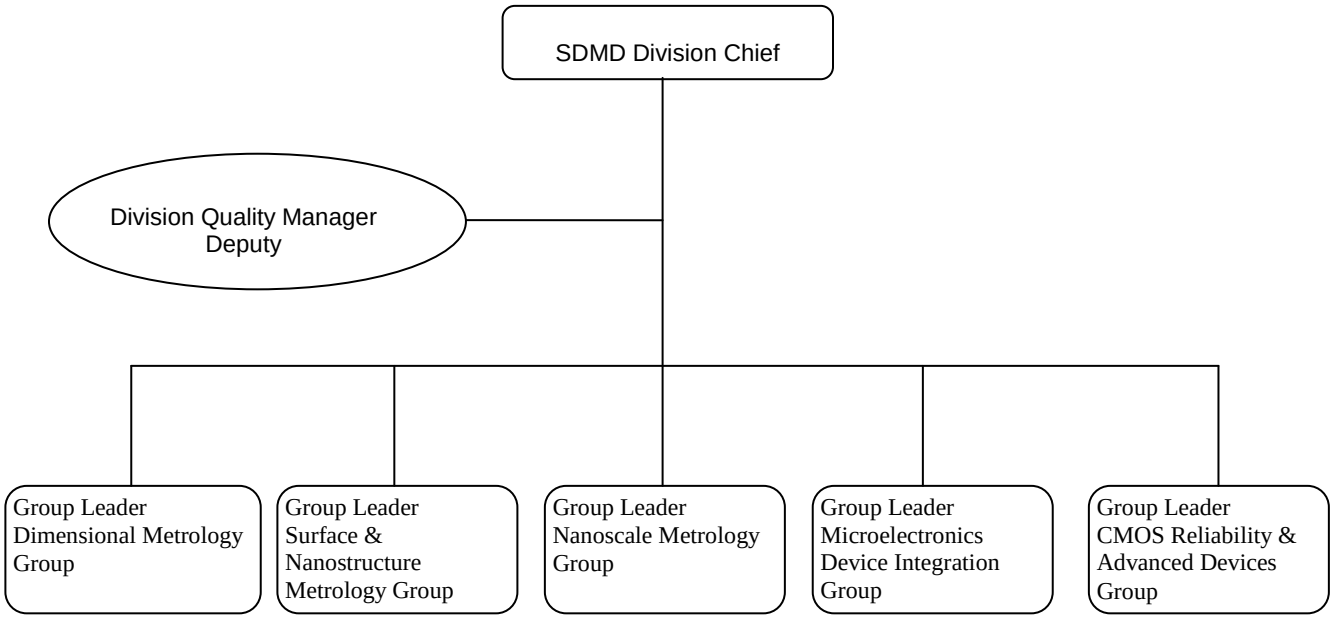

Figure 4.2.1 Organizational hierarchy of the management of the SDMD-QS

4.2.2 Responsibilities, Authorities, and Delegations

The Division Chief is responsible for implementing the Division-level of the NIST Quality System for Measurement Services. Division Chief is also responsible for assuring completion of audits and reviews in a timely manner, and for implementation of actions resulting from the findings of these audits and reviews. Division Chief appoints a Division Quality Manager and Deputy. The Quality Manager has direct access to the Division Chief, the highest level of management at which decisions are made on SDMD laboratory policy or resources. The names of the current Group Leaders, Quality Manager, and Deputy Quality Manager can be found on SDMD webpage for Calibration Programs/Projects.

SDMD Group Leaders are both administrative and technical managers of their group. As such, they are responsible for the administrative and technical operation of the SDMD measurement services. The Group Leader has the following responsibilities and authorities:

1. Implement and enforce good laboratory practices by specifying and approving all technical methods used, by providing instruction and training as needed, and by developing work plans and procedures.
2. Ensure that laboratory notebooks and laboratory documentation are used appropriately and kept up-to-date.
3. Provide resources and assign only competent personnel to complete tests and adjust workloads.
4. Identify, develop, and implement improvement for the laboratory measurement capability.
5. Analyze relevant proficiency test, round robins and inter-laboratory collaborative studies.
6. Sign reports of calibration and special tests, as per NIST Administrative Manual Section 14.01.03.
7. Assign acting group leaders and project leaders in the case of absence, as needed.
8. Delegate authority for these tasks to a Project Leader, a qualified individual within the group.
9. Report names of Project Leaders to the Quality Manager.
10. Delegate authority for Group Leader tasks to qualified individuals within the group.
11. Appoint SRM Leaders.
12. Authorize SRM projects.
13. Approve the fee for at-cost services.
14. Approve annual rates for fixed-fee services.
15. Inform Division Chief and Quality Manager of nonconformance of measurement services.

SRM Leader

Efforts to create and certify an SRM are led by an SRM Leader responsible for that particular SRM. The SRM Leader constructs or procures the SRM artifact and performs the certification measurements; he/she ensures that the associated measurement systems are maintained, and oversees the measurement process, including training and overseeing the work of others authorized to perform the service. The SRM Leader is responsible for providing technical assistance to customers and scheduling work flow (bringing any scheduling issues to the attention of the Project Leader).

Authorized Staff are those technical staff authorized by his/her Group or Project Leader to certify the value(s) for an SRM. Authorization may be limited to specific services. Authorized Staff may perform standard reference material certification measurements without direct supervision, and may oversee unauthorized staff perform measurement service activities during training and observation periods.

SRM Leaders responsibilities and authorities are:

1. Assure that all requirements in the NIST Guide to NIST SRM Development and Production (2004) are fulfilled.

2. Oversee the measurement service, including overseeing the work of others authorized to perform the service.
3. Ensure that the associated measurement systems (hardware and software) are maintained.
4. Ensure that the SDMD SRM Procedure for this service is followed and maintained, and that Division and NIST requirements are met.
5. Ensure that laboratory notebooks and laboratory documentation are used appropriately and kept up-to-date.
6. Provide technical information for customers as requested.
7. Host customer visits and provide demonstrations.
8. Train and observe staff for the specific measurement service.
9. Inform Group Leader and Project Leader of nonconformance of measurement services.
10. Assess significance of complaints, take actions required to resolve complaints (meeting requirements of 4.5.3), and documents this in the complaint notebook.
11. Ensure that measurement service software and data are backed up as required in the SRM Procedure document.

The Quality Manager:

Coordinates internal audits of the laboratory;

Identifies improvement needs and develops plans for improvement of the Division quality system;

Maintains and updates the Quality manual and has direct access to the Division Chief and the Group Leaders.

Assures that the system's documentation is communicated to, understood by, available to, and implemented by the appropriate personnel.

Keeps a record of the relevant technical contacts for calibrations and Reference Material development and production.

The Deputy Quality Manager assumes the full responsibility and authority of the Quality Manager in his absence.

4.3 Control of Documents, Records, and Data

4.3.1 Scope

In general, SDMD QS documents are managed as described in the NIST QM-I. The discussion below applies only to the SDMD QS. All SDMD quality procedures, technical procedures, and the worksheets called out in the procedures are division level controlled documents. All controlled documents are reviewed and approved for use by appropriate staff prior to use.

4.3.2 Document Approval and Issue

This section describes how we control all of the documents that form part of the quality system (internally generated and from external sources), such as regulations, standards, other normative documents, test and/or measurement methods, as well as drawings, specifications, instructions and manuals. Each division controlled document will have a unique name, and the revision number, date authorized, the name of the originating and approving staff members on the first page, the name and revision number on every page, and suitable paginating on each page of the document. The Quality Manager will maintain a document log as Appendix H of the Quality Manual showing document number, title, revision, approving staff member, and date approved or released.

Quality Manager Responsibilities:

1. Periodically reviews the Quality Documents to ensure continuing suitability.
2. Identifies quality-related activities requiring controlled documentation.
3. Documents the control system methods as follows:
    a. Identifies the documents to be controlled (Appendix H).
    b. Assigns responsibility for preparing, reviewing, and approving documents to qualified personnel.
    c. Reviews documents for adequacy, completeness, and correctness prior to approval.
    d. Establishes and maintains controlled document files on intranet.
4. Verifies that changes to controlled documents are properly approved by authorized personnel.
5. Maintains a document log (Appendix H) or record showing document number, title, revision, date, approving staff member, and date approved or released.
6. Evaluates requests for revisions, determines which are appropriate, and notifies requestors of actions taken.

Technical Manager Responsibilities

1. Periodically reviews technical documentation to ensure continuing suitability;

2. Identifies technical activities requiring controlled documentation and identifies the documents to be controlled (Appendix H).

3. Assigns responsibility for preparing, reviewing, and approving documents to qualified personnel.
4. Reviews documents for adequacy, completeness, and correctness prior to approval.
5. Verifies that changes to controlled documents are properly approved by authorized personnel.
6. Submits to Quality Manager who maintains a document log or record showing document number, title, revision, date distributed for review and date approved or released.
7. Evaluates requests for revisions, determines which are appropriate, and notifies requestors of actions taken.

Document Originator Responsibilities

1. Drafts or revises the assigned documents.
2. Distributes draft documents to appropriate individuals and organizations for review and comment.
3. Resolves comments, incorporates recommendations, and notifies reviewers of disposition.
4. Maintains documentation of review comments and their resolution.

The SDMD QM and all quality procedures are approved by the Division Chief. The Division Quality Manager authorizes the drafting of quality procedures and reviews them for submission to the Division Chief for approval. Technical Procedures, Work Instructions and related Forms are authorized and approved by Group Leader or his/her designee who oversees the relevant measurements.

4.3.3 Document Changes

All SDMD controlled document changes will be authorized and approved by the functions that authorized and approved the original document. In the case of significant changes in a quality system procedure, the Quality Manager is responsible for informing affected staff and arranging any training that might be needed.

After a revision of a SDMD quality procedure or document is approved as the official version, the division quality manager notifies all staff affected by the changes. This notice shall indicate those sections of the document that have been revised.

The implementation of changes in technical procedures is the responsibility of the Group Leader in the affected area.

A copy of the official version, as well as historical records pertaining to, and copies (clearly marked as obsolete) of all previous versions of quality documentation shall be maintained on a separate backup system. The file name of obsolete documents and records will have “Obsolete” added to the front of the file IA-Q-8.

4.3.4 Document Availability

The official versions of the SDMD Quality Manual and some other division generated controlled documents are maintained on the NIST network in the Engineering Metrology Toolbox (emtoolbox.nist.gov). This network is readily available to all SDMD staff and, as indicated above, also provides access to controlling documents that are not specific to the SDMD Quality System, e.g. the NIST-QS and NIST Administrative Manual. This official version of SDMD QM and other quality procedures and instructions will be read/print-only documents. Procedures may be printed out for training purposes or for short term reference. It is the responsibility of all staff to dispose of such copies as soon as the training or calibrations are finished to assure that any printed copies of documents are current. All printed copies of SDMD procedures; work instructions and forms are uncontrolled documents. The quality related and technical documents are maintained on the system by the Quality Manager or his designate.

Documents which are not division generated, such as equipment manuals, operating instructions, reference data, specifications, and tolerance tables relevant to division measurements and tests are maintained in the appropriate laboratory area.

Invalid or obsolete documents will be removed from the Quality System on the network. The Quality Manager will maintain a file of obsolete documents on CD-ROMs. A backup copy will be kept in a group secretary's office.

4.4 Review of Requests

Each technician is responsible for the review of requests for SP250 calibrations in their area. The customer is informed of the estimated cost and time in writing before any work is done. The standard process and documentation is described in Appendix F: SDMD Calibration Narrative.

Requests for Special Tests that do not have current procedures are brought to the Group Leader for consultation. It is then the responsibility of the Group Leader to ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements.

d) the procedure is developed and verified as described in Section 5.4 of this Manual.

e) a preliminary uncertainty budget is developed.

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client. The NIST-64 Acceptance Form is generated and sent to the customer, usually by the staff member who will perform the calibration.

If the laboratory is using the SDMD calibration to satisfy traceability requirements for accreditation the customer must be notified in two cases. First, if the calibration service is not in the international Mutual Recognition Arrangement (MRA) Appendix C it is possible that the customer's accrediting organization will not accept it as traceable. Secondly, for calibrations in Appendix C the accrediting agency may not accept as valid an uncertainty below the stated measurement capability. The inquiry and response must be documented and put in the envelope.

The client shall be informed of any deviation from the contract, and if a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

Records of such reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. These records will be stored in the calibration envelope and retained with the other records concerning the calibration.

4.5 Subcontracting and Collaboration

4.5.1 Subcontracting

The Semiconductor and Dimensional Metrology Division does not subcontract calibrations.

4.5.2 Collaborators

4.5.2.1 When a collaborator is involved in the production of a Reference Material, SDMD will assure the quality of the product by analysis of the collaborator's data and verification of the results by independent tests. Records of these analyses and verifications will be kept by the Project Leader as described in Section 4.12 of this Manual.

SDMD staff, with the assistance of NIST statisticians, as needed, shall review and/or develop all uncertainty budgets for collaborator data.

4.5.2.2 The RM or SRM Leader shall ensure that details of the methodology, results, and all the procedures performed by collaborators are available if required, and records of all collaborators and their accreditation/registration or other forms of competence status are maintained.

4.5.2.3 The SRM Leader shall ensure that all environmental requirements are also met by Collaborators involved in the Reference Material production process.

4.6 Procuring Products and Services, External Sources

4.6.1 Calibrations

We use very few consumables. Solvents for cleaning, ethanol and mineral spirits, are bought from the NIST chemical storeroom or from commercial suppliers. Ethanol is kept in cabinet in original container and in plastic squeeze bottles in the laboratory cleaning areas. Mineral spirits is kept in approved safety can. Oils and other lubricants are bought according to manufacturers' recommendations, and the preservative used for steel gages has not changed in 40 years.

If a consumables and/or supplies used for a measurement service that critically effect the quality of a measurement service the source will be evaluated and the results of these evaluations shall be maintained as a quality record and kept by the Quality Manager or Group Leader involved in the measurement.

Where outside support service quality is not assured, PED uses the items only after they have been inspected or otherwise verified for adequate quality.

Purchase orders are reviewed by Group Leaders for any needed technical specifications. All purchase are inspected on arrival as required by NIST administrative procedures (see 4.4.2 of NIST QM-I).

4.6.2 Reference Materials

Most SRM and RM materials are supplied by vendors outside of NIST. The quality of the supplied material is critical to the successful production of the Reference Material, and therefore these materials must be rigorously tested and the results documented in the SRM Notebook.

Any aspect of the supplied material that affects the uncertainty or usability of the final product shall be verified and documented. These records should include all pertinent information, such as:

Source
Date
Batch Number
Supplier Measurements, if any
Purchase Order Number
NIST verification method
Uncertainty Budget
Data and analyses.

These records will be kept by the Project Leader for the Reference Material.

4.7 Service to the client

We allow clients or their representatives to visit and discuss any aspects of our measurements. Because of site security these visits must be arranged in advance.

In addition to answering technical inquiries from customers, the Division also provides opportunities for formal training to customers either individually or through professional conferences. Division staff also work to better understand customer needs through visits to customer sites, conference attendance, and collaborations. Customer needs are also ascertained through work with trade and standards groups or customer working groups. Specific issues that arise and the Division's response are documented in our quarterly quality reports.

4.8 Complaints

Each staff member is responsible to assess the significance of a complaint, with guidance from their supervisor if needed, to be sure that appropriate level of NIST management is aware of the complaint and approves of responses thereto. In the case of customer complaints that imply that an activity has not been compliant with the requirements of the NIST-QS, the procedure of section 4.9 (Non-Compliance) shall be followed. For less serious problems, such as typographical errors, shipping or turnaround problems, the following procedure shall be performed.

4.8.1 SDMD Complaint Procedure

Whoever takes the complaint is responsible for reporting it, and the following information to the appropriate Group Leader:

Date:
Information: company name; contact person; phone number.
Description: include possible resolution if suggested by complainant.
Control #: NIST test number, or Reference Material Number

The Group Leader then assigns a person to be responsible for handling the complaint and e-mails the information to the Quality Manager for entry into the Quality Event Log.

The person responsible for complaint works with the customer to resolve the problem, and with the agreement of the Group Leader takes the agreed upon action to close out the complaint. The action taken is recorded and filed with any other documentation in the envelope for the measurement in question. The Group Leader sends the following information to the Quality Manager to end the QEL record:

Actions taken to resolve the complaint.
Resolution date.
Recommendation for corrective or preventive action.

4.9 SDMD Non-Conforming Work Procedure

If there is evidence from any source that the data, uncertainty, or conformance decision reported to a customer is incorrect the Corrective Action Procedure (4.11) shall be used to explore and resolve the problem.

If a specific customer requirement has been agreed to by NIST and the requirement is not met the corrective Action Procedure shall be followed to resolve the issue.

Lesser problems which do not affect the calibration results like typographical errors on reports, shall be handled with the Quality Event Log Procedures.

4.9.1 The Group Leader of the area affected by the non-conformance shall be responsible for managing the response. The GL shall inform the QM of the incident for entry into the QEL, and provide basic information about the suspected non-conformance.

4.9.2 The Group Leader will:

1. Collect basic information about the problem and send it to the Quality Manager for entry into the Quality Event Log;
2. Take appropriate actions, including
   a. halting of work and withholding of reports, as necessary;
   b. evaluating the significance of the nonconforming work;
   c. when necessary, notifying the client and recall affected work;
3. Cause analysis – conduct an investigation to determine the root cause(s) of the problem
4. Select the action(s) most likely to eliminate the problem and to prevent recurrence
5. Implementation
   Authorize implementation of selected changes;
   Direct validation of revised procedure(s);
   Authorize the resumption of work;
6. Monitor the results to ensure that the actions taken have been effective;
7. Notify the Quality Manager of the actions taken;

4.9.3 Documentation

All steps taken in responding to reported non-conformances shall be documented using the SDMD Corrective Action System. The Corrective Action Form, when completed, along with all other documentation such as correspondence, test and verification results shall be kept in the Corrective Action File kept by the Quality Manager.

4.9.4 The Quality Manager will monitor all open Quality Events and facilitate a timely resolution of the problem. The Quality Event Log shall be checked at least once a month to assure the log is up to date and check that open events are being processed.

4.10 Improvement

NIST expects continuous improvement in the provision of measurement services and encourages identification of opportunities for improvement from all staff. These efforts are documented in the quarterly quality report which is read by the Division Chief and presented at professional meetings.

4.11 Corrective action

There are many ways that a problem with the quality system or with the technical operations of the laboratory may be identified; such as control of nonconforming work, internal or external audits, management reviews, feedback from clients or staff observations. Problems with the technical performance of SDMD are addressed by the procedure in section 4.9, Technical Non-conformances. Any other problem uncovered, or suspected, shall be reported to the Quality Manager.

The Quality Manager judges the importance of the problem and does one of two things. For minor problems such as typographical errors the email reporting the problem is saved in the Quality Event System and entered into the Quality Event Log. The QM shall monitor the staff response to the problem and close out the event when satisfied that the problem has been resolved.

For major problems such as non-conforming work, significant findings in assessments or internal assessments, serious customer complaints, the QM shall start a Corrective Action.

4.11.1 Addressing a problem the following procedure shall be used.

1. Quality Manager will collect basic information about the problem and enter it into the Quality Event Log;
2. If the problem is with the Quality System, the Quality Manager shall decide the level of response which could be notes in the Quality Event System or a full Corrective action using the Corrective Action template or equivalent.
3. For technical problems the affected Group Leader shall decide the level of response.
4. For Quality System problems the Quality Manager shall conduct a formal Corrective Action. For technical problems the Group Leader in the area of the problem shall perform conduct a full Corrective Action and report the results to the Quality Manager.
5. Corrective Action recommended by the Quality Manager or Group Leader is applied and documented.
6. The Quality Manager shall monitor the results to ensure that the corrective actions taken have been effective.

4.11.2 All steps taken in responding to reported non-conformances shall be documented using the components of the SDMD Corrective Action Form, Appendix D. Staff may use the form or submit an email that covers all of the components in place of the form. The Quality Manager shall be keep all communications relevant to the event.

4.11.3 Where the identification of non-conformances or departures casts doubts on SDMD compliance with its own policies and procedures, or on its compliance with any element of the quality system, the Quality Manager shall ensure that the appropriate areas of activity are promptly audited as soon as possible.

4.12 Preventive Actions

Excellence, a NIST CORE VALUE, relies on continuous improvement. All NIST employees are encouraged to identify needs and opportunities to improve our technical and quality procedures and policies. The appropriate levels of technical and quality management will respond to staff suggestions by examining the opportunity or need and develop action plans to implement any changes required. The outcome will be communicated to the employee whose suggestion stimulated the actions.

SDMD participates in numerous international and domestic interlaboratory comparisons every year. These results are carefully analyzed to monitor the performance of our measurement systems and to suggest improvements in either efficiency or accuracy. In addition, most measurements are performed under statistical process control, and the results of these systems allow us to examine differences in performance related to equipment, operators and standards.

All of this work is done with the goal of characterizing the measurement system and uncovering possible improvements.

Finally, each year the division must submit proposals to the Physical Measurement Laboratory or funds to develop new calibration methods or to improve current systems. This exercise includes analysis of current performance as well as consideration of the changing needs of our customer base.

Any actions made to the Quality System shall be documented using the Quality Event System.

4.13 Control of records

4.13.1 Quality System Records

4.13.1.1 The Quality Manager will maintain all quality records. Quality records include:

Internal Audit results,
Management Review material and minutes,
Complaints and Corrective Action records,
Technical and Quality related training records,
Quality Event System and Log.

Paper records will be filed in labelled folders in the Quality Manager's Office. Most new records are scanned and kept as pdf files. Reports back to 1995 have also been scanned.

NIST has a number of networks that offer backup services. Use of any of these services are adequate for the storage of calibration records as long as the computer is password protected. Electronic records can also be backed up locally but the proprietary nature of calibration records requires encrypted storage devices.

4.13.1.2 Retention Times

The table below lists the classifications of controlled documents, retention periods, and location.

Document	**Retention Time**
Complaints/Feedback/Corrective Action	10 years
Internal Assessment Results	5 years
Management Review Results	5 years
Training Records	Until end of employment
Interlaboratory Comparison Data	Life of calibration process

4.13.2 Administrative Records

Each Group secretary or his designate is responsible for the administrative records generated by calibrations or Reference Material production. These records are spelled out in the Calibration Narrative, and include customer information entered into the Calibration Database, copies of fee calculation sheets and shipping forms, and completed calibration reports.

4.13.3 Technical records

4.13.3.1 Original observations, derived data, sufficient information to establish an audit trail such that there is sufficient detail to reproduce the calibration as close as possible to the original conditions. These records include worksheets or calibration records, and a copy of each test report or calibration certificate issued are kept for a defined period. These records shall be filed securely in a manner that allows them to be efficiently found. Traditionally folders or envelops were used but the use of computerized records is allowed. For files stored digitally a separate folder should be used for each calibration folder. Information stored on portable media must be encrypted.

Similar records for Reference Material production are kept in a SRM or RM notebook for a defined period by the Reference Material Leader or Group Leader. The use of electronic storage of this material is allowed. The records for each measurement shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel who perform of each measurement and checks the results.

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

4.13.3.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible nor deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

Technical records	Retention Times
Calibration and Test Reports	Copies of all reports kept in historical file
Envelopes (Test Data, etc.)	10 years
Environmental Conditions/ Deviations Log	2 years
Software Verification	Verification kept for last two revisions Date and summary entered in Maintenance Log
Calibration and Maintenance (Standards and Equipment)	Life of equipment or standard
Measurement Assurance Data	Life of calibration process
Reference Material Records	Until Reference Material is discontinued

4.13.3.4 Technical records that are stored electronically shall be backed up in an organized fashion. Any particular media is allowed with the provision that since calibration data is proprietary the storage must be password protected and portable devices must be encrypted.

4.14 Internal Audits

Each year some part of the Quality System will be audited, the entire System being covered in a 2 year span. The Quality Manager shall organize the audits as required.

The Quality Manager will review the SDMD quality procedures in the Quality Manual against any new versions of ISO 17025, Guide 34, NIST QM-I and the SRM process requirements to assure continuing conformance.

Sometime during the audit cycle Group Leaders will review their technical procedures and documentation to assure their continued suitability. Any changes that result from this review shall be reported to the Quality Manager for inclusion in the Management Review and quarterly Division Quality Report. Significant changes in a procedure that require validation of the changes shall be documented using the Corrective Action Procedure.

The Quality Manager shall organize the audits as required.

4.15 Management Reviews

4.15.1 Each quarter the Quality Manager shall draft a report for the Division Chief, who will prepare a Quarterly Report for the Director of PML. Each report should cover any the following topics if appropriate:

- New SRMs
- Turnaround time for Calibration work
    - How many for editorial purposes?
    - How many for data/results revision?
    - For SRMs: Restrictions or Certificate Revisions
- Decreased measurement uncertainty
- Increase in range or parameters
- Customer feedback
- Complaints, Action Plans, Implementation, and Outcomes Thereof
- Revisions to Quality Manuals
- NIST Assessments and Division Internal Audits
- CMCs: Reviewed? Any changes to CMC's?
- Intercomparisons:
- Significant changes in volume of work or type of work – demand of the service
- Termination or planned stoppage of services: None planned
- Changes in policies or procedures
- Staffing changes (including management changes)
- Training given/received
- Visits/Visitors (technical visits resulting in training or collaborations)
- Other NMIs, Companies/Industry, Peer evaluator or assessor activities Publications
- Peer evaluations or assessment activities outside of NIST (for other NMIs)
- Standards meetings (ASTM, ISO, IEC, etc.) related to measurement service capability
- Other factors or considerations

In January of each year the Quality Manager shall present a review summarizing the state of the SDMD measurement system. This review shall include the items listed above, financial data and statistics as well as any other issues that might require changes in the measurement services offered by SDMD.

4.15.2 Any findings from management reviews and the actions that arise from them shall be recorded in the Quality Event Log. The Quality Manager shall monitor any actions to assure that they are addressed within an appropriate and agreed timescale.

5 Technical Requirements For Calibrations

5.1 Introduction

The Semiconductor and Dimensional Metrology Division (SDMD) is part of the NIST Physical Measurement Laboratory (PML). Participation in the development of consensus standards, development of measurement methods and test structures, provision of Reference and Standard Reference Materials, calibration services and special tests are essential elements of the work of the Division in fulfillment of its mission.

The measurement services of the National Institute of Standards and Technology (NIST) are designed to help the makers and users of precision instruments achieve the highest possible levels of measurement quality and productivity. NIST provides Calibration Services using well-characterized, stable and predictable measurement processes. NIST calibrates instruments and devices that are metrologically suitable as reference or transfer standards, and directly link a customer's precision equipment or transfer standards to national and international measurement standards. SDMD management is responsible for taking sources of uncertainty and customer needs into account in developing appropriate measurement methods, procedures, training and qualifications of staff and selection of appropriate equipment.

5.2 Personnel

5.2.1 Competence

Assuring competence is the direct responsibility of the management chain for scientific research and services of the relevant technical Divisions, as described in Section 4.1.1.

Appropriate supervision will be provided for staff undergoing training. Staff performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills as required by the SDMD Training Procedure.

5.2.2 Education and Training Goals

5.2.2.1 The SDMD technical staff must have the necessary technical background to ensure comprehension of the laboratory tests and operations. SDMD management provides continuing education opportunities and on-the-job training to ensure proficiency in measurement and testing.

5.2.2.2 The Semiconductor and Dimensional Metrology Division mandates training every year for all technical staff. It is the responsibility of each group leader to identify the training needs of his staff based on the present and anticipated tasks of the laboratory. This is done at least once a year in preparation of the staff performance plans for the year.

5.2.3.1 The laboratory only uses personnel who are employed by NIST for calibrations.

5.2.3.2 For reference materials there can be collaborators who are not employees. These staff shall satisfy the same training requirements as NIST employees. The results of their work, documented in the calibration report or Reference Material records, shall be reviewed in the same manner as that from regular employees.

5.2.4 Detailed descriptions of staff duties are contained in their yearly performance plan. These documents have a mid-year appraisal to update changes in duties during the year. The documents are kept by the SDMD Office.

5.2.5 Group Leaders shall authorize specific personnel to perform particular types of sampling, tests and/or measurements, to issue test reports and calibration certificates, and to operate particular types of equipment. This authorization is based on the competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.

The Quality Manager shall maintain records of the relevant authorization(s) and the date on which authorization was confirmed in an authorization matrix. The matrix shall also list who is, by education, training and experience, authorized to train staff in each measurement.

5.2.6 For processes that are not in regular use, such as certifying restocked Reference Material inventory, the Group Leader will ensure that the staff meet the training requirements and provide retraining or re-verification in the needed skills as necessary.

5.2.7 On-the-job training

SDMD staff receive assigned tasks based on their individual training and verified competence. On-the-job training conducted by SDMD staff and training conducted by external sources will be performed and documented according to the SDMD Training Procedure in Appendix B.

5.3 Accommodations and Environmental Conditions

NIST recognizes the critical role that the physical plant and laboratory environment play in the provision of the state-of-the-art measurements, calibrations, and standards required to fulfill its role as the Nation's primary reference laboratory. Assuring the quality and adequacy of the laboratory accommodations and environment is a key responsibility of the Institute's executive management. The technical division determines the requisite conditions and working in collaboration with the Facilities-, Plant-, and Engineering, Maintenance, Safety, and Support Divisions is responsible to assure that environmental conditions do not adversely affect the quality of measurement services.

5.3.1 General Conditions

General environmental conditions maintained by each measurement area are listed in the technical procedures that are used in the area. Facilities used for storage of customer and/or in-house artifacts and measurement equipment will be appropriate to prevent deterioration.

5.3.2 For measurement processes under statistical process control, check standards are chosen that monitor the effects of environmental influences. For these cases direct monitoring of individual influences is not required as long as the systems are in control.

The environmental requirements for measurements or tests that are not adequately monitored via check standards have separate statements of environmental limits in their technical procedures. The variation in conditions that affect the measurement or test is documented as to its impact on the uncertainty in each corresponding uncertainty budget.

5.3.3 Laboratory staff shall:

- Assure that environmental requirements of the technical procedures are met.

- Maintain good housekeeping practices promoting a clean, uncluttered laboratory.

- Maintain a convenient, efficient work environment with effective separation of incompatible activities.

- Limit the amount of paper products used or stored in sensitive and/or clean areas to prevent excessive dust contamination.

- Effectively monitor, control, and record environmental conditions where appropriate (i.e. humidity, temperature, vibration, etc). These requirements will be specified in each technical procedure if applicable. Deviation from acceptable conditions are reported to the Group Leader and problem is communicated to the relevant NIST Plant Division staff.

- Cease measurements when environment exceeds limits stated in the lab procedure. Staff members are authorized to contact Physical Plant about environmental problems, and shall notify the Group Leader of the situation. Work shall not resume until environment is back within limits. Systems under statistical process control (SPC) should not resume measurements until systems are consistently in control.

- Laboratories are locked when not currently in use, at the end of the working day, or when disturbance during testing affects the measurement integrity.

5.3.4 Records

Where appropriate, each measurement area shall maintain continuous records of environmental conditions to assure the integrity of subsequent measurements. These records are maintained in each individual laboratory or within the applicable notebook.

5.4 Test and Calibration Procedures and Procedure Validation

5.4.1 General

Appropriate methods and procedures shall be used for all tests and/or measurements SDMD. These include sampling, handling, transport, storage and preparation of items to be measured tested and/or calibrated. Where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of measurements, test and/or calibration data are included.

The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for measurement, test and/or calibration, where the absence of such instructions could jeopardize the results of the measurements, tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).

Any deviation from a written technical procedure must be approved by the appropriate Group Leader, documented in the calibration records, and if appropriate approved by the customer.

5.4.2 SP250 Calibrations

The great majority of calibration services provided by NIST are based on well-characterized, stable and predictable measurement procedures that have been documented in peer-reviewed, published reports. Approval of new SP250 calibrations is controlled by NIST policies. If any changes are made to existing procedures, the new procedure shall be verified before implementation for customer calibration. Verification tests will be documented. The verification documentation shall be filed in an envelope under the NIST Folder number in the same manner as a calibration. The reports for these calibrations shall refer to the associated publication, and these publications shall be made available to customers.

The staff members of SDMD are charged with developing new, more accurate procedures for calibrations as part of the NIST Charter. The scientific process of developing new measurement methods is very complex, and is beyond the scope of this quality system. The approval process and criteria for new SP250 calibrations is described in Appendix A.

For measurements based on written standards, the latest edition of the standard will be used, and the procedure reviewed any time a new edition is published. The standards are kept by the technician or engineer assigned to these calibrations.

For standard calibrations or Special Tests the customer is informed of the method to be used.

5.4.3 There are a number of calibration methods used in SDMD to calibrate working gages or measurement equipment. The introduction of calibration methods developed by the laboratory for its own use shall be a planned activity, shall be assigned to qualified personnel with adequate resources, and shall satisfy the requirements for Special Tests in Section 5.4.4. These methods

shall be documented in the same manner as customer calibrations and satisfy all of the requirements of ISO 17025 and the SDMD Quality System.

5.4.4 Non-Standard Methods (SP250 Special Tests)

5.4.4.1 These measurements are performed upon specific customer request, assuming the Division has available staff and the appropriate equipment. Customer proposed methods will be considered. If the method is inappropriate the customer will be informed. Customer proposed methods shall be subject to the same development and verification procedures as SDMD developed methods. These procedures are approved by, and the measurements performed under the close supervision of, a Group Leader or designated senior technical staff. The procedure, estimated cost, turnaround, and uncertainty will be discussed with the customer and the NIST Pro Forma is used as a written confirmation of the proposed measurement. The procedure will be fully verified using known artifacts or other suitable methods. The results of the verification shall be documented and filed in the calibration envelope.

5.4.4.2 The following information shall be recorded for each special test procedure and kept as a record in the calibration envelope.

a) appropriate identification;
b) description of the type of item to be tested or calibrated;
c) parameters or quantities and ranges to be determined;
d) apparatus and equipment, including technical performance requirements;
e) reference standards and reference materials required;
f) environmental conditions required and any stabilization period needed;
g) description of the procedure, including
- affixing identification marks, handling, transporting, storing and preparation of items,
- checks to be made before the work is started,
- checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
- the method of recording the observations and results,
- any safety measures to be observed;
- results of verification tests of the method;

h) data to be recorded and method of analysis and presentation;
i) the uncertainty or procedure for estimating uncertainty.

5.4.4.3 Special Test Reports

Each report of Special Test shall include the evidence of the following (numbers refer to clauses in ISO/IEC 17026:2005)::

· Records of calibration method validation (5.4.5)
· Procedures for estimation of uncertainty (5.4.6)
· Documentation for traceability of measurements (5.6)
· Documentation for assuring the quality of calibration results (5.9)

· Documentation for competence of staff (5.2)
· Documentation for accommodation and environmental conditions (5.3)
· Audits of the calibration laboratory (4.6.4 and 4.14)

5.4.5 Validation of Methods

All measurement methods shall be extensively studied and the verification process shall be documented in the peer-review publication describing the method. If any substantive change is made to a standard procedure it will be completely verified. All methods used by SDMD will be verified using artifacts of known dimensions or characteristics with uncertainties small enough to be statistically relevant to test the method and/or the use of scientifically accepted models. The artifacts or model validity shall also span a suitable range to cover the proposed method use.

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.6 Estimation of Uncertainty

All reported NIST measurement results shall be accompanied by quantitative statements of uncertainty. To ensure that such statements are consistent with each other and with present international practice, NIST adopts in substance the approach to expressing measurement uncertainty recommended by the International Committee for Weights and Measures (CIPM). "This approach is described in Appendix C of the NIST-QM-I manual."

The uncertainty analyses of nearly all standard SDMD calibrations and Reference Materials have been published and are listed in Appendix Y, the annotated Bibliography of this Quality Manual.

For Reference Materials the process of estimating uncertainties of the property values of interest, any uncertainties resulting from between-unit variations and/or from possible doubts on stability (both during storage and during transportation) shall be assessed in accordance with ISO Guide 35 and shall be included in the assigned uncertainty.

For non-standard measurements or complex measurements the uncertainty budget is included in the calibration report.

5.4.7 Control of data

5.4.7.1 Measurement records are maintained for all tests, measurements, calibrations, and verifications performed for either internal use or for a customer. Measurement records include at least a copy of the test or measurement report, data records, external customer purchase order, fee record, and any other relevant test order information. Each record must identify who performed the measurements, the procedure used (by procedure number), and the record itself must be identified with the internal control number. These records are kept in the calibration envelope and/or a file that has the NIST number as part of the file name in a suitably secure and backed up computer.

5.4.7.2 Content of measurement records for calibrations and special tests, and the retention location of these records is either specified as specific instructions in the technical procedure or encompassed under the general log-in/log-out procedures. Measurement records, including those in computer files, are accessible to authorized personnel only. Computer files are duplicated for protection against loss. All staff office workstations are backed up daily by the NIST Tivoli Storage Manager (TSM) system, and the reliability of the system has been verified. Customer data that is kept in laboratories on disks are checked for reliability on their next use since the history on the disk is used in the analysis of the current calibration results.

5.4.7.3 For systems under process control, the check standards provide a routine check on the integrity of the data transfers and a verification of the software data analysis. Any problems in data transfer, or changes in algorithms or corrections in the software will cause a shift in the control value of the check standards.

5.4.7.4 All measurement records are treated as confidential information and are not distributed to any person, company, or organization unless officially authorized, in writing, by the customer for whom the work was performed.

Computer code, calculations, and data files will have some level of unauthorized access security. The level of security will depend on specific conditions of use. If customer proprietary data is stored on a portable memory device, the device must be encrypted as required by ITAC.

5.4.7.5 Calculations and data transfers are subject to appropriate checks in a systematic manner. Most measurements use a multiply-redundant measurement design with check standards. These two techniques provide detection of most common data transcription errors.

5.4.7.6 Prior to use, all programs, spreadsheets, macros, etc. used for capture, processing, manipulation, recording, reporting, storage or retrieval of data will be documented, verified, approved, and retained. Verification is primarily obtained from the check standards used in SP250 procedures. In other cases it may be obtained from standard test data sets, or comparison of the software results with another, already verified, system. The results for special tests will be filed in the calibration envelope or its electronic analog.

5.4.7.7 If discrepancies are detected during verification, the Corrective Action Process for documentation, correction, and impact evaluation will be performed.

5.5 Equipment

Division Management is responsible for furnishing all material resources required for the correct performance of measurements relating to measurement services.

5.5.1 Equipment and artifacts used within the Division whether owned, borrowed, or leased must be calibrated and the measurement or calibration documented prior to use in a measurement service. All relevant specifications shall be subject to documented acceptance testing and uncertainties determined using sound statistical techniques. Verification of measurement or calibration results will be maintained in the appropriate service log and associated file. Equipment and its software used in calibrations shall be capable of achieving the accuracy required and shall comply with specifications relevant to the calibrations concerned.

Instruments shall be calibrated before and after any adjustment.

5.5.2 Calibration of equipment is conducted at a frequency suitable to provide assurance that the equipment remains in calibration during its use in the laboratory. All measuring equipment is calibrated on entering service. There are four classes of instrument calibration in SDMD to assure that equipment is in calibration for all measurements. These are explained in section 5.5.4.

The Semiconductor and Dimensional Metrology Division will not generally accept manufacture's specifications, external uncertainties, or calibrations. The only exceptions will be for calibrations performed by other NIST Technical Units or Laboratories that are accredited by NVLAP or other accreditation body with a Mutual Recognition Agreement with NVLAP.

All instrumentation used in SDMD associated with the performance of a measurement service will be handled and maintained according to its manufacturer's recommended practice and be operated by authorized personnel. Maintenance procedures may be in the form of the manufacturer's operating manual, the user's written maintenance procedure, or where appropriate incorporated into the technical procedure/s involving the particular instrument. Calibration procedures shall include steps to ensure that any correction factors are properly updated.

Instrumentation and artifacts that have been either mishandled, suspect of incorrect results, or have been shown by testing to be defective will be identified and handled according to the SDMD Non-conforming Work (Section 4.9) Procedure.

5.5.3 The training procedures cover the proper use of instruments in a calibration and the Authorization Matrix shows which personnel are authorized.

5.5.4 All NIST equipment has an inventory number as its unique identification.

5.5.5 Each group maintains an inventory of all instrumentation and artifacts used in association with its measurement services. This inventory is maintained under the supervision of the Group Leaders and includes the following information:

- Manufacturer Serial Number;
- Manufacturer Model Number;
- NIST Property Number;
- Item Description;
- Calibration or Service Status;
- Location (if appropriate);
- Location of manuals and other appropriate information on the instrument;
- Dates, results and copies of reports and certificates of all calibrations, adjustments, and the due date for next calibration if relevant.;
- Maintenance plan, where appropriate, and maintenance carried out to date;
- Damage, malfunction, modification or repair to the instrument.
- Procedures for safe handling, transport, storage if needed.

5.5.7 Instrumentation and artifacts that have been either mishandled, suspect of incorrect results, or have been shown by testing to be defective will be identified and handled according to the SDMD Non-conforming Work (Section 4.9) Procedure.

The status of all measurement equipment and reference materials associated with measurement services will be identified in accordance with this section.

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

Statistical Process Control - Does not require calibration at specified intervals. Measurements are performed using statistical process control methods. Failure of statistical tests more than twice shall be investigated. Equipment under process control will have a label that says “Under Statistical Process Control” or “Under SPC” if a smaller label is needed.

Calibrated - Refers to instrumentation or reference materials not under statistical process control, used as absolute indication and not checked with each use (e.g. temperature indicators, humidity indicators, pressure gages, and lasers using for interferometry). Item must be calibrated at specific intervals as identified in the item’s service log, unless the interval is extended. Calibration labels will indicate the date of calibration, date of next calibration, and any important corrections and/or values

Calibrate on Use - item is not "Under Statistical Process Control" and is not "Calibrated". May be used for performing a measurement but must be checked using a suitable means. Identification of this item and calibration data must be maintained with the measurement service record for the test item. (Label Not Required, items not labeled are assumed to be in this status)

Do Not Use - item is broken, malfunctioning, etc.

Labels will be displayed on the items directly, except in cases where reference items are maintained, as a set or the item does not physically permit placement. In these cases the label will be displayed on the item's container.

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

5.5.10 Intermediate checks are carried out according to the principles in Appendix I, Measurement Assurance.

5.5.11 Equipment and software that have changeable correction factors shall be safeguarded from adjustments that would invalidate the test and/or calibration results. For calibrations that are not under the measurement assurance process the adjustments shall be checked by another staff and/or tested against standard data sets.

5.6 Measurement Traceability

5.6.1 NIST Traceability Policy

It is NIST policy to establish traceability of the results of its own measurements and values of its own standards and of results and values provided to customers of NIST measurement services. Specific evidence of traceability is found in the NIST sub-level quality documentation and other documents referenced therein.

Consistent with the CIPM, NIST measurements are directly traceable to the SI (or for chemical or materials metrology to other recognized standards) as realized or represented by NIST or in rare cases by another NMI. For those measurements, e.g., ambient temperature, that do not provide a significant influence on the overall measurement uncertainty, traceability can also be obtained from a calibration laboratory that is accredited by an ILAC signatory accreditation body. For use of an accredited laboratory the traceability of the reported results must be to NIST.

5.6.2 Calibration of Dimensional Artifacts

Master dimensional gages are calibrated by comparison of to the wavelength of stabilized HeNe laser light or the wavelengths of well-characterized atomic lamps. These calibration processes are monitored by measurement assurance programs established in the Division and are in the custody of trained metrologists. Each calibration process has a documented uncertainty budget prepared according to the guidelines in NIST Technical Note 1297.

Recalibration of master artifacts is a complex decision that depends on numerous factors. Since all standard comparison calibrations have active measurement assurance programs with check standards, any significant change in master values will be discovered through the check standard measurements. In addition, on a regular basis, the check standard history is analyzed to update the SPC parameters. Any suspicious behavior in the value of check standards is investigated and the master artifact recalibrated. In addition to the suspicious sizes, enough of the sizes in control are recalibrated so that the entire range of masters is calibrated in a 3 to 5 year cycle. See Appendix I: Measurement Assurance.

Master Artifacts held by the Division will be used for Division calibration purposes only, and for no other purpose, unless it can be demonstrated that their performance as reference standards will not be invalidated.

5.6.2.1 Most SDMD customer calibrations are made by comparison to master gages. These gages are calibrated by comparison to one or more frequencies of a stabilized laser or atomic spectral lamps. The values of these frequencies are taken from the BIPM "Mis en Pratique", a published document available on the BIPM website (http://www.bipm.org/en/publications/mep.html).

5.6.2.2 Where appropriate, an assessment of the stability of the assigned property values of reference standards shall be performed. Most standards are part of our Measurement Assurance Program, and changes in a reference standard are detected as a matter of course.

5.6.3 Traceability in Vibration and Sound

Interferometric primary methods use interferometry to determine either displacement or velocity of the motion of a moving surface upon which the unit under test is mounted. Acceleration is then inferred by differentiation of the output of the interferometer. These measurements form the basic traceability of the measurements.

For acoustic calibrations the most accurate free-field measurements traceable to NIST are achieved by obtaining the NIST free-field calibration of a microphone by the reciprocity method.

5.6.4 Traceability of Reference and Standard Reference Materials

Standard Reference Materials have a wide span of traceability paths and the traceability is that which is required by the NIST reference materials policiesl.

5.6.5 External Calibrations of SDMD Equipment and Standards

Some instruments and standards for auxiliary measurements (temperature, force, pressure, etc.) are calibrated by the appropriate NIST calibration service or an outside supplier that is accredited by NVLAP or organizations that has mutual recognition with NVLAP. Secondary standards are calibrated against these primary standards by Division staff. Records of all calibrations are kept

as part of the measurement assurance program as check on the consistency of these calibration processes.

5.7 Sampling

SDMD calibrates individual instruments and explicitly states that the measurement results apply only to that specific instrument. Current SDMD calibrations and special tests do not rely on sampling. If sampling is required for any application it is the responsibility of the relevant Group Leader to insure its validity.

5.8 Handling of Calibration Items and Reference Materials

NIST measurement services are designed to enable the makers and users of precision instruments achieve the highest possible levels of measurement quality and productivity. These services directly link the customer's precision equipment or transfer standards to national and international measurement standards. The handling of the customer's precision equipment or transfer standard is extremely important to the validity of the measurement results and their subsequent use in the customer's facility. Handling, storage, and shipping of measurement items requires skill and due diligence to assure the integrity of the test or measurement items. Chiefs of the technical and support divisions are to assure that staff are properly trained, understand proper handling, and consistently do so.

Items received for calibration or test are unpacked, inspected, identified, logged in, stored, and upon completion are repacked and logged out according to the SDMD Calibration Narrative in Appendix F.

5.8.1 Upon receipt the condition of the calibration or test item, including any abnormalities or departure from standard condition as prescribed in the relevant calibration or test method, shall be recorded. In cases of visible damage the item is photographed. The technician shall consult the customer for further instruction when there is any doubt as to the item's suitability for calibration or test, the item does not conform to the description provided; or the calibration or test required is not fully specified. These transactions are recorded and kept with the calibration folder.

5.8.2 Each item shall be uniquely identified and/or marked to ensure that there can be no confusion regarding the identity of such items at any time. Since the items are stored in our calibration laboratories, the storage, security, environmental, and safety provisions are adequate to protect the integrity of the calibration or test item.

5.8.3 Most items are cleaned with ethanol and wiped dry. In some cases there is thicker grease and mineral spirits is used. The basic process is the same for all gauges and is documented in "Preparations for Gage Block Comparison Measurements"; NBSIR 74-523; 1974.

5.8.4 Items are, in general, returned to the customer in the same shipping container in which it arrived. In cases where we feel the original packaging was inadequate, the original package will be put inside a large box with adequate packing material to protect the artifacts. If the original packaging needs to be replaced the customer is contacted for permission.

5.9 Quality Assurance Practices

The Semiconductor and Dimensional Metrology Division applies a wide variety of measurement assurance practices on a regular basis. These include:

- Statistical Process Control (SPC): Most SDMD calibrations that generate a statistically reliable amount of data are under SPC using check standards. These data are used both for control of the calibration process and determination of the long term reproducibility used uncertainty analysis (See Appendix I, Measurement Assurance).

- Check Standards: For processes that do not generate suitable data to warrant SPC, well characterized reference materials are used as checks.

- Interlaboratory Comparisons: SDMD participates in numerous interlaboratory comparisons on both national and international scales. The Group Leader in each technical area is responsible for keeping records of these comparisons and initiating appropriate actions if needed. Copies of intercomparison reports are kept by the Quality Manager.

5.10 Reporting Results

5.10.1 General

Report of Calibration, Report of Test, Report of Special Test, Certificate of Calibration, and all other variants are equivalent. All data reported to customers in a SP250 calibration must be a result of the SDMD Quality System and follow the process set down in the NIST QM and the SDMD QM.

In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the customer, the results may be reported in a simplified way.

Any information listed in Section 5.10 and Appendix E of this manual that is not reported to the client shall be readily available in the laboratory which carried out the tests and/or calibrations.

5.10.2 Test Reports and Calibration Certificates

SDMD requirements for calibration certificates are in Appendix E of this document.

5.10.3 Test Reports

SDMD does not currently perform any tests.

5.10.4 Calibration certificates

All results, unless requested by the customer, shall be reported corrected to the standard International Reference Temperature, 20 ºC. In cases where there is significant uncertainty in the coefficient of thermal expansion used to correct the results to this temperature the actual measurement temperature and assumed Coefficient of Thermal Expansion (CTE) shall be reported. This will allow the customer to revise the results if better thermal expansion information is obtained.

Calibration certificates shall not contain any recommendation on the calibration interval except where this has been agreed with the client.

5.10.5 Opinions and interpretations

SDMD does not include opinions or interpretations on calibration certificates.

5.10.6 Testing and calibration results obtained from contractors.

SDMD does not subcontract calibrations.

5.10.7 Electronic transmission of results.

The Group Leader or designate shall only sign one report, which is the copy sent to the customer. Reports with the original signatures shall be mailed to the customer. Copies of the report for the book, envelope, Calibration Program, or other purposes should be a xerographic copy of the original report.

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met and the transmission is approved by the Group Leader.

5.10.8 Format of reports and certificates

All calibration reports in SDMD shall conform to the Report Format in Appendix E unless there are legitimate reasons for the variation.

5.10.9 Amendments to calibration certificates

Material amendments to a measurement report after issue will be made only in the form of an amended or supplemental report.

Reissue of a measurement report to the customer for whom the work was performed is permitted if the requestor provides sufficient information as proof of identity (i.e. purchase order number, group control number, NIST Test Number, etc.).

Technical Requirements for SRMs

6.1 Introduction

The technical requirements included in SDMD QM-II apply across the Division. See NIST-QM-I for NIST-wide requirements.

Where replacement batches of reference materials are produced by applying the same procedures used for previous batches to similar starting materials which lead to final products with equivalent properties, appropriate verification assessments are required to ensure that uncertainty estimations obtained on previous batches remain applicable for the new batch; see 6.4.3 n).

6.2 Personnel

6.2.1 Competence

Each RM or SRM project will be led by an SRM Leader, appointed by the Group Leader in the subject area. The appointment is based on the SRM Leader's demonstrated competence in the field including education, training, technical knowledge and experience. The SRM Leader will be specifically authorized for the project and the authorization is documented by the Group Leader, with a copy sent to the Quality Manager. Only NIST personnel can be Authorized Staff. The Division will have on staff, or have regular advisory access to, a nationally or internationally recognized expert in the measurement service area.

6.2.2 Education and Training Goals

NIST's goal is described in NIST-QM-I. **Group Leaders** are responsible for achieving this goal in the context of measurement services.

6.2.3 For processes that are not in regular use, such as certifying restocked Reference Material inventory, the Group Leader will ensure that the staff meet the training requirements and provide retraining or re-verification in the needed skills as necessary.

6.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

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

6.2.6 Any technical staff working on the project will be authorized for their duties based on training or previous experience. Being authorized is required before a technical staff member may perform a measurement service without supervision. Any needed training shall be done by the SRM Leader or his designate. The training may be repeated as necessary until the SRM Leader is assured that the candidate fully understands the procedure. At his/her discretion, the SRM Leader or Group Leader may require an observation period, during which the candidate performs measurements under close observation by the **SRM Leader**. When fully satisfied, the Group Leader can add the candidate to the **List of Authorized Staff** that may perform the measurements in the appropriate area. Addition of authorized staff will be reported to the Quality Manager.

The **Group or SRM Leader**, at his/her discretion, may require that all or part of this training regime be repeated.

6.3 Collaborators

Collaborators (non-NIST laboratories and personnel) may support NIST in the development and certification of a reference material. Any such collaborator will be selected by the Division on the basis of technical excellence with regard to the measurement and materials required. Their collaboration will be carefully documented and appropriately referenced on applicable certificates.

6.3.1 SRM collaborators who part of the procedure for the production, including processing, homogeneity and stability testing, characterization, handling, storage or distribution of a reference material, the SRM Leader shall be able to demonstrate that the collaborator is competent to perform the concerned part of the procedure, and that the work carried out and/or the results produced are of the required quality.

The competence of a collaborator be evaluated from information on the collaborator's knowledge of the subject and details of past experience and make sure that experienced staff is available as well as appropriate accommodation and environmental conditions, instrumentation and measuring equipment as required.

NIST is solely responsible for value assignments in all measurement services. Because NIST retains this responsibility, the Division has complete discretion in defining the extent that collaborators must comply with this quality system and the informative references.

6.3.2 The evaluation of all collaborators shall be documented and kept by the SRM Leader.

6.3.3 If NIST facilities are not used for processing or measurement of the reference material the SRM Leader shall employ staff having knowledge to ensure that collaborator activities are executed in compliance with Guide 34 and ISO 17025, and evaluate the results of all collaborator activites.

6.3.4 The SRM Leader shall ensure that all details of the methodology, results and the descriptions of procedures of any collaborators are available. Suitable details of method shall be maintained by the SRM Leader to allow the technical evaluation of data.

6.4 Production Planning

6.4.1 The SRM Leader shall identify and plan those processes which directly affect the quality of reference material production and shall ensure that they are carried out in accordance with specified procedures. Where available, procedures given in technical standards for the production of specific reference materials shall be used.

6.4.2 Technical input of the different collaborators involved shall be identified and the necessary information documented and regularly reviewed.

6.4.3 In planning the production processes, the reference material producer shall have procedures and service facilities, for:

a) definitions of storage conditions;
b) material selection (including, where appropriate, sampling);
c) maintaining suitable environments for all aspects of production (6.6);
d) material processing (6.8);
e) measuring/testing (6.9, 6.10);
f) validation measurement methods (6.9);
g) verification and calibration of equipment (6.10)
h) assessing material homogeneity (6.13);
i) assessing material stability (6.14);
j) designing and organizing appropriate interlaboratory exercises for the purpose of assigning property values, if applicable (6.15);
k) assessing commutability (where appropriate);
l) Assigning property values based on the results of measurements; if applicable (6.16);
m) establishing uncertainty budgets and estimating uncertainties of the assigned property values, if applicable (6.16);
n) defining acceptance criteria for verifying that uncertainty estimates are applicable for replacement batches of reference materials produced under conditions described in 6.1;
o) establishing metrological traceability of the measurement result(s) (6.12);
p) issuing certificates and/or other documentation (6.17);
q) ensuring adequate storage facilities and conditions (6.7);
r) ensuring appropriate labeling and packaging of the samples meeting safety regulations (6.7);
s) ensuring appropriate transport arrangements which comply with shipping regulations (6.18);
t) ensuring post-certification stability monitoring, if applicable (6.14);
u) ensuring an adequate post-distribution service for reference material customers (6.18).

6.5 Production Control

The SRM Leader shall identify the verification procedures necessary to ensure the quality of each stage of reference material production, and shall assign adequate resources and personnel

for such activities. These **activities should include inspection, testing and monitoring of all stages of production**.

6.6 Accommodations and Environmental Conditions

6.6.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

Specific requirements and methods for achieving such conditions are detailed in the SRM Plan. If an SRM certification must be stopped because environmental conditions exceed the acceptable range described in the Plan, this event must be recorded in a laboratory notebook or other controlled document.

All measurement service labs shall have locked doors while the SRM is being prepared/measured, with access limited to Division staff, NIST police, and NIST Engineering Maintenance, and Support Services (EMSS) personnel. Access to NIST laboratories is limited to badged NIST employees, associates, contractors, and visitors that have checked in at the visitor center, have temporary badges, and have a NIST escort.

6.6.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.

6.7 Material Handling and Storage

Handling, storage, and shipping of SRMs requires skill and due diligence to assure the integrity of the SRMs. It is Division 683 policy that SRMs and candidate SRMs be carefully identified, separated, stored, and shipped to assure the integrity of the material with respect to its certified value and uncertainty.

The SRM Leader shall ensure that all NIST requirements for labeling, storing, and maintenance are followed.

6.8 Material Processing

The SRM Leader shall establish procedures to ensure that the item or material has undergone adequate processing for its intended use. Procedures for material preparation shall include, where appropriate:

a) Qualitative analysis for verification of material type and/or identity;
b) synthesis, purification (e.g. distillation, extraction), transformation into the final form (e.g. machining, grinding, blending, sieving and riffling extrusion, melting);
c) homogenization;
d) proper handling (e.g. protection from contamination and use of inert equipment);
e) measurements for processing control (e.g. particle size distribution, moisture content);
f) cleaning of sample containers;
g) stabilization of material (e.g. drying, irradiation, sterilization);
h) packaging (e.g. bottling, ampouling) of the batch.

6.9 Measurement Methods

6.9.1 SRM measurements, tests, or calibrations shall meet the requirements of ISO 17025, and are certified using appropriate, documented methods and procedures. Each method and procedure used is validated as being consistent with the accuracy required for use in the value-assignment of a given reference material.

6.9.2 New measurement methods are developed and validated by the technical staff, and such methods are thoroughly investigated, and clearly describe the necessary conditions and procedures for which the measurement of the property values of interest are valid at the level of accuracy commensurate with the intended use of the reference material. When available, certification is based on agreement of multiple independent methods of measurement. When method-dependent properties are certified, the method specific to certification and proper use is clearly indicated.

The procedures used to initially validate SRM certification are reviewed and approved by the relevant Group Leader. Services are validated on an ongoing basis by measurements of check standards, use of control charts or history files, or intramural comparisons. These procedures are described in the appropriate service-level quality manual.

Detailed descriptions of SRM certification methods and procedures, methods of validation, and measurement uncertainty, are documented in the SRM Plan. SRM customers receive a Certificate with each SRM that provides the certified values of the target measurand, an associated uncertainty, instructions for use, technical references, and an expiration date (if applicable).

6.9.3 Preparation, homogeneity, and stability assessment are specific to each reference material certified. The details of the Division processes for assuring the quality of homogeneity and stability measurements and procedures are documented in the SRM Plan documentation.

6.9.4 Estimation of Uncertainty

All reported NIST measurement results shall be accompanied by quantitative statements of uncertainty. To ensure that such statements are consistent with each other and with present international practice, NIST policy is to express measurement uncertainty using methods recommended by the International Committee for Weights and Measures (CIPM). This approach is described in Appendix C of the NIST-QM-I manual.

6.10 Measurement Equipment

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.

6.10.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).
Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

6.10.2 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure.

Table 6.1. Example generic equipment list

Item	Service critical?	Calibration required?	Required performance
Dual beam laser vibrometer	Y	Y	Alignment checked
Stroboscopic interferometer	Y	Y	% error should be < 1.00 % for the average of all the calibration measurements
Stylus profilometer	Y	Y	within ±0.5 % (the one sigma standard deviation of the step height) for the average of all the calibration measurements

Equipment in Table 6.1 that is critical to the measurement service requires additional documentation. This information shall be supplied in a second table in the SRM Plan (see Table 6.2) or can be kept on file with the location stated in the Plan. Ideally, each critical equipment item will have its own table kept as a running log as information changes. The entry date will allow one to determine the past configuration of the system if needed in the future. The required information includes:

- Identity,
- Manufacturer and model number,
- Unique identifier (NIST property number or manufacturer serial number),
- Critical performance or required uncertainty,
- Due date of next calibration (if required). Calibration certificates should be kept on file,
- Software name and version, and
- Date of table entry and reason for update.

Table 6.2. Stroboscopic Interferometer
(an example log for history table for this instrument)

manuf	model	NIST ID	Critical performance	Frequency of Calibration	Software	Entry date
Veeco	Wyko NT1100	628959 635776 A218734 A218735	% error should be < 1.00 % for the average of all the calibration measurements	Every data session	Vision v3.60	4/25/07 (Installed)
Veeco	Wyko NT1100	628959 635776 A218734 A218735	% error should be < 1.00 % for the average of all the calibration measurements	Every data session	Vision v3.60	8/26/08 (Upgraded)

6.10.3 For equipment that requires calibration, the calibration procedure and calibration intervals should be stated in the SRM Plan documentation. If a correction factor arises from the calibration, there must be a documented procedure to ensure that this value is properly updated in all locations. If a calibration factor is tied to a single instrument, the calibration factor should be included as a column in the critical equipment history table (Table 6.2).

6.10.4 Before placing any equipment into the measurement service, the equipment must be calibrated or checked to verify that it meets the performance specification required by the measurement service. The procedure and results of this performance check should be documented, and the results kept with the instrument document file). Measurement equipment, including hardware and software, shall be safeguarded from adjustments that would invalidate the measurement results, and any safeguards shall be described in the SRM Plan.

6.10.5 If intermediate checks are required to maintain confidence in the calibration status of equipment, the procedure for such check shall be described in the SRM Plan or associated documents.

6.10.6 Measurement service equipment shall not go outside the direct control of technical personnel without permission of the Group or Project Leader. If allowed to leave Division

control, the equipment must be checked and performance verified before it is placed back into service. Equipment that has been subject to mishandling or damage, or not operating within critical performance requirements, must be removed from service and clearly labeled “removed from service” until repaired and checked to verify that performance meets requirements.

6.11 Control of Software

6.11.1 The SRM Procedures shall ensure that calculations and data transfers are subject to appropriate checks, including those from its own sources.

6.11.2 The SRM project may require the development and use of software for measurement automation, data acquisition, data analysis, calculation of uncertainty, etc. Before placed into a measurement service, this software must be validated to ensure that it performs as required and provides accurate results. The SRM Plan should describe a validation procedure for portions of code that effect accuracy and uncertainty of measurement service results. Changes in software that could potentially affect accuracy and uncertainty must be validated using the proscribed procedure. Software changes should not be made without the knowledge of the SRM Leader.

Software changes must be tracked using a revision number and a brief description of the change. (See Table 6.3 for an example that does not require a new revision number for the software.) The method for validating, tracking, and authorizing software revision depends on the scope of the change as defined below.

1. Critical software changes. Critical changes include those that alter data analysis code or otherwise affect the accuracy and uncertainty of measurement service results. Such changes are expected to be permanent, in other words used for all future measurement procedures.

Critical software must be documented. The specific changes should be documented as required in the SRM Plan or by reference and approved by the SRM Leader.

2. Temporary software changes. Temporary changes are those needed temporarily for a specific measurement. Software revisions are documented in a file, notebook, etc. that is described (by name and location) in the SRM Plan.

The documentation should clearly state the measurement(s) affected by the change by listing the SRM serial number(s).

3. Non-critical software changes. Non-critical changes are those that do not affect measurement accuracy. Such changes might include modifications of output file names, data analysis sheet formats, etc. Non-critical software revisions are documented in a file, notebook, etc. that is described (by name) in the SRM Plan. It is recommended that a formal software revision, including approvals in item 1 above, be adopted when the number of non-critical software changes becomes significant.

Where possible the SRM Plan should define standard data sets that can be used to validate software that calculates values (calibration factors, certified values, measurands, uncertainties, etc.) from measurement data. Temporary changes that could potentially affect accuracy and uncertainty must be validated using the proscribed procedure.

When software is revised the earlier version shall be retained. Ideally, the version number of the software should be appended to the filename to simplify tracking.

Commercial software applications, for example compilers, programming languages, operating systems, etc., are assumed validated. However, the scripts or application used with this software may have unanticipated interactions. Thus, the performance and accuracy of lab-developed software should be validated when commercial packages that run this software are upgraded or changed. These changes should be documented in the software revision history.

Table 6.3. Revision history for MEMSCalculator.htm

filename	version	date	change
MEMSCalculator.htm	1.0	6/8/09	New format of web page to highlight the MEMS 5-in-1 activities
MEMSCalculator.htm	1.1	8/12/09	1. Replaced SRM User's Guide with revision 1 of this User's Guide 2. Added 5n1 symbol next to Data Sheet T.1 3. Updated the date at the bottom of the page

6.12 Metrological Traceability

6.12.1 Traceability is a property of the results of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. The NIST policy on traceability is made available in NIST-QM-I.

The Division requires traceability of the results of its own standards and of results and values provided to customers in NIST measurement services. Specific evidence of traceability is found in the SRM Plan documentation and other documents referenced therein.

6.12.2 The concept of "metrological traceability" applies to the measurement results for the assessment of homogeneity and stability as well as to the assignment of values as the result of the characterization process. The definition of reference material as "sufficiently homogeneous and stable with respect to one or more specified properties" inherently requires a clear definition of these properties. Metrological traceability of measurement results to the chosen reference shall be ensured to make relevant statements on the degree of homogeneity and stability.

6.12.3 For studies in which the absolute values are compared (e.g. characterization studies, stability studies with measurements under reproducibility conditions), it shall be ensured that
a) the measurand in the study is the same as the one for which the value is assigned (i.e. the chosen method is selective);
b) the calibration function for the measurement procedure is valid in the working range of the measurement results;
c) the measurement procedure has an appropriate limit of quantification;
d) the measurement procedure is sufficiently precise to make meaningful statements about the variation of the measurement results;
e) the measurement procedure is calibrated with standards traceable to the same reference as the assigned value (refer to Annex A for more information);
f) all other relevant input quantities have been appropriately calibrated.

6.12.4 To ensure the metrological traceability of the assigned values, the reference material producer shall provide documentary evidence that all measurement results used for value assignment are traceable to the same reference as the assigned value.

6.13 Assessment of homogeneity

6.13.1 Assessment of homogeneity is always required to establish that the degree of homogeneity of the reference material with respect to the property(ies) of interest is fit for purpose. The SRM Plan shall include a statistical plan for sub-sampling and measurement (including appropriate homogeneity assessment, and requirements for homogeneity and stability for the intended use. The provisions of ISO Guide 35 for homogeneity testing also apply for the production of non-certified reference materials.

6.13.2 Testing, calibration, measurement, sampling or other activities performed for the assessment of homogeneity shall be carried out in compliance with ISO/IEC 17025. Measurement procedures shall be selected so that the repeatability is fit for the purpose required. Although the measurement values do not have to be communicated to customers, the degree of homogeneity (e.g. expressed as maximum between bottle variation) shall be indicated in the documentation accompanying the reference material.

If the material is produced in several batches, it is necessary to test the equivalence of the batches (or to assign property values to each batch separately).

The assessment shall be performed after the material has been packaged in its final form unless stability studies indicate that storage should be maintained in bulk form. In some cases, intermediate homogeneity checks may be necessary (e.g. prior to bottling/ampouling).

6.13.3 The amount of tested material on which the homogeneity of the reference material has been established shall be specified in the documentation supplied by the reference material producer. This documentation shall also state the minimum sample size for use.

6.14 Assessment of stability

6.14.1 Assessment of stability is always required to establish that the degree of stability of the reference material is fit for purpose.

The definition of reference material as "sufficiently stable" inherently requires quantification or limits for degradation to demonstrate fitness for purpose. Therefore, the provisions of ISO Guide 35 for stability testing also apply for the production of non-certified reference materials.

6.14.2 The stability of the reference material shall be assessed. Testing, calibration, measurement, sampling and other activities performed for the assessment of stability shall be carried out in compliance with ISO/IEC 17025. Stability testing can be performed only if sufficient homogeneity is demonstrated. The stability studies shall be designed and performed in accordance to ISO Guide 35.

Stability testing is conducted by each Laboratory on units already in inventory for which deterioration is expected to occur. SDMD technical staff determines which SRMs will require stability testing in the following year and the amount of funding necessary to support the work.

The evaluation of measurement data as described in ISO Guide 35 covers only apparently stable materials. In case of detectable degradation, both the degradation and its uncertainty shall be included in the assessment.

The properties of interest of the candidate reference material shall be evaluated for the adopted storage conditions. Effects of, for example, light, moisture and temperature shall be evaluated in function of time for estimating a lifetime of the reference material and hence establishing a period of validity of the certificate.

The degree of stability shall be indicated in the documentation accompanying the reference material.

6.14.3 The stability of the material under transport conditions shall be assessed.

6.14.4 Where appropriate, an assessment of the stability of the reference material shall be performed at periodic intervals after characterization to confirm that all values are maintained from production until its expiry date. The reference material producer shall provide a period of validity of the certificate which is stated in the documentation accompanying the material. It shall be made clear on the documentation on which starting date the period of validity is based (e.g. the date of certification, the date of shipment of the reference material or the date of opening the packaging).

6.14.5 NIST shall inform the SRM office about shelf-life changes of the reference material including possible consequences for its use. The SRM office shall inform customers about the changes.

6.15 Characterization

For certified reference materials, the reference material producer shall use and document technically valid procedures to characterize its reference materials. The characterization shall comply with the requirements of ISO Guide 35 and ISO/IEC 17025 for testing, calibration and related activities.

6.15.1 There are several technically valid approaches to characterizing a reference material as described in ISO Guide 35. These include carrying out measurements using:

a) certification at NIST using a primary method with confirmation by other methods;
b) certification at NIST using two or more critically evaluated independent methods,;
c) certification or value assignment using one method at NIST;
d) different methods by outside collaborating laboratories.

6.15.2 Results obtained from proficiency testing can be used only if the competence of the laboratories involved has been checked and it has been ensured that the measurements done comply with ISO/IEC 17025.

6.15.3 The reference material producer **shall** never rely entirely on a statistical analysis of the characterization data when assessing the property values of interest. Outliers should not be excluded on statistical evidence until they have been thoroughly investigated and, where possible, the reasons for the discrepancies identified

6.16 Assignment of property values and their uncertainties

6.16.1 At the time of the proposal, the Laboratory's technical project leader of the SRM project has established an experimental design and certification plan for the SRM. The experimental design should include

(i) the required properties of the base material and SRM unit,
(ii) the statistical plan for sub-sampling and measurement,
(iii) the required scope of measurement data and limits of uncertainty, techniques, and methods to be used in the measurement process, and
(iv) the measures of traceability and verification.

The certification for non-chemical measurements requires certification or value assignment using at least one method at NIST. The certification plan includes either

(i) certification at NIST using a primary method with confirmation by other methods,
(ii) certification at NIST using two or more critically evaluated independent methods,
(iii) certification or value assignment using one method at NIST, or (iv) different methods by outside collaborating laboratories.

The certification plan should identify if SED will conduct the analysis of the data or if the Laboratory will do the analysis using verified SED procedures or software. It should also include the need and level of effort for stability testing. Laboratory and SED staff determines certified

values or reference values with their uncertainties, as well as information values. The Laboratory staff develops the draft certificate in consultation with SED staff, as appropriate, for submission to MSD.

The reference material producer shall never rely entirely on a statistical analysis of the characterization data when assessing the property values of interest. Outliers should not be excluded on statistical evidence until they have been thoroughly investigated and, where possible, the reasons for the discrepancies identified. Alternatively, the uses of robust statistics may be appropriate in some cases.

In assigning the property values of interest, the reference material producer shall consider establishing a group of independent experts whose responsibility is to check that all work, data and documents are fit for their purpose.

6.16.2 An important aspect of establishing the property values of the reference material being produced is an assessment of their uncertainties. The reference material producer shall carry out an assessment of the measurement uncertainties to be included in the assignment of property values in accordance with the requirements of the GUM (JCGM 100). In the process of estimating uncertainties of the property values of interest, any uncertainties resulting from between-unit variations and/or from possible doubts on stability (both during storage and during transportation) shall be assessed in accordance with ISO Guide 35 and shall be included in the assigned uncertainty.

A statement of the measurement uncertainty is mandatory for certified values.

For Reference Materials the process of estimating uncertainties of the property values of interest, any uncertainties resulting from between-unit variations and/or from possible doubts on stability (both during storage and during transportation) shall be assessed in accordance with ISO Guide 35 and shall be included in the assigned uncertainty.

6.17 Certificates of documentation for users

6.17.1 Certificates for Standard Reference Materials

A Certificate accompanies SRMs in which assigned values and their associated uncertainties are provided. Guidelines in the “Guide to NIST Development and Production” shall be followed.

6.17.2 Signatory Authority

Division Chiefs, or their designees, sign reports of calibration and test, and reference material Certificates and Certificates of Analysis in the name of the NIST Director.

6.18 Distribution Service

The SRM office fulfills these requirements, and SDMD has no significant duties.

Appendix A: Establishment of NIST Calibration Service

Approved by Measurement Services Advisory Group
January 29, 2002

Establishment of NIST Calibration Services

The decision to provide a new NIST calibration service requires a careful assessment of the role the service will play for NIST's customers. The following policy documents the procedures and roles and responsibilities in reaching that decision. This policy applies to Regular Calibration Tests (as listed in SP250), Special Tests, and Measurement Assurance Programs. In this policy, the phrase "calibration service" refers to all three types of service.

A Laboratory proposing to establish a new NIST calibration service will inform the NIST Measurement Services Advisory Group (MSAG) of the intended new service. The Laboratory should do this early in the process of developing the new service. This will ensure that the proposed service does not conflict with existing or planned measurement services of other Laboratories.

It is the responsibility of the individual Laboratories to ensure that the new calibration service is in compliance with the NIST System for Assuring Quality in the Results of Measurements Delivered to Customers in Calibration and Measurement Certificates.

Appendix B: Training

B.1 General Criteria

It is the responsibility of the Group Leader to design and assure the implementation of a training program for each group member which includes all technical and administrative policies and procedures needed to do his or her assigned duties. The Group Leader may designate this task to a senior staff member.

Development of the training program should begin with an examination of the person's previous educational and work experiences. A program is prepared for approval of the Group Leader, generally in the form of a checklist of the assigned tasks, technical and quality procedures and standards relevant to assigned duties. The breakdown should be detailed enough that the Group Leader could examine progress on at least a weekly basis.

The training program may consist of reading relevant literature and documentation, external training, and on-the-job under the supervision of a qualified trainer. A demonstration of capability in the intended area of qualification must be included in every training plan.

The training plan should be detailed enough to assure that the candidate can, when qualified, perform the assigned duties with little or no reference to written procedures.

Employees are encouraged to maintain their technical competency by attending training courses and conferences and participating in professional organizations. There are no firm criteria on the frequency of these professional activities, but consistent neglect in this area is harmful to good professional practice. Presentation of research findings at meetings or professional organizations is encouraged, as is committee work and serving as an officer of such groups.

B.2 Scope of Training

Personnel must be qualified for an activity under the following circumstances:

- personnel have not been trained in the activity before;
- proficiency requirements for the activity are not being met;
- new techniques or instruments have been implemented which demand new skills;

B.3 Training Process

1. Group Leader or designate develops a training program that includes all procedures, policies, standards and skills needed for the activity. A sample training plan is shown in section B.4.

2. The Group Leader approves the plan and appoints a qualified trainer who is responsible for the detailed implementation of the plan. This responsibility includes monitoring the progress and signing off on the plan tasks as they are performed in an

adequate manner. The trainer will also design a proficiency test for each assigned task and assure that the analysis of the test results is adequate and fair.

3. The trainer will report on the progress of the training program to the Group Leader on a regular basis, typically once a week. Once the training plan is completed the Group Leader will review the documentation, including any performance tests results. The Group Leader will then either sign that the qualification criteria have been met, or in the case of deficiency further training will be assigned.

B.4 Example Training Plan

Name: _____

Scope of Qualification: Skills and procedures needed for gage block calibrations

Previous Experience and Training:

		Approved	Date
Reading:	Chapter 1-3, Dimensional Metrology by Ted Busch	_____	_____
	Chapter 1-4, Gage Book Handbook	_____	_____
	ANSI/ASME B89.1.9, Gage Blocks	_____	_____

Skill or Procedure	Approved	Date
1. Login Procedure	_____	_____
2. Unpacking and inspection	_____	_____
3. Cleaning and setup	_____	_____
4. Gage Block software - setup procedure	_____	_____
5. Calibration of Gage Blocks by Mechanical Comparison	_____	_____
6. Gage Block process control procedures	_____	_____
7. Gage Block history program and analysis	_____	_____
8. Calibration report procedure	_____	_____
9. Filling out folder and final signoff procedure	_____	_____
10. Preparations for shipping gages	_____	_____
11. Shipping and logout procedure	_____	_____
12. Calibration of known gages - test phase	_____	_____
13. Complete calibration cycle performance evaluation	_____	_____

Final Approval: _____ Date: _____

Authorization: _____ Date: _____

Appendix C: Technical Procedures

Technical procedures are designed for the expertise and experience level typical of the staff of a National Measurement Institute. Staff receive 1-on-1 training from recognized experts in the field, and are not allowed to perform unsupervised until they have demonstrated, by consistent performance, their competence in the procedure. This performance is generally judged by comparisons to the results from established staff on the same or similar (in the case of destructive measurements) units.

Besides assuring the competence of each staff member by actual performance, the level of expertise that results allow us to have relatively high level documentation of the methods used and their validation and implementation. A technician who needs a step by step procedure for calibrations does not meet the requirements for authorization (see Appendix B.1).

The level of detail is up to each SDMD Group Leader to decide what level of documentation is required, balancing the difficulty of the calibration, the experience of the assigned staff, and availability of staff to train new technical staff.

At a minimum, each measurement method is documented in a published document which gives a description of the method, the steps to establish traceability path, and a complete discussion of measurement uncertainty. The adequacy of these documents will be reviewed as part of the SDMD Internal Assessment.

Appendix D – Corrective Action Form

Date Initiated	
Person Responsible	
Description and Extent of Problem	
Cause Analysis	
Suggested resolution	
Verification tests	
Suggested Further Action	
Date Resolved	
Authorized by:	

Number of Attached Sheets: _____

Appendix E: Format of Reports or Certificates Sent to Calibration Customers

E.1 Paper Type

The front page of the report is to be printed on paper with the standard NIST letterhead and each additional page printed on similar paper without the letterhead.

E.2 Type Style

All reports are to be typed using Times New Roman or Courier. The character size is restricted to a minimum of 10 pt. Margins may be reduced, but standard one-inch margins are desirable. Additionally, the body of the report may be full justified, but this is not required.

E.3 Report Title

The title, Report of Calibration or Report of Test, will be centered at the top of the first page, bold, capitalized, enlarged font size, and located following the letterhead. Alternate titles may be used at the request of the customer.

E.4 Report Number:

"NIST Test No. 683/######-YY," centered, bold, and located on the second line down from the title. This same information will also be located on each additional page in the upper left corner, but will not be in bold print.

There are cases where there is more than one report generated from the same folder. In this case the ID of the gage or set of gages will be placed on a separate line below the "NIST Test No…."

E.5 Customer Identification

"For:" will be left justified on the second line down from report number. The information will identify the customer for whom the calibration or test is being performed.

E.6 Item Description

"Item:" will be left justified on the second line down from the customer identification. The information following the standard heading for this section will describe in detail the artifact being measured. Examples include, nominal size, material, set serial number or item serial number, model number and manufacturer if appropriate, and *NIST/NBS Artifact Number, if applicable.

*NIST/NBS Artifact Numbers are used for such things API Gages (for identification purposes and signifies that gage meets relevant API specifications), line scales (for identification purposes only), and tapes (for identification purposes only).

The item description with identification number will be on all additional pages. This information will be located immediately below the NIST Test Number or Internal Control Number.

E.7 Report Body

The text of the report body is to begin on the second line down from the last line of the item description.

The body of the report must include the following:

- **Calibration/Measurement Process Description**
  The Calibration Report will describe the measurement procedure in enough detail that a knowledgeable metrologist could repeat the measurement or refer to an available document that satisfies this requirement.

- **Critical Interpretation and Usage Information**
  This is information that the user must have to understand the measurement results or uncertainty. The information must be detailed enough so that the user understands how to correctly use the measurement result. Examples include graphical representations identifying the measurement positions and recorded environmental conditions. This information will also include an explanation of any deviations from the standard technical procedure.

- All results, unless otherwise requested by the customer, shall be reported corrected to the standard International Reference Temperature, 20 ºC. In cases where there is uncertainty in the coefficient of thermal expansion used to correct the results to this temperature the actual measurement temperature and assumed coefficient of thermal expansion shall be reported. This will allow the customer to revise the results if better thermal expansion information is obtained.

- If statements of compliance/non-compliance to a standard are made, the standard will be identified. If all of the clauses of the standard are not tested, the clauses that were tested shall be identified. Uncertainty shall be used in compliance decisions as specified in the relevant standard.

- **Uncertainty Paragraph**
  This will include a statement that all uncertainties are calculated according to NIST Technical Note 1297 and that all stated uncertainties are based on coverage factor of k=2.

- **Reference Document Availability Statement**
  If appropriate there will be a statement informing the customer that the NIST Documents referenced in this report are available upon request.

- **Reproduction Statement**

All reports will include the following statement, "This report shall not be reproduced except in full without the written approval of the [Group Name]."

E.8 Measurement Personnel Identification

This section will appear on the second line below the last sentence of the report body.

"Measurements were made by _____."
Typed Name of Person [*Phone No. - Optional]

* This phone number should be either the group office phone or the general laboratory number.

E.9 Report Approval Section

E.9.1 Format

This information should be aligned on the left and indented from the left margin to the point where the end of the longest line is approximately one space from the right margin. The space allocated for the authorizing signature may be reduced but four lines for the signature is desirable.

"For the Director,
National Institute of Standards and Technology

Group Leader's Signature or Acting Group Leader's Signature in the case of the Group Leader's Absence (The Acting Group Leader signs their name followed by "for [Group Leader's Initials]")

Mr./Mrs./Ms./Dr. Group Leader's Name, Group Leader
Group Name
Division Name
Laboratory Name"

E.9.2 Approval Requirements

The Division Chief and Group Leaders are authorized to sign calibration and special test reports for the Director (Refer to NIST Administrative Manual, Section 5.20.04 DELEGATION OF AUTHORITY).

All calibration reports are to be reviewed and signed by the Group Leader who is responsible for the specific calibration service. In the case of the Group Leader's absence, the Acting Group Leader will be responsible for reviewing and signing of reports.

E.10 Additional information

The information in this section will be flush with the left margin and located on next line or on the second line down from the laboratory name in the previous section.

- Purchase Order No.
- Date: Month Day, Year (No abbreviations)

E.11 Page Numbering

"1 of n, 2 of n," must be on all pages including the front page.

E.12 Data

Following the body of the report, all data is to be presented in table form or column form. If measurements for more than one item will be presented in the report, each measurement will be identified by the nominal size and item identification number. Other information found in the data table may include values for material properties that were used in corrections, measurement temperature if appropriate, and other environmental readings, if applicable.

Data will be reported according to NIST Special Publication 811 "Guide for the Use of the International System of Units (SI).

E.13 Report Amendments

E.13.1 Format

Amended Reports must follow the requirements listed in Section E.0 and must be identified by "AMENDED Month Day, Year (No abbreviations)." This will be located immediately following the Report Title, bold, and centered. This will also appear following the NIST Test No. on each subsequent page.

E.13.2 Amendment Identification

A description of the Amendment must appear on the report. This can be as simple as correcting a typographical error in the data table, identifying it with an "*," then defining the meaning of the "*" at the end of the data table.

E.13.3 Review and Signature

All amended reports must be reviewed and signed by the Group Leader or Acting Group Leader.

Appendix F: Calibration Narrative for Standard Calibrations

This narrative describes the nominal process for handling outside calibrations in SDMD. It is not strictly a procedure that is followed exactly each time because of the many creative ways that customers choose to interact with our calibration service. It is the responsibility of each technician to see that the necessary steps are taken, in whatever order is needed, to produce the calibration and quality records required by the quality system.

Changes to this process for Special Tests are given at the end of this appendix.

(F1) Requests for Information - Customer contacts NIST: email, phone, mail, FAX, or visit.

(F2) Estimates Provided

NIST provides Customer information requested and explores customer's need. Calibration staff provides cost and time estimates for calibration. If the cost is not the standard price in the SP-250, the person giving the quotation shall document the details in the SDMD Quote Log on the EMG Toolbox web site. Each staff member is responsible for keeping the log accurate and up to date. The information recorded:

Date
Staff Member giving quote
Company and company representative names
Brief description of work

(F3) Purchase Order Prepared

Customer prepares purchase order using information provided in (2). Or customer may prepare purchase order using NIST SP-250 or prior experience without requesting specific information (1).

(F4) Purchase Order Received

Purchase order is usually sent directly to Division, but on occasion they are sent to the Calibration Program Group. In either case, the PO is given to the appropriate staff member to be logged in. If there is a question of who is the proper staff member for a calibration the Quality Manager should be consulted.

(F5) Purchase Order Logged In

The staff member assigned to the calibration prepares the Incoming Calibration Information Sheet as completely as possible. The artifacts are treated as in step 8 below. The calibration is logged in:

a. Incoming Calibration Information Sheet is filled out as completely as possible and given to the Database Administrator. Sheet, P.O., packing slip, and any other documents that might have relevant information, like contact names or shipping information, are given to the CSS Division Administrator.

b. In the case of multiple calibrations on the same order, the customer information should be put on the form and copies made for each staff member who has a calibration in the order. They should be marked as "page 1 or 3" etc, so the Database administrator can keep track of the order. Each staff member should fill out the cost and estimated completion date, as well as any other needed information for their calibration, and return the form to the Database Administrator.

c. For orders with multiple kinds of calibrations, the Administrator checks the estimated calibration date against the table of typical turnaround times prepared by the Quality Manager.

d. PO and forms are sent to the Calibration Program Group.

e. Order is entered into CSS Database, a proforma is generated and sent to customer. When the signed proforma is returned, the order is assigned a NIST Test Number.

f. Calibration Program Group generates test folder and sends it back to SDMD and the NIST-64 acceptance and fee sheets are printed out.

g. The test folder containing the NIST 64's are distributed to the technical staff. All relevant material, such as drawings, notes, worksheets, etc. should be kept with the calibration folder.

If the folder information is not correct, the staff member works with the CSS coordinator until it is correct and approved.

(F6) Acceptance Copy Sent - The group staff member involved sends the NIST-64 Acceptance to customer.

(F7) Artifacts Received

Customer artifacts to be calibrated are received in Shipping and Receiving and delivered to Division. They may come in several packages spread over time. All packages must be examined the day they arrive to confirm their identity and destination. Boxes are often sent to the attention of the wrong staff member, and even the wrong division.

(F8) Artifacts Unpacked

The boxes may be brought to the shipping room (or lab) by any staff member, or taken directly to the staff member responsible for the calibration. Artifacts are unpacked and separated from packing material in one of the shipping areas (or lab). Artifacts are tagged with customer information. Any customer provided handling instructions shall be followed. . Once in the shipping room the box and artifact are labeled. If artifacts are shipped in special packing case or packing material is reusable, packing material is tagged and stored for return shipment. Tagging includes customer name, type of artifact, and date. The artifact is then delivered to the appropriate staff member.

Any paperwork sent with the order is used to log in the calibration with the process giving in step F5. The paperwork is then placed in the test folder wants received and is given to the responsible staff member or put in their mailbox.

(F9) Artifacts Inspected

Artifacts to be calibrated are inspected for damage and prepared for calibration. If artifacts are damaged, photographs are taken for documentation and customer is notified. Documentation is placed in the calibration folder.

(F10) Artifacts Stored

If the items must be stored, they will be held in a secure area with suitable environmental conditions. Any precautions needed to protect the condition and integrity of the items shall be taken

(F11) Artifacts Calibrated

Artifacts are calibrated either manually, automatically, or a combination of the two. Calibration may be extensive or minimal depending on equipment and number of test points. Calibrations may be done over a number of days to assure accuracy. After calibration, equipment may be temporarily stored while data is analyzed and reports generated.

All available data are analyzed. Data analysis may be made manually or by computer. If results are not consistent with expectations, calibration is repeated. Calibration data, if available, compared to historical data on artifacts. If there are any indications of discrepant results the appropriate Group Leader is notified, and the incident is investigated as required by section 4.9 of the SDMD Quality Manual (Nonconforming Work).

(F12) Report Prepared

The Report of Calibration is prepared. The report is prepared using the SDMD Report Format, Appendix E of the SDMD Quality Manual.

(F13) Test Folder Complete

All data and other documentation collected and assembled in the test folder.

(F14) Overall Review by Tester

Technical person(s) who conducted the tests reviews all information in Test Folder for completeness, accuracy, calibration results, and conclusions.

(F15) Supervisory Review

Folder reviewed by Group Leader or designated senior staff member.

(F16) Fee Calculated

Technical staff reviews fees from SP-250 for listed tests and calculates fees for special tests. Completes NIST-64 Fee Record (Parts 2 and 3) and returns them to the test folder.

(F17) Approval by Group Leader

Group Leader reviews test results, fees, etc., and signs Report of Calibration (or Report of Test) as final approving authority as designated by NIST Director. The Group Leader will designate a staff member to sign reports in their absence.

(F18) Test Folder Logged Out

Test Folder is logged out in CSS Database with date of completion.

(F19) Test Results to Customer

Approved calibration report original is sent to customer.

(F20) Test Folder Returned to Calibration Program Group

Completed Test Folder is returned to the Measurement Services Division.

(F21) Fee Record Transmitted

Administrator enters the fee record (NIST-64, Part 3) into the CSS Database for the Accounting Department and PML Administrative Office.

(F22) Documentation Filed

All information is placed in an envelope; the envelope is marked with the NIST Test Number, M-number, Customer Name, and Date. Information includes:

Copy of Calibration Report
Incoming Calibration Information Sheet
Calibration procedure and verification data for Special Tests.
Calibration worksheets, data, and sufficient information to facilitate, if possible, identification offactors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.

Electronic records can be put in the envelope on a disc, CD or thumb drive. Records can also be stored on the CSS Database. The envelopes are kept by each group in the group office, or by the staff member.

A second copy of the calibration report is filed in the report binders. The current binders are in the Dimensional Metrology Group Office, and the binders for older records are kept in another group members office. Reports are scanned and stored on a division computer

(F23) Preparations for Shipment

Artifacts are taken out of storage and readied for shipment and Shipping Record (NIST-64, part 5) is prepared. Artifacts are shipped after there is no doubt that artifacts do not have to be recalibrated or additional data taken.

Artifacts are packaged using original packing material or new packing material provided.

(F24) Artifacts Shipped

Packing Slip (NIST-64, part 4), is prepared and equipment shipped to customer "COLLECT." (If not return shipping information is provided by the customer a flat shipping charge is added to the calibration fee).

Special Tests

Special tests are the result of customer requests for non-routine calibrations or measurements. Since these measurements, by their very nature, do not have verified procedures and uncertainty budgets, special precautions are needed to assure that the requirements of ISO 17025 are satisfied.

- When a special test is proposed, the information is brought to the appropriate Group Leader for consultation.

- If customer provides drawings or other reference material, the material labeled if needed, and is kept together until the customer decides whether or not to proceed with the calibration. The material is filed with the calibration or returned to the customer as appropriate.

- Once there is assurance that there are adequate resources, an acceptable procedure, a preliminary cost estimate, and a rough estimate of uncertainty, the job is assigned to a staff member. The assigned staff member writes a quotation, enters it in the Quote Log, and communicates it to the customer. If the customer agrees to the quoted estimates, the Calibration Narrative is entered at step 4.

Appendix G – Reference and Standard Reference Materials

a. For RMs and SRMs, MSD's Lab Partners Website (http://msd-i.nist.gov/labpartners/) can be visited for pertinent information, forms, and links. The "Guide to NIST SRM Development and Production" downloadable from this website is a good place to start. Also accessible from this website is the "SRM Project Tracking System" which requires login permission. This system is used to record or monitor the progress of each project. An SP 260 (although not required) is typically written for each RM or SRM. This document contains most, if not all the information requested of the Report of Analysis specified in Appendix A of the "Guide to NIST SRM Development and Production."

Appendix H – List of Records and Controlled Documents

Controlled Documents are defined as "*4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue.*"

Controlled Documents	Where Held	Approval	Revision-Date
SDMD Quality Manual	Ted Doiron, QM	Dave Seiler, DC	7 -
Techncial Procedures	Group Leader	Group Leader	
Short Gage Blocks by Comparison	Ted Doiron	Ted Doiron, GL	001 – 2/25/2014
683.03-SOP.V.CA	John Kramar	Group Leader	001 – 2/26/2014
683.03-SOP.V.CC	John Kramar	Group Leader	001 – 2/26/2014
683.03-SOP.V.FC	John Kramar	John Kramar	001 – 2/26/2014
683.03-SOP.V.FD	John Kramar	John Kramar	001 – 2/26/2014
683.03-CMP-MPR-COMP	John Kramar	John Kramar	01 – 2/26/2014
683.03-CMP-MPR-RECIP	John Kramar	John Kramar	01 – 2/26-2014
683.03-CMP-SPL-CAL	John Kramar	John Kramar	01 – 2/26/2014
Step Height Calibration - Talystep	Group Leader	Group Leader	2.2 – 6/6/2013
Step Height Calibrataion – Form Talysurf	Group Leader	Group Leader	2.2 – 6/6/2013
Roughness Calibration	Group Leader	Group Leader	2.2 – 6/6/2013

Records

Corrective Actions	Quality Manager in Quality Event Log
customer complaints	Quality Manager in Quality Event Log
Internal Audit Reports	Quality Manager
Personnel Training and Competency (matrix)	Quality Manager
Management Review Minutes	Quality Manager
Reference Material Project Leader List	Quality Manager
Standard Administrative Procedures (SAPs);	Administrative Manual
Laboratory Log	CSS database

Equipment Documents

Statistical Process Control Charts.	Kept by engineer responsible for calibration
Maintenance (Standards and Equipment)	Kept in Equipment Folder
Equipment Manuals.	Kept with equipment or in Equipment Folder
Primary Standards Calibration Reports	Kept in Equipment Folder
Service Reports	Kept in Equipment Folder
Environmental Conditions/Deviations	Log in each Lab as appropriate

Customer Calibration Documents

Customer Purchase Orders & Amendments	Envelope (or equivalent)
Customer specifications/Drawings,	Envelope (or equivalent)
Contract Review Records	Envelope (or equivalent)
Order Acknowledgements	Envelope (or equivalent)
Original Calibration/Test Data	Envelope (or equivalent)
Laboratory Log	CSS database

Standard Administrative Procedures (SAPs)	Administrative Manual

Equipment Documents

Statistical Process Control Charts.	Kept by engineer responsible for calibration
Maintenance (Standards and Equipment)	Kept in Equipment Folder
Equipment Manuals.	Kept with equipment or in Equipment Folder
Primary Standards Calibration Reports	Kept in Equipment Folder
Service Reports	Kept in Equipment Folder
Environmental Conditions/Deviations	Log in each Lab as appropriate

Customer Calibration Documents

Customer Purchase Orders & Amendments	Envelope (or equivalent)
Customer specifications/Drawings,	Envelope (or equivalent)
Contract Review Records	Envelope (or equivalent)
Order Acknowledgements	Envelope (or equivalent)

Original Calibration/Test Data	Envelope (or equivalent) when available
Calibration and Test Reports	Binders in Office, NIST Folder
Supplements to Calibration and Test Reports	Binders in Office
Reference Material records	Reference Material Project Leader
Shipping Records	Envelope (or equivalent)
Software Verification Records	Kept by programmer
Assessment of Uncertainties	Procedure in Quality Manual
Process Measurement Assurance	Kept by engineer responsible for calibration
Statistical Process Control Data	Kept by engineer responsible for calibration
interlaboratory test data/analysis	GL and copy to Quality Manager
Deviations from Accepted Procedure	Envelope (or equivalent)
Table of Typical Turnaround Times	Kept by ISSC Database Administrator

References

Standards	Primary copy in Secretaries Office
Other Normative Documents	Primary copy in Secretaries Office
Regulations	Primary copy in Secretaries Office when available
Calibration and Test Reports	Binders in Office, NIST Folder
Supplements to Calibration and Test Reports	Binders in Office or scanned to QM Computer
Reference Material records	Reference Material Project Leader
Shipping Records	Envelope (or equivalent)

Appendix I: Measurement Assurance

A key element in most SDMD calibrations is the use of check standards to monitor the short and long term performance of calibration processes. Nearly all of the systems employ either a check standard in each measurement or periodic use of a specific standard. The Gauge Block Handbook (Doiron) and paper on the Linescale Interferometer (Beers), in the Bibliography, are the best references for these types of systems.

There are also a number of calibrations that generate statistical measures of consistency without the use of check standards. Roundness and many angle calibrations use closure techniques, which result in measures that are used as check standards. The 12 position roundness calibrations and reversal measures used in roundness and two dimensional artifact calibrations generate a characteristic of the machine (roundness and squareness, respectively) used in the calibration to match against history.

Check standards are chosen so that changes in any influence quantity (temperature, pressure, humidity, etc.) are directly monitored as changes in the value of the check standard. For example, the two master gauge blocks in each size are different materials, steel and chrome carbide. Even though the master block used for each material is the like material, canceling out most of the effects of temperature change, the relative lengths of the two masters is used as a check standard. In this case, the response of the check standard is an order of magnitude larger than the actual effect on the customer measurement.

Similarly, if the measurement system temperature drifts, and the temperature is an influence quantity, the drift will be seen as a repeatability problem. All of our measurements are made with multiply-redundant measurement schemes which include provisions for the elimination of linear drift. Failure of the measurement scheme to correct for environmental change will cause the repeatability of the measurement to increase, and thus fail the statistical tests.

Finally, nearly all recalibrations of gauges are compared to their history. This gives a final assurance of the system stability. There are a few calibrations for which the artifacts have been studied and found to have very high long term stability, such as optical flats and angle blocks, that the history checks are much more frequent than any reasonable recalibration schedule.

Any suspicious behavior of the check standards, consistency checks, or anomalies with the know history of calibrations is examined. Generally, this consists of a re-test, and if the re-test fails the system is recalibrated. If any changes of significance are found, the Nonconforming Product process (section 4.9) is followed.

Because of these monitoring systems, we do not have many calibrations that are set on a definite schedule. The check standard data is analyzed on a regular basis, usually annually, to update the process parameters. This analysis includes checking for secular stability. Any suspicious behavior is cause to recalibrate the affected master gauges. There is also a longer-term cycle, in that all master gauges are recalibrated inside of a 3 to 5 year interval.

Records:

Each group is responsible for keeping records of their measurement assurance program analyses, master artifact calibrations, trend analyses, and any anomalous behavior investigated.

Appendix J: Traceability and Measurement Assurance for SDMD SP 250 Calibrations

	Method		Measurement Assurance		
Calibration	Direct Comparison	Calibrated Instrument	Check Standards	Closure	Calibrate on Use
Gauge Block - Mechanical Comparisons	Yes		yes		
Gauge Block Interferometry		yes	yes		
Line Scale Calibrations		yes	yes		
Special Tests of Sieves		yes			Yes
Plug and Pin Gages by comparison	Yes		yes		
Cylindrical Diameter - absolute		yes	yes		
Measuring Single Wire	Yes		yes		
Diameter of Sphere - Mechanical Comparison	Yes		yes		
Sphere diameter - Interferometry		yes			
Plain Ring Gages, per ring	Yes		yes		
API		yes			Yes
Optical Reference Planes (Flats), by comparison	Yes				
Roundness: 12 Trace Method		yes		yes	yes
Roundness: Single Traces of 3 Diameters		yes			Yes
Angle Gage Blocks by comparison	Yes		yes		
Angle Block by closure		yes		yes	
Rotary and Indexing Tables:		yes		yes	
Optical Wedges: Fixed-–Angle Wedge		yes		yes	
Laser Frequency/Wavelength	yes				
Laser Full Calibration	yes				
Surface Finish		yes			Yes
Step Height	yes				Yes
Tapes		yes			
Leveling Rods		yes			
TwoDimensional Gauges		Yes		yes	

Appendix Y: Bibliography

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Appendix Z: Year Revision History

Revision Number	Date	Authorized	Changes
2	6/7/04	D. Swyt	Revision for Assessment Findings. Changes detailed in Assessment Summary filed in Quality Event System. Changes, other than typographical changes, are highlighted.
3	7/23/05	D. Swyt	Additions for procedures and policies of SRMs generated by SDMD for the NIST Standard Reference Program.
4	9/27/07	M. Postek	Addition of language about use of MRA Appendix C entries during the contract review stage of calibrations. Restricts Group Leader signatures to the customer copy of reports. Changes internal audit and management review schedule to reduce redundancy with quarterly MSAG reports.
5.0	5/29/2009	M. Postek	Changes required to satisfy the findings of the NIST assessment of the SDMD quality system. Changes primarily to criteria for written procedures, changes in the ILAC policy on best measurement capability, and schedules for internal audit and management review.
6	10/1/2010	Seiler	Changes to address the 2011 reorganization.
7.1	9/21/2014	Seiler	Interim changes from internal audit
7.2	3/31/2014	Seiler	Changes to address the findings of the 2014 NIST assessment are highlighted in yellow.