NIST Quality Manual for Measurement Services

QM-I

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1. Introduction

1.1 Institutional Commitment to Quality

The provision of measurement services, which include ***calibrations*** and ***certified reference material*** related services, is an essential element of the work of the National Institute of Standards and Technology (NIST) in fulfillment of its mission. In the conduct of this vital work, as in all its efforts, NIST is committed to performance excellence characteristic of a global leader in measurements and standards. Our goal is to provide measurement services that 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.

Achievement of this goal has been a hallmark of NIST (known as the National Bureau of Standards prior to 1988) for over a century. It has always resulted from, and continues to rely on, the excellence and commitment of NIST staff at every level of the Institute. The NIST Quality Management System (NIST QMS) comprises policies and procedures that NIST follows in the pursuit of performance excellence. They are documented in the NIST Quality Manual (NIST QM). All staff members whose activities affect the quality of our ***measurement services*** are to be familiar with the NIST QMS described herein, and to implement it in their work. NIST commits that its QMS 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***® (***SRMs***®) and related services that NIST delivers.

Signed: _____, Date 30 July 2010

Dr. Patrick D. Gallagher,
Director
National Institute of Standards and Technology

1.2 Scope

The quality management system described in this manual covers measurement (calibration and reference material) services provided to customers both internal and external to NIST. These services are essential to achieving NIST's goal to deliver high levels of satisfaction and value to its customers in academia, other government organizations, and established and emerging industries where NIST's ***measurements*** and standards can increase productivity, lower market transaction costs, raise product and process quality, and reduce technical barriers to trade.

In general, the scope of the NIST quality management system for ***measurement services*** encompasses all services listed in the ***NIST Special Publication (SP) 250, NIST Calibration Services Users Guide*** and the ***NIST Special Publication (SP) 260, Standard Reference Materials Catalog***. In particular, specific services covered by the NIST QMS are those that are declared in conformity by the ***NIST Measurement Services Advisory Group (MSAG)***. For the purposes of this document, the term "reference material" refers to the entire category of NIST SRM services such as ***Standard Reference***

Materials, Reference Materials, etc. See **Definitions, Section 3** of this document for a listing of terms shown in bold italics and their respective official NIST designations.

By implication, the scope of the NIST QMS for Measurement Services includes the ***Calibration and Measurement Capabilities (CMCs)*** listed in Appendix C of the ***Comité International des Poids et Measures Mutual Recognition Arrangement (CIPM MRA)*** [http://www1.bipm.org/en/convention/mra/].

1.3 Format of NIST Quality Manual for Measurement Services

The NIST QM for Measurement Services is organized in multiple levels:

- The first level, this document (NIST-QM-I), contains NIST-wide policies and procedures stemming (primarily) from the executive leadership of NIST (i.e., the NIST Director and Laboratory Directors). Many of these policies and procedures govern all activities at NIST and thereby are controlling in so far as these activities are part of providing ***measurement services***.

- The subsequent levels also known as ***sub-level quality documentation*** (including the NIST-QM-xx series) contain policies and procedures established and maintained by each Division (or Technical Operating Unit) to meet its technical needs. The sub-level quality management systems and quality manuals vary in detail among the NIST Divisions that provide ***measurement services*** within the scope of the NIST QMS. The NIST-QM-xx series explicitly references NIST-QM-I and contains the quality-specific policies and procedures for activities such as acceptance of requests for ***measurement services***; acquisition of materials and supporting services; technical procedures for ***calibrations***; ***reference material*** certification ***measurements***; staff qualifications, responsibilities, and training; handling and storage of ***calibration*** and ***reference material*** items; quality assurance procedures; creation, storage, and control of technical records of all types; and document development, approval, and control relevant to the Division quality management system. For ***reference materials***, the NIST-QM-xx series contains, in addition to the above items, procedures for candidate material selection, identification, preparation, storage, and characterization. Included in characterization are homogeneity, stability, value assignment, and uncertainty of certified values.

2. References

NIST is a non-regulatory federal agency within the U.S. Department of Commerce. All aspects of NIST's activities are compliant with Federal statutes and regulations, Executive Orders, and Departmental Administrative Orders. The policies and procedures derived from these controlling documents, as well as those specifically developed for NIST, are contained in the NIST Administrative Manual, and are included by reference in this document. Policies and procedures specifically developed and approved for the NIST Quality Management System for Measurement Services as documented in the NIST-QM-I are controlling. They may be included by reference or directly in the NIST Administrative Manual. If changes in these policies and procedures are approved for the NIST QMS, the NIST Quality Manager (cf., Section 4.2.3.2 below) notifies the NIST Management and

Organization Division (cf., Section 4.1.3.1 below), which is responsible for their inclusion in the Administrative Manual.

The NIST QMS does not separately address policy or procedures for environmental-, safety-, or health-related activities or compliance. These are established elsewhere and documented on the NIST internal website [http://safety.nist.gov/] [http://www-i.nist.gov/admin/ems/]. Compliance with these policies is both mandatory and essential for providing quality services safely and in an environmentally acceptable fashion.

2.1 Informative References

ILAC-G12:2000 – Guidelines for the Requirements for the Competence of Reference Material Producers [http://tsapps-i.nist.gov/qs4ms/standards_guides/ilac-g12.pdf]

ISO Guide 30:1992 Terms and definitions used in connection with reference materials Amd 1:2008 Revision of definitions for reference material and certified reference material

ISO Guide 31:2000 Reference materials – Contents of certificates and labels

ISO Guide 32:1997 Calibration in analytical chemistry and use of certified reference materials

ISO Guide 33:2000 Uses of certified reference materials

ISO Guide 34:2000 General requirements for the competence of reference material producers

ISO Guide 35:2006 Reference materials – General and statistical principles for certification

ISO/IEC Guide 98:1995 Guide to the expression of uncertainty in measurement (GUM)

JCGM 200:2008 International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd Edition.

JCGM 100:2008 *Evaluation of Measurement Data — Guide to the Expression of Uncertainty in Measurement* (ISO GUM 1995 with Minor Corrections); Joint Committee for Guides in Metrology (2008) [http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf].

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

"Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes", (MRA), Comité International des Poids et Mesures (CIPM), Paris, 14 October 1999 [http://www1.bipm.org/utils/en/pdf/mra_2003.pdf]

NIST Policies for Measurement Services (policies established by the MSAG include: establishments of NIST calibration services, termination of NIST calibration services, setting predetermined NIST calibration fees, and US representation in CIPM MRA comparisons) [http://www-i.nist.gov/msag/]

NIST Special Publication 260-136 – "Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements" (2000). [http://ts.nist.gov/MeasurementServices/ReferenceMaterials/PUBLICATIONS.cfm]

NIST Technical Note 1297 – "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results" [http://physics.nist.gov/Document/tn1297.pdf]

NIST Administrative Manual – complete copy stored in each Division Office and OU Office; sections available at [http://www-i.nist.gov/admin/mo/adman/contents.htm]

Position Classification Manual of the NIST Alternative Personnel Management System [http://www-i.nist.gov/hr/classification/classificationmanual/manual.htm]

3. Definitions

All terms requiring definitions to assure the consistency and clarity of the NIST QMS are indicated by ***bold italics*** and their definitions are provided in this section.

BIPM (Bureau International des Poids et Mesures) was established by the Convention of the Metre and has its headquarters near Paris, France. It is financed jointly by the Member States of the Convention and operates under the exclusive supervision of the ***CIPM***. Its mandate is to provide the basis for a single, coherent system of measurements throughout the world, traceable to the International System of Units (SI). [http://www.bipm.org/en/home/]

BIPM Key Comparison Database is the database [http://kcdb.bipm.org/] maintained by the BIPM that contains Appendices A, B, C and D of the ***CIPM Mutual Recognition Arrangement (MRA)***.

calibration*:** Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with ***measurement uncertainties provided by measurement standards and corresponding indications with associated ***measurement uncertainties*** and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. [JCGM 200:2008, 2.39]

Calibration and Measurement Capabilities (CMCs) are declared capability claims by signatories to the ***CIPM MRA*** that are listed in Appendix C of the ***BIPM Key Comparison Database***. [http://kcdb.bipm.org/appendixC/default.asp and http://icdb.nist.gov]

calibration method: Defined technical procedure for performing a calibration.

Calibration Services (Note: use of title case is specific and intended): a function carried out by the Measurement Services Division of Technology Services. This function includes responding to general inquiries about NIST calibration services, providing copies of calibration service-related documents, and providing web access to descriptions and technical contacts for specific calibration services. [http://ts.nist.gov/MeasurementServices/Calibrations/]

calibration services (Note: use of lower case is specific and intended) are performed on instruments and devices that are metrologically suitable as reference or transfer standards and are designed to help the manufacturers and users of precision instruments achieve the highest possible levels of measurement quality and productivity. Services directly link a customer's precision equipment or transfer standards to national and international measurement standards using well-characterized, stable and predictable measurement processes.

certificate, reference material certificate*:** Document accompanying a ***Certified Reference Material stating one or more property values and their uncertainties, and confirming that the necessary procedures have been carried out to ensure their validity and traceability. [ISO Guide 30:1992] Numerous certificates are issued by NIST. See sub-level quality documents for specific descriptions**.**

(NIST SRM) Certificate, Certificate of Analysis: Documents 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, a 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.
Certified Reference Material (CRM)*:** A ***reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by a ***certificate*** that provides the value of the specified property, its associated uncertainty, and a statement of ***metrological traceability***.

Notes:

1. The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.
2. Metrologically valid procedures for the production and certification of ***reference materials*** are given in, among others, ISO Guides 34 and 35.
3. ISO Guide 31 gives guidance on the contents of ***certificates***.
4. VIM has an analogous definition (JCGM 200:2008, 5.14).

[ISO Guide 30:1992/Amd 1:2008]

Comité International des Poids et Measures (CIPM) is the International Committee for Weights and Measures. The CIPM is made up of eighteen individuals, each from a different country from among the fifty-one Member States of the Metre Convention. Its principal task is to ensure world-wide uniformity in units of measurement. The CIPM has established a number of Consultative Committees (CCs), which bring together the world's experts in their respective fields of measurement as advisers on scientific and technical matters. Another task for the CCs is the identification and implementation of Key Comparisons of calibration and measurement capabilities that underpin the measurement services provided by National Metrology Institutes, called for in the ***CIPM MRA***.
[http://www1.bipm.org/en/committees/cipm/]

CIPM Key Comparison*:** A ***key comparison executed by a Consultative Committee or the ***BIPM*** leading to a ***key comparison reference value***.

CIPM MRA is a Mutual Recognition Arrangement on national measurement standards and calibration and measurement ***certificates*** issued by national metrology institutes. Signed by the Directors of National Metrology Institutes for the thirty-eight member states of the Meter Convention in October 1999, this MRA provides an open, transparent, and comprehensive framework for obtaining reliable quantitative information on the comparability of metrological services provided by the signatory NMIs. It also provides governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce, and regulatory affairs. Signatories to this MRA have responsibilities for:

- declaring and documenting their calibration and measurement capabilities
- participating in relevant international key comparisons to benchmark these capabilities
- documenting the existence of a system for assuring the quality of measurement services provided using these capabilities

[http://www1.bipm.org/utils/en/pdf/mra_2003.pdf]

***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. (See Sections 4.4.4 and 5.2.4)

***concerns*:** Any issue that is brought to NIST staff attention that may be perceived to affect the quality of NIST measurement services. Concerns are typically derived from communications with a customer (i.e., customer feedback), but may also result from NIST measurement services staff. Significant concerns are recorded in a Division concerns log that also includes any actions that result (see sections 4.5.2 and 4.6.2).

***customer feedback*:** Comments from a customer or client, internal or external to NIST, directly (first party) or indirectly (second party; e.g., communication at a trade show or given to another NIST staff member) to measurement service personnel. The comments may be positive or negative, or may provide information such as expected future needs or suggestions for improvements. Negative customer feedback typically may result in a Quality Management System "concern".

IEC (International Electrotechnical Commission*)*: The international standards and conformity assessment body for all fields of electrotechnology

***Information System to Support Calibrations (ISSC)*:** The Information System to Support Calibrations (ISSC) is a web–based database system that provides access to technical, financial, and administrative data on calibrations performed by NIST. It automates most of the calibration services workflow ranging from providing data entry forms for inputting purchase orders to generating invoices after calibrations have been completed. The status of each calibration job is tracked through the ISSC, and NIST managers and technical staff are automatically sent email warnings of impending late jobs. The ISSC generates most of the paperwork required for calibration services such as forms, reports, invoices, and letters to customers. Documentation about the ISSC is found at the following hyperlink ISSC quality documentation [http://wwwi.nist.gov/ts/tsintranet/calibrations/issc_ovr.htm].

International Laboratory Accreditation Cooperation (ILAC): - An international cooperation of laboratory and inspection accreditation bodies formed more than 30 years ago to help remove technical barriers to trade

ISO (International Organization for Standardization) is a network of national standards institutes from 148 countries working in partnership with international organizations, governments, industry, business, and consumer representatives. ISO is a non-governmental organization that serves as a bridge between public and private sectors.

key comparison: One of the set of comparisons selected by a Consultative Committee or RMO to test the principal techniques and methods in the field. (Key comparisons may include comparisons of representations of multiples and sub-multiples of SI base and derived units and comparisons of artifacts)

key comparison reference value*:** The reference value accompanied by its uncertainty resulting from a ***CIPM key comparison.

Laboratory (Note: use of title case is specific and intended) refers to an organizational layer at NIST, sometimes referred to as an organizational unit (OU). For measurement services purposes and scope of this quality manual, many NIST OUs are involved in the delivery of NIST measurement services at one level or another (i.e., actual measurement or value-assignment, handling of the shipping and receiving, accounts receivable, management, strategic planning, etc.). (See 4.1.3.1 Organizational Charts)

[http://www.nist.gov/laboratories.cfm]

laboratory (Note: use of lower case is specific and intended) refers to the physical location where specific calibration, measurement, and characterization activities take place.

***measurement*:** Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity. [JCGM 200:2008, 2.1]

***(NIST) 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 are defined in Section 1.2 (Scope) of this document. Other related services may be included at the discretion of the Divisions. Such services are identified in the relevant sublevel quality documents.

Measurement Services Division within Technology Services provides business, administrative, and documentary support for NIST Standard Reference Materials (SRMs), Calibrations, and Standard Reference Data (SRD).

***Measurement Services Advisory Group (MSAG)*:** As a group, serves as the NIST corporate quality manager. The MSAG is composed of the Directors of the NIST Laboratories, or their designees, and the Director of Technology Services. Specifically, the MSAG (i) establishes policies related to measurement services to ensure consistent practices across NIST while preserving the independence of each Laboratory's measurement service activities as much as possible, and (ii) resolves matters that relate to more than one NIST Laboratory. [http://www-i.nist.gov/admin/mo/adman/301ms.htm and http://www-i.nist.gov/msag/]

***measurement uncertainty*:** Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. [JCGM 200:2008, 2.26]

metrological traceability*:** Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of ***calibrations, each contributing to the ***measurement uncertainty***. [JCGM 200:2008, 2.41]

National Center for Standards and Certification Information (NCSCI) provides on-site NIST access to CD-ROM and hard copy collections of U.S. industry, Federal and Military, Foreign, Regional, and International standards; technical regulations; and conformity assessment procedures; the Code of Federal Regulations and Federal Register; etc. [http://ts.nist.gov/Standards/information/index.cfm].

National Metrology Institutes (NMIs) maintain national measurement standards and provide services that link their country's measurement system to the International System of Units. NIST serves as the NMI for the United States of America.

National Voluntary Laboratory Accreditation Program (NVLAP) provides third-party accreditation to testing and calibration laboratories. NVLAP's accreditation programs are established in response to Congressional mandates or administrative actions by the Federal Government or from requests by private-sector organizations. NVLAP is in full conformance with the standards of ***ISO*** and ***IEC***, including ISO/IEC 17011:2004. In addition, for the ***MSAG***, ***NVLAP*** maintains the NIST Quality Management System websites and is responsible for coordinating and maintaining records from the assessments for the quality management system that underpins the measurement services provided by NIST Laboratories.

NIST Special Publication (SP) 250, NIST Calibration Services Users Guide is the catalog describing the ***calibration services*** that are available from NIST, which can be found on the web at SP 250 catalog [http://ts.nist.gov/MeasurementServices/Calibrations/].

NIST Special Publication (SP) 260, Standard Reference Materials Catalog is the catalog of ***reference materials*** available from NIST. (Also, see ***Standard Reference Materials*** definition) [http://www.nist.gov/srm].

NIST Traceable Reference Material^{CM} (NTRM^{CM}): A commercially produced ***reference material*** with a well-defined traceability linkage to existing NIST standards for measurements. This traceability linkage is established via criteria and protocols defined by NIST to meet the needs of the metrological community to be served.

reference material (RM): Material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Notes:

1. ***RM*** is a generic term.
2. Properties can be quantitative or qualitative, e.g., identity of substances or species.
3. Uses may include the ***calibration*** of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.
4. A single ***RM*** cannot be used for both calibration and validation of results in the same measurement procedure.
5. ***VIM*** has an analogous definition (JCGM 200:2008, 5.13), but restricts the term "measurement" to apply to quantitative values and not to qualitative properties. However, Note 3 of JCGM 200:2008, 5.13 specifically includes the concept of qualitative attributes, called "nominal properties".

[ISO Guide 30:1992/Amd 1:2008]

remote calibration: A calibration performed at a customer's laboratory by personnel located at an NMI. The device under test remains at the customer's laboratory. If necessary, measurement equipment is sent by the NMI to the customer. A communications link, typically the Internet, connects the customer to the NMI during the calibration. This link is used for observation, verification, data transfer, and in some cases, instrument control.

RMO Key Comparison**:** A ***key comparison*** executed by an RMO (regional metrology organization). . For a ***key comparison*** carried out by a RMO, the link to the ***key comparison reference value*** is obtained by reference to the results from those institutes which have also taken part in the ***CIPM key comparison***.

SP 250 Series publications: The ***NIST Special Publication (SP) 250, NIST Calibration Services Users Guide*** is supplemented by a number of Special Publications that provide detailed descriptions of the important features of specific NIST ***calibration services***. These documents provide a description of the: 1) specifications for the services; 2) design philosophy and theory; 3) NIST measurement system; 4) NIST operational procedures; 5) assessment of the measurement uncertainty including random and systematic errors and error budget; and 6) internal quality control procedures used by NIST. These documents present more detail than can be given in NIST calibration reports, or than is generally allowed in articles in scientific journals. The complete library of published SP 250's is available on the web [http://ts.nist.gov/MeasurementServices/Calibrations/sp250_series.cfm].

SP 260 Series publications: The ***NIST Special Publication (SP) 260***, ***Standard Reference Materials Catalog*** is supplemented by a number of Special Publications that provide detailed descriptions of methods and measurements used in the value-assignment of NIST ***Standard Reference Materials***. The SP 260 Series generally contains more detailed information than can be found in the ***certificate*** of analysis. The complete library of published SP 260s is available on the web [http://ts.nist.gov/MeasurementServices/ReferenceMaterials/PUBLICATIONS.cfm].

Special Test is a unique test that does not justify the complete characterization of the measurement process; or a test that is not a regularly offered test that may be requested by a Customer; or is a measurement method that is being refined or modified.

Standard Reference Material® (SRM®)*:** A CRM issued by NIST that also meets additional NIST-specified certification criteria. NIST SRMs are issued with ***Certificates of Analysis or ***Certificates*** that report the results of their characterizations and provide information regarding the appropriate use(s) of the material. [NIST SP 260-136: 2000]

***Sub-level quality documents*:** (NIST-QM-xx's [NIST-QM-II's, NIST-QM-III's, etc.]) NIST's quality management system is designed as being multi-level. NIST-QM-I is the NIST-level manual. Typically, NIST-QM-II is the division-level manual, and NIST-QM-III and subsequent documents are the service specific manuals. Sub-level quality documents refer to documentation and manuals that are not included specifically in NIST-QM-I.

***Subcontractor*:** (In context of NIST use of this term for activities covered in the scope of this Quality Manual) one who provides a complete measurement service to a NIST customer, for NIST, without participation by NIST. NIST does not subcontract measurement services in this manner. (See Section 4.4.4)

Supplementary Comparison*:** Comparisons carried out by the Consultative Committees, the RMOs and the ***BIPM to meet specific needs not covered by ***key comparisons***, including comparisons to support confidence in calibration and measurement certificates.

***Test Folder Number*:** a unique serial number issued by NIST TS Measurement Services Division that indicates an official calibration or test has been requested by a Customer (external to NIST).

VIM The international vocabulary of metrology maintained by the BIPM.

4. Management Requirements

4.1 The National Institute of Standards and Technology

4.1.1 Description

Founded in 1901, NIST is a non-regulatory federal agency within the U.S. Department of Commerce. The National Institute of Standards and Technology Act is the "organic act" (NIST Organic Act) that defines NIST and its functions. The legislation authorizing NIST's activities is codified in 15 USC Chapters 7 & 7a [http://www4.law.cornell.edu/uscode/15/ch7.html]; highlights of this legislation are summarized in Subchapter 1.01 of the NIST Administrative Manual (available on the NIST intranet).

NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

NIST carries out its mission in four cooperative programs (an organizational chart showing all of these programs is available at [http://www.nist.gov/director/orgchart.cfm]):

1. the NIST ***Laboratory*** Programs conduct research and provide services that advance the nation's technology infrastructure and are needed by U.S. industry to continually improve products and services;
2. the Baldrige National Quality Program promotes performance excellence among U.S. manufacturers, service companies, educational institutions, and health care providers; conducts outreach programs and manages the annual Malcolm Baldrige National Quality Award recognizing performance excellence and quality achievement;
3. the Hollings Manufacturing Extension Partnership offers technical and business assistance to smaller manufacturers through a nationwide network of local centers; and
4. the Technology Innovation Program (TIP) provides cost-shared awards to industry, universities and consortia for research on potentially revolutionary technologies that address critical national and societal needs.

Preeminent performance in these programs will allow realization of NIST's VISION:

- To be the world's leader in creating critical measurement solutions and promoting equitable standards. Our efforts stimulate innovation, foster industrial competitiveness, and improve the quality of life.

In all its activities, NIST emphasizes performance consistent with its CORE VALUES:

- **People**: We respect, value, and support each other in all our activities.
- **Integrity**: We are objective, ethical, and honest.
- **Customer focus**: We anticipate the needs of our customers and are committed to meeting or exceeding their expectations.
- **Excellence**: We expect world-class performance and continuous improvement in all we do.

NIST is committed to providing a workplace that is free of undue commercial, financial, and other internal and external pressures that would adversely affect the fit-for-purpose quality of the technical work of the Institute. High standards of ethical conduct, impartiality, objectivity and protection of confidential or proprietary information are vital to the success of NIST programs and required of all employees. Specific legal requirements and administrative guidance are provided to all employees in the publication Standards of Ethical Conduct for Employees of the Executive Branch (5 C.F.R. Part 2635, Subpart A – I, cf., Search Code of Federal Regulations), on the NIST website [http://otp-i.nist.gov/], and in Subchapter 5.06 of the NIST Administrative Manual [http://www-i.nist.gov/admin/mo/adman/506.htm].

4.1.2 Physical Locations

Calibrations and ***reference materials certifications*** are conducted at the NIST sites [http://www.nist.gov/public_affairs/general_information.cfm] in Gaithersburg (Maryland), Boulder (Colorado), and Charleston (South Carolina), and in some cases at special facilities away from the NIST campuses. If special facilities are used, these facilities are documented in the NIST ***sub-level quality documents***.

4.1.3 Organizational Structure for Scientific and Technical Research and Services; Responsibilities and Authorities

4.1.3.1 Organization Charts

Measurement services are critical to the success of the NIST ***Laboratory*** Program. All eight (8) of the major organizational units within this Program that are directly involved with the provision of the calibration reports, reports-of-test, and/or ***reference material certificates*** are covered by this manual. Figure 4.1 provides a schematic representation of this part of the NIST organization.

The technical effort required to deliver ***NIST measurement services*** is made by scientific and technical staff within the appropriate listed Division. The specific organization of these efforts varies among the various Divisions and is documented in the NIST ***sub-level quality documents***. Liaison with external customers is done by staff in the NIST ***Laboratory*** technical divisions and in the ***Measurement Services Division*** of Technology Services. The Statistical Engineering Division supports the development of statements of uncertainty for NIST ***calibrations***, ***reference materials***, and for measurements that NIST contributes to interlaboratory studies and to ***key comparisons***. The ***Measurement Services Division*** also provides business, administrative, and documentary support for ***NIST measurement services***.

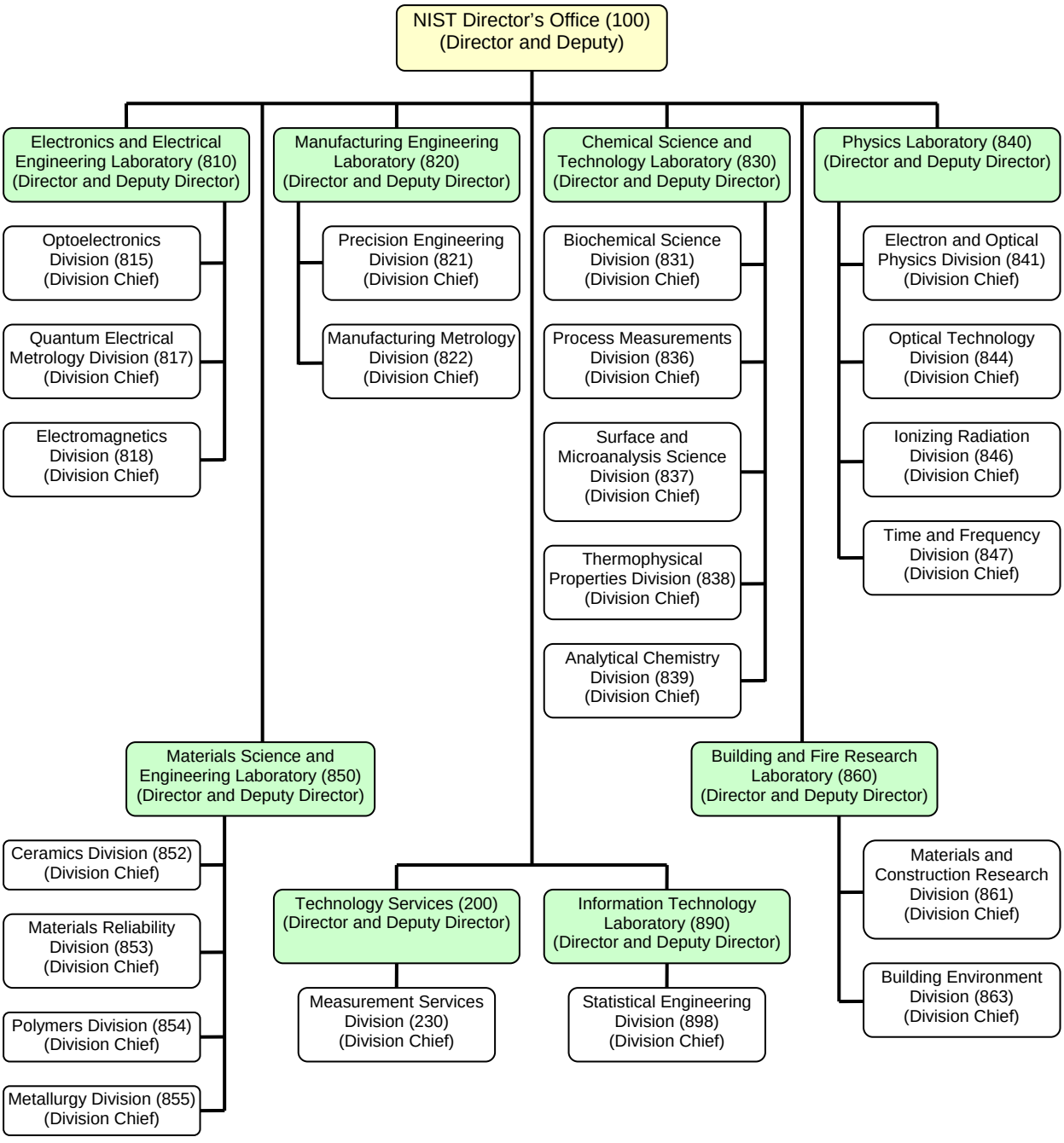

Figure 4.1 Schematic organization chart for units directly involved in provision of ***NIST measurement services***.

Many other parts of the NIST organization have functions that impact in some way the provision of ***measurement services***. For completeness, their position in the NIST organization is indicated in Figure 4.2. These offices and examples of their functions that affect the provision of ***measurement services*** are:

Finance, which handles customer billing and payment;
Management and Organization, whose responsibilities include the NIST Administrative Manual;
Human Resources Management, which provides assistance with hiring, training, position classification, and personnel records;
Acquisition and Logistics, which provides support for procurement of equipment and materials and shipping and receiving;
Facilities Services, Plant, and Engineering Safety, Maintenance and Support, whose efforts focus on providing and maintaining the physical facilities and laboratory environment;
Information Technology Security and Networking, Customer Access and Support, Applications Systems, Enterprise Systems, and Telecommunications and CIO Support, which provide facilities and support critical to operation of all NIST's information technology infrastructure.

Neither the NIST Quality Management System nor this quality manual governs the actions of these organizations with regard to ***Measurement Services***. However, a high degree of collaboration among all technical and support organizations is required to achieve performance excellence. A complete organizational chart is available at [http://orgchart.nist.gov/] and detailed descriptions of the functions of various units can be found in Chapter 9 of the Administrative Manual [http://www-i.nist.gov/admin/mo/adman/903APPA.HTM#Appendix%20A]. The functional statements that pertain to all NIST organizational units can be found at [http://www-i.nist.gov/admin/mo/adman/902.htm].

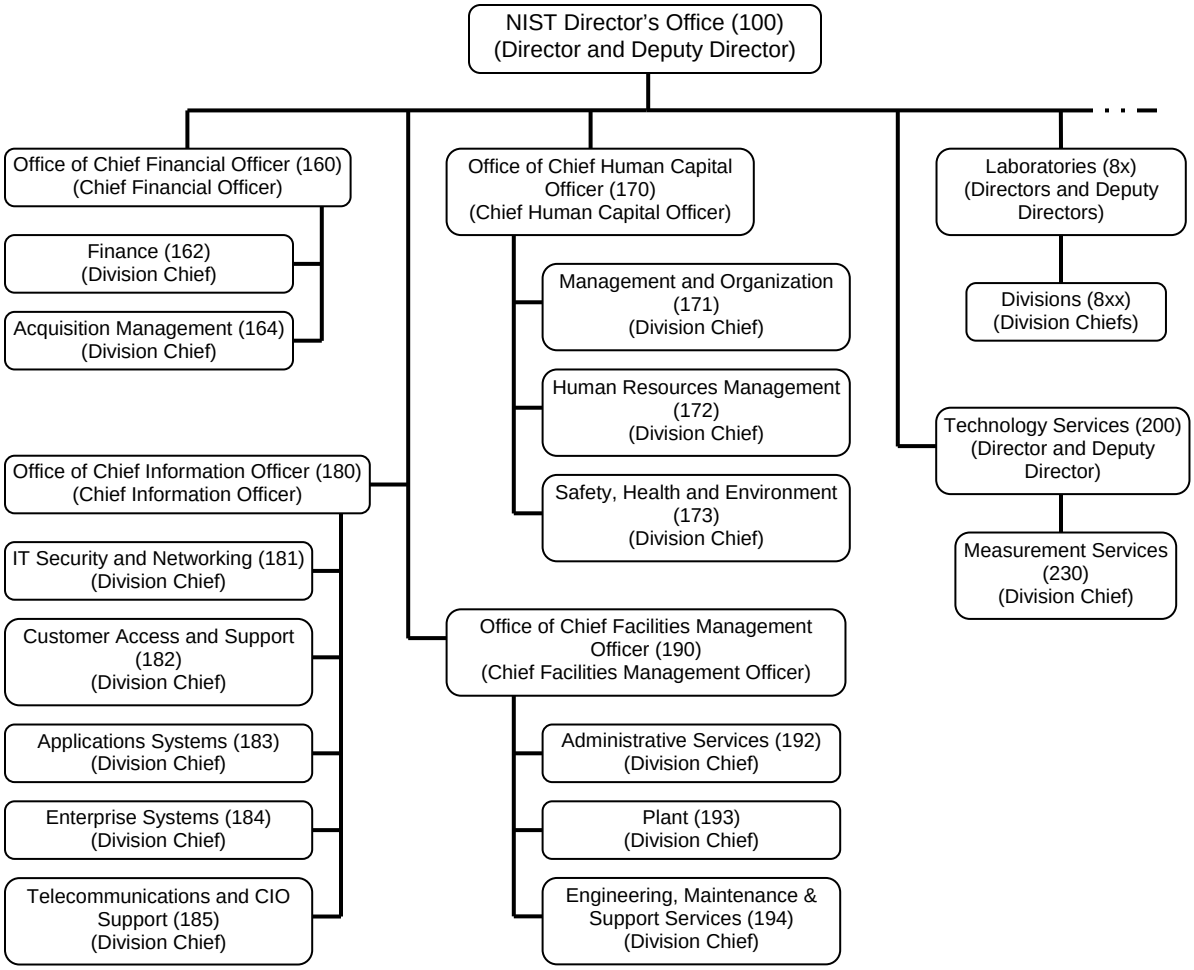

Figure 4.2 Schematic organization chart for units that contribute to the provision of ***NIST measurement services***. (TS and participating ***Laboratories*** (8x) and Divisions (8xx), (cf., Figure 4.1) are included to indicate relative positions in the organizational hierarchy.)

4.1.3.2 Responsibilities, Authorities, and Delegations

Measurement services are essential parts of NIST's Congressionally-mandated programmatic efforts. Therefore the responsibilities, authorities, delegations, and management of resources are identical to those that govern all work within the NIST ***Laboratories***. The hierarchy evident in Figure 4.1, i.e., NIST Director, ***Laboratory*** Director, and Division Chief, applies to all management activities. The NIST organizational structure allows that individuals be designated to act on behalf of key managerial, administrative, and technical staff as appropriate.

The NIST Director is responsible for NIST's mandated function to develop, maintain, and retain custody of the national standards of measurement, and provide the means and methods for making measurements consistent with those standards [NIST Organic Act].

Laboratory Directors, acting through Division Chiefs, are responsible for the development and maintenance of the national standards of measurement and, where appropriate, for providing ***measurement services*** that facilitate making ***measurements*** consistent with those standards. Resource allocations (personnel, fiscal, equipment, and space) to the technical Divisions are authorized by the ***Laboratory*** Director. ***Laboratory*** Directors also identify and, acting through the ***Measurement Services Advisory Group*** (cf., Section 4.2.3.2), approve initiation or cessation of specific ***measurement services***. They are also responsible for the implementation of corrective or preventive measures required to assure the effectiveness of the NIST QMS and its conformity to ISO/IEC 17025.

Division Chiefs, acting through their leadership staff, are responsible for the technical and scientific work involved in the development, maintenance and provision of national standards of measurement and the associated ***measurement services***. Division Chiefs authorize resource allocations (personnel, fiscal, equipment, and space) specifically for these efforts. The Division Chief is also responsible for ensuring the institutional competency needed to provide a ***calibration service*** or ***reference material***. Division Chiefs, or their designees, sign reports of calibration and test, and ***reference material*** certification records in the name of the NIST Director.

Performance excellence is the responsibility of every NIST staff member and every level of management. Organizational responsibilities specific to the NIST Quality Management System for ***measurement services***, cf., Section 4.2.3.2, parallel the programmatic responsibilities described above.

The responsibilities of the NIST Director and Laboratory Directors are documented in Chapter 9 of the Administrative Manual [http://www-i.nist.gov/admin/mo/adman/903APPA.HTM#Appendix%20A], in official Position Descriptions, and in their individual Performance Plans. The responsibilities of all other management, administrative, support, scientific, and technical staff are documented in official Position Descriptions and individual Performance Agreements or Plans.

4.2 NIST Quality Management System for Measurement Services

4.2.1 NIST Quality Policy

It is recognized that:

- ***Measurement services*** are essential to the fulfillment of NIST's mission. In the conduct of this vital work, as in all its efforts, it is NIST's vision to achieve performance excellence characteristic of a global leader in measurements and standards. We provide ***measurement services*** that meet the needs of our customers and, through continuous improvement, seek to anticipate their needs and exceed their expectations, while delivering outstanding value to the nation.
- Furthermore, quality depends first and foremost on the commitment and excellence of NIST staff. Therefore the Institute commits to:
  - fostering the attitude of excellence among the staff by recognizing valued performance and affording opportunities for continuing education and training;
  - providing the resources required to achieve our vision for ***measurement services***; and

- empowering employees to identify and establish policies and procedures to assure continuous improvement in the performance of ***NIST measurement services***.

This Quality Policy is a reflection of the CORE VALUES of NIST.

NIST is committed to the formal Quality Management System outlined in this manual, which conforms to international standard ISO/IEC 17025 and to the relevant requirements of ISO Guide 34 as they apply to ***Standard Reference Materials®*** ***(SRMs®)*** and related services to the extent permitted by statute and regulation. It is NIST policy to rely on the system described in the NIST QM-I when declaring NIST ***Calibration and Measurement Capabilities (CMCs)*** and submitting these for inclusion in Appendix C of the International Committee for Weights and Measures ***(CIPM) Mutual Recognition Arrangement (MRA)***.

Further, it is NIST policy that its ***measurement services*** will not be subcontracted. (See Section 4.4.4)

NIST certifies its results for calibrated instruments and reference materials. NIST cannot and does not certify any calibrated instrument's performance relative to specifications, its suitability for an intended customer application, or its future performance. Further, NIST does not provide warranty for tests or analyses performed using reference materials in a customer's laboratory.

4.2.2 NIST Quality Objectives

NIST's principal quality goal is to consistently meet or exceed customer needs and expectations and provide high value, continually improving services. NIST's quality objectives support this goal. These quality objectives are as follows:

- NIST develops and maintains U.S. national realizations and representations, as appropriate, of the International System of Units (SI). These realizations will have measurement uncertainties appropriate to current and anticipated needs of U.S. industry and Government.

- To the extent permitted by resources, NIST participates in comparisons of its national standards with those of other ***National Metrology Institutes (NMIs)***, both as a means of assuring the quality of its ***measurement services*** and to satisfy the requirement that the U.S. standards are consistent with those of other NMIs, and with the SI, within stated uncertainty. Special priority is given to key comparisons conducted under the auspices of the International Committee on Weights and Measures ***(CIPM)*** in support of the ***CIPM MRA***.

- NIST provides ***measurement services*** that are customer focused and, at a minimum, are:
  - marked by clear and open communication with customers to assure mutual understanding of customer needs and NIST capabilities;
  - technically consistent with customer needs; and
  - timely and cost effective.

NIST provides secure and confidential customer access to information on work in progress via the NIST ***Information System to Support Calibrations (ISSC)***.

NIST expects continuous improvement in the provision of ***measurement services*** and encourages

identification of opportunities for improvement from all staff.

4.2.3 Organizational Structure of the NIST QMS: Responsibilities and Authorities

4.2.3.1 NIST QMS Organization Chart

The organizational hierarchy of the NIST QMS, Figure 4.3, is essentially identical to that shown in Figure 4.1 for the NIST ***Laboratory*** Program.

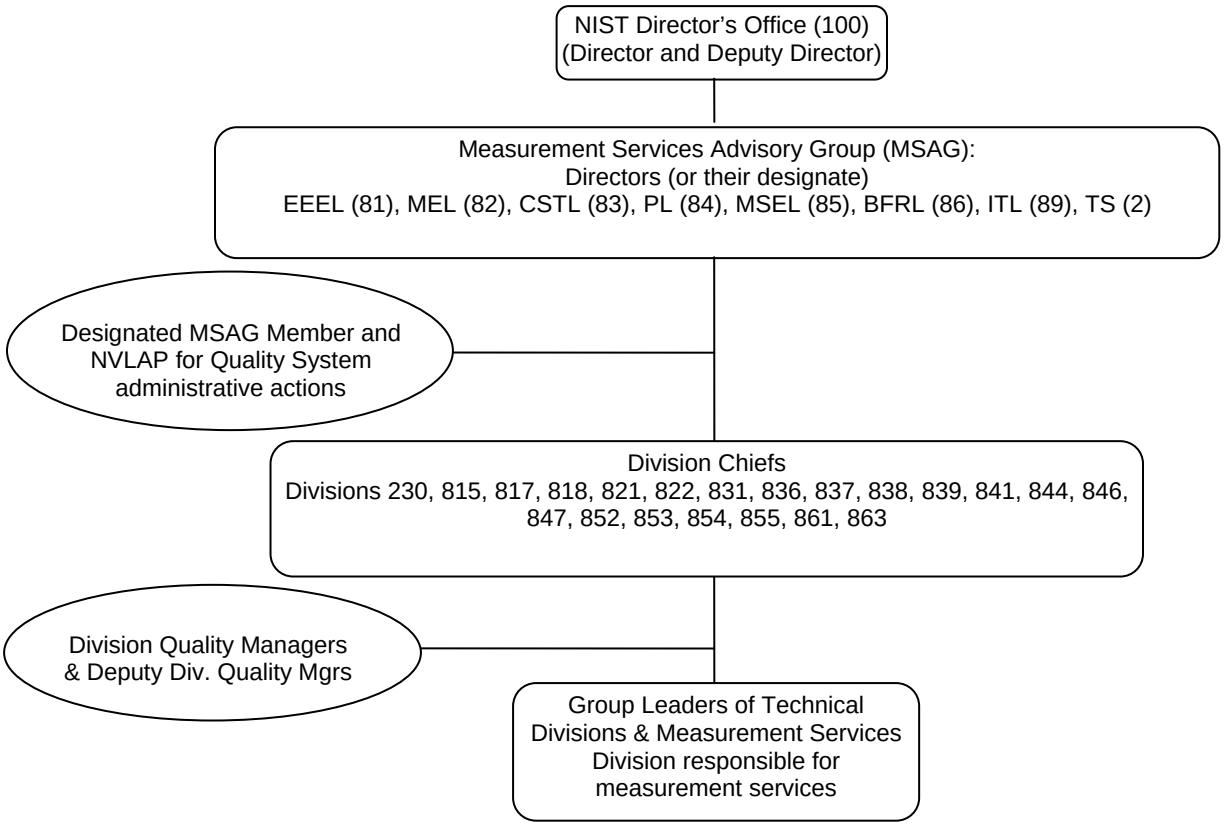

Figure 4.3 Organizational hierarchy of the management of the NIST QMS (See the NIST organizational chart available at [http://orgchart.nist.gov/] for complete names of the listed ***Laboratories*** and Divisions)

4.2.3.2 Responsibilities, Authorities, and Delegations

The NIST Director is responsible for the quality of ***NIST measurement services***. The Directors of the ***Laboratories*** directly involved in providing these services and the Director of Technology Services are members of an official NIST Committee called the ***Measurement Services Advisory Group (MSAG)***. In addition to its other responsibilities (cf., Section 4.1.3.2), the ***MSAG*** serves corporately as the NIST Quality Manager. In this capacity, the ***MSAG*** has the responsibility to approve the NIST QMS and report to the NIST Director the results of its reviews of ***NIST measurement services*** and implementation of the NIST QMS. The ***MSAG*** is responsible for implementation of the NIST QMS and any action plans resulting from its reviews thereof. The ***MSAG*** approves the NIST-QM-I, which, when so approved, becomes the official version. The authority for approval of an individual Division's part of the NIST ***sub-level quality documents*** is delegated to the Chief of that Division.

The ***MSAG*** designates one of its members to be responsible for administrative functions including but not limited to the following functions:

1) document and obtain executive management approval of the NIST QMS;
2) organize and schedule NIST-level quality management system assessments and executive management reviews;
3) assure timely completion of any required revisions of NIST-QM-I and obtain approval thereof;
4) assure that NIST-QM-I is kept consistent with successive editions of applicable international standards such as ISO 17025; and
5) maintain document control for NIST-QM-I, including revision and distribution status.

The Division Chiefs are responsible for implementing the NIST Quality Management System for ***Measurement Services*** at the Division level. Division Chiefs are also responsible for assuring completion of assessments and reviews in a timely manner, and for implementing actions resulting from the findings of these assessments and reviews. Division Chiefs appoint a Division Quality Manager and Deputy.

Specific responsibilities with respect to:

- performing tests and/or calibrations;
- planning of tests and/or calibrations and evaluation of results;
- reporting opinions and interpretations; and
- method modification and development and validation of new methods

are documented in NIST ***sub-level quality document***s.

4.3 Control of Documents and Records

4.3.1 Scope

In general, NIST QMS documents are managed following Administrative Manual Subchapter 2.06 on Records Management. Laboratory records and data specifically obtained as part of a calibration procedure or reference material certification are managed under Section 2.06.03b of that Subchapter. NIST's Information quality standards for laboratory notebooks and scientific data are addressed in the NIST Guidelines, Information Quality Standards, and Administrative Mechanism [http://www.nist.gov/director/quality_standards.cfm]. The discussion below applies only to

NIST-QM-I. The policies and procedures governing control of documents, records, and data that are part of the ***sub-level quality documentation*** are specified therein. The NIST ***sub-level quality documentation*** contains procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal (including retention times) of all Division-level quality and technical records. The policies and procedures herein are supplemental to the more general Federal and NIST requirements governing computer and information security [http://www-i.nist.gov/admin/mo/adman/1102.HTM].

4.3.2 Document Approval and Issue

The official version of NIST-QM-I is maintained on the NIST intranet server [http://www-i.nist.gov/nistqs]. The NIST intranet is readily available to all NIST staff, and, as indicated above, also provides access to controlling documents that are not specific to the NIST QMS, e.g., the NIST Administrative Manual. This official version of NIST-QM-I is a read/print-only document.

An uncontrolled (read/print-only) copy of NIST-QM-I is available to anyone external to NIST on the NIST website [http://www.nist.gov/nistqs]. This copy is updated (replaced) with each new and approved version of NIST-QM-I. Controlled electronic documents are those resident on specially identified NIST servers. These servers have appropriate security and backup systems in place.

The ***MSAG***, through its designee, is responsible for assuring that the current versions of NIST-QM-I and the NIST ***sub-level quality document***s that are available on the internal and external websites are the official versions and copies thereof, respectively.

4.3.3 Document Changes

After a revision of NIST-QM-I is approved as the official version, the ***MSAG*** notifies all Division Chiefs and Division Quality Managers that a revised version of NIST-QM-I is now official and available on the NIST intranet. This notice shall indicate those sections of NIST-QM-I that have been revised. A copy of the official version as well as historical records pertaining to, and copies (clearly marked as obsolete) of all previous versions of NIST-QM-I shall be maintained on a separate backup system. These documents are official parts of the NIST QMS documents.

4.4 Administrative Requirements for Providing Measurement Services

4.4.1 Review and Approval of Requests, Tenders and Contracts for Procurement of Measurement Services

All external requests for existing and routinely available ***measurement services*** offered by NIST are governed by policies (policies for domestic customers and policies for foreign customers) maintained by the ***Measurement Services Division*** at Policies for Domestic Customers Calibration Services, Policies for Foreign Customers - Calibration Services, and the SRM Catalog Ordering site. These policies apply NIST-wide and are approved by the ***MSAG***.

The provision of a NIST test or calibration generally involves the following steps:

1) The customer speaks with a technical contact responsible for the calibration service (the customer can find technical contacts listed under the heading Catalog of NIST ***Calibration Services*** at the Calibration Services Website), or is referred by a staff person from the ***Measurement Services Division***.
2) This contact initiates a process to determine the customer's needs and the ability of the technical division to address them. Agreement with the customer and approval from the technical division leads to acceptance of a customer's purchase order (PO).
3) Upon receipt of the approved PO, the TS ***Measurement Services Division (MSD)*** assigns the calibration or test an official "***Test Folder Number***" and enters the requisite information into the NIST ***ISSC***. The customer is notified of acceptance and provided a password (unique to the ***Test Folder Number***) to allow monitoring the progress of the calibration via Internet access to the ***ISSC***.
4) Calibration items are received at NIST by the Logistics Group in the Acquisition and Logistics Division and delivered to the appropriate technical division. Unpacking and inspection of the calibration items is done in the technical division and a go-ahead for calibration sent to MSD for entry as the start date of calibration. The technical division maintains current status of the calibration in the ***ISSC***.
5) Calibrations typically involve data gathering, data analysis, report preparation, technical review of the report, and approval for signature. After the report is signed, the technical division sends it to the customer and notifies MSD and the Accounts Receivable Group, which sends an invoice to the customer. Also, the ***ISSC*** record is then designated complete.
6) Typically, the technical division prepares the calibration item for shipping, and the Logistics Group arranges for pick up by the shipping agency. Variations are detailed in ***sub-level quality documents***.

The procurement of a NIST reference material can be accomplished through the ***Measurement Services Division*** Sales and Customer Services Group. Orders can be placed by phone, fax, or through the SRM website http://www.nist.gov/srm. The SRM website also contains the catalog of currently available reference materials from NIST.

Additional information about the activities within this general framework and the staff responsible for various steps are presented for each Division in the NIST ***sub-level quality document***s.

4.4.2 Procuring Products and Services, External Sources

Federal Procurement Policy and Regulations govern procurement of products and services from sources external to NIST. These policies, supporting guidance, and procedures applicable to all NIST procurements are detailed on the NIST intranet at [http://www-i.nist.gov/admin/amd/index.html]. In cases where the required products and services must meet special requirements to assure the quality of a particular NIST ***calibration service***, these requirements are authorized by the Division Chief and documented in the NIST ***sub-level quality document***s.

4.4.3 Interaction with NIST Supporting Divisions

As discussed in section 4.1.3.1 and indicated schematically in Figure 4.2, many divisions support the provision of ***NIST measurement services***. It is NIST policy that these supporting divisions will collaborate cooperatively with the technical divisions in assuring services and facilities that are in conformity with the NIST QMS. It is the responsibility of the technical divisions to communicate concisely and clearly the actions desired/required of NIST supporting services to allow quality goals to be achieved.

In some cases technical divisions require measurements be performed by other divisions as part of their measurement service. These measurements must be covered by a quality management system, either of the division providing the service or the division providing the actual measurements.

4.4.4 Subcontracting of Tests, Calibrations and Reference Material Certifications

It is NIST policy that ***calibration services*** and ***reference material certifications*** will not be subcontracted. (See Section 5.2.4 Collaborators)

4.4.5 Reference Materials Production Planning and Control

Each technical ***laboratory*** prepares an annual program of work and funding to produce ***reference materials***. Many, if not most, of the materials require multi-year production efforts. For each material to be produced in the program, the involved technical division(s) prepares an SRM Statement of Work.

See NIST Administrative Manual Subchapter 5.19 ***Standard Reference Materials*** [http://www-i.nist.gov/admin/mo/adman/519.htm] for production flowcharts and control processes.

4.5 Corrective and Preventive Actions

4.5.1 Non-conformity and Corrective Actions

If there is evidence derived from any source, including customer feedback, that any activity supporting the provision of a ***measurement service*** is or has not been in conformity with the requirements of the NIST QMS, management of the division providing that ***measurement service*** is directed to:

1) institute a timely investigation of root causes;
2) assess the significance of the non-conformity to all completed and in-progress work, and, if warranted, notify customers and/or cease work, with resumption only after proper authorization as defined in ***sub-level quality documents***.
3) develop and execute corrective and/or preventive actions if warranted;
4) monitor implementation and determine outcomes of such actions;

5) initiate an audit, if required; and,
6) maintain records of the non-conformities, action plans, implementation, and outcomes thereof.

All such incidents should be documented in the division's quarterly quality report, which is ultimately sent to ***MSAG***.

4.5.2 Customer Feedback and Concerns

All staff members are responsible for assessing the significance of complaints, with guidance from their supervisor if necessary, to be sure that the appropriate levels of NIST management are aware of the complaints and approve of the responses thereto. In the case of complaints regarding any aspect of a ***measurement service***, the actions shall be in accord with the provisions of Section 4.5.1. In addition, the actions shall include recording:

1) the nature of the complaint, date received, name of person registering the complaint, NIST recipient, ***Test Folder Number*** (if relevant), and initial response to the complainant;
2) the final resolution of the complaint to include applicable elements of Section 4.5.1;
3) a brief summary of all follow-up and the (required) final communication with the complainant; and,
4) entry of the complaint in a Division-maintained complaint log.

Collection and recording of this information can be facilitated by use, as appropriate, of the NIST Calibration Service or Standard Reference Material Complaint Form, Appendix A or another form as specified in the ***sub-level quality document***s. Complaints related to ***measurement services*** of other divisions should be forwarded to the relevant divisions through division quality managers.

4.5.3 Preventive Actions

Excellence, a NIST CORE VALUE, relies on continual 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 respond to staff suggestions by examining the opportunity or need and developing action plans to implement any changes required. The outcome is communicated to the employee whose suggestion stimulated the actions. Technical division managers and staff members review trends and analyze data in search of preventive actions that would foster continued and improved quality.

4.6 Internal Assessments and Management Reviews

4.6.1 Assessments

NIST-level assessments are organized by the ***MSAG*** and conducted in accordance with the assessment process described in Appendix B. The frequency of assessments is determined by the ***MSAG*** as part of the management review (see Section 4.6.2); the frequency shall be at least once every 5 years.

With regard to Appendix B:

- Findings, recommendations, action plans (if appropriate), implementation thereof, and results arising from these assessments are reported to the appropriate management and included as part of the NIST-QMS documentation, which is maintained by the ***MSAG*** or by others on behalf of the ***MSAG***.
- All members of the assessment teams shall have completed assessor/auditor training with, or equivalent to that provided by, the ***National Voluntary Laboratory Accreditation Program (NVLAP)***. Team leaders shall be NIST employees. In most cases all the assessors shall be NIST employees or former NIST employees. International metrologists may also participate with OU Director approval and MSAG concurrence.

In addition to undergoing the assessments outlined in Appendix B, each ***Laboratory***/Division is responsible for assuring the technical quality of its measurement results. To that end, each Division reviews (a) its documentation from a technical standpoint, and (b) the results of its quality assurance practices (e.g., interlaboratory comparisons). These internal audits must occur at least every two years, but preferably each year. Each internal audit might not cover all aspects of a division's quality management system. Because these technical reviews may vary in detail from service to service, they are documented in the NIST ***sub-level quality document***s. In conducting these technical reviews, an individual ***Laboratory***/Division may involve internal and/or external technical experts. For additional information on quality assurance practices, see Section 5.9.

4.6.2 Management Reviews

NIST-level executive management reviews are the responsibility of the ***MSAG*** and shall be conducted quarterly via written reports from the Divisions to ***Laboratories*** and then to the ***MSAG***. Technology Services will be responsible for providing the ***MSAG*** with a consolidated report on the NIST cross-cut issues addressed in the Division reports. The ***MSAG*** shall:

- organize and schedule executive management reviews of NIST measurement services, implementation of the NIST QMS, and conformity assessments relative to ISO/IEC 17025;
- report to the NIST Director summaries of its findings, recommendations, and implementation plans, if required;
- record this report and a report of actions taken subsequent to its presentation to the NIST Director as part of the documentation of the NIST QMS; and
- make determinations of the frequencies of internal assessments and management reviews.

Typically, management reviews will rely on information reported from the Division Chief to his or her respective ***Laboratory*** Director (the representative to the ***MSAG***) and will address the following:

- the suitability of policies and procedures
- reports from managerial and supervisory personnel
- the results of internal assessments
- revisions and changes to sub-level quality manuals
- cross-cutting issues for the ***MSAG*** to address
- reports from the Assessment Review Board (see Appendix B)
- corrective and preventive actions

- recommendations for improvement
- non-conformities, action plans, implementation, and outcomes thereof
- the results of interlaboratory comparisons
- changes in the volume and type of the work
- customer feedback
- concerns
- other relevant factors, such as quality control activities, resources, and staff training.

4.7 Service to the client

NIST technical representatives who provide ***measurement services*** are expected to maintain communication with their clients. Communication can occur through a variety of means, including phone calls and email correspondence. Such communication is especially called for in the event of delays in the delivery of service, anomalies regarding customer equipment, or unexpected issues arising during tests, ***measurements***, or ***calibrations***.

In addition, NIST technical staff participate in a number of activities where they have direct interaction with their customers and clients; examples of these activities include attendance and participation at technical and metrology-specific conferences, formal participation in national and international technical committees (such as ISO, IUPAC, CIPM Consultative Committees, ASTM, AOAC, etc.), and meeting with trade groups or industry associations from various sectors. A number of divisions offer workshops and short courses that allow their clients the opportunity to receive hands-on training and direct communication with the technical staff. NIST has also implemented the use of the ***ISSC*** website and customer feedback cards and distributes them with each calibration report and ***SRM certificate***. A number of NIST websites, including the ***SRM*** site, contain customer feedback mechanisms. Other specific client service measures may be found in the NIST ***sub-level quality documents***.

5. Technical Requirements

5.1 Introduction

The policies and procedures included in NIST-QM-I with respect to technical requirements are only those that apply across the Institute. All other technical requirements are located in, or referenced in, the NIST ***sub-level quality documents***.

5.2 Personnel

5.2.1 Competence

It is NIST policy that:

1) the person(s) authorized to conduct ***measurement(s)*** needed for ***calibrations*** or ***reference material certification*** must be proficient in performing the required tasks in the opinion of the

NIST expert responsible for the ***calibration***, ***measurement***, or ***reference material***; and
2) NIST must have on staff, or have regular advisory access to, a nationally or internationally recognized expert in the ***calibration***, ***measurement***, or ***reference material*** area.

Assuring competence is the direct responsibility of the management chain for scientific research and services of the relevant technical Divisions, as described in Section 4.1.3.2.

5.2.2 Education and Training Goals

It is NIST's goal [http://www-i.nist.gov/admin/mo/adman/1008.htm] that all employees will receive, on a continuing basis, the education and training required to improve performance in their jobs. Responsibility for achieving this goal in the context of ***calibration***, ***reference material***, and related ***measurement services*** is that of the management chain for scientific and technical research and services, as described in Section 4.1.3.2.

Training goals and training programs (relevant to present and anticipated tasks of the laboratory) with respect to the skills of the ***laboratory*** personnel are described in the NIST ***sub-level quality documents***. The criteria for evaluating the effectiveness of the training are found in the ***sub-level quality documents***.

5.2.3 Job Descriptions

Primary responsibilities, experience, and qualifications pertinent to calibrations and reference materials are appropriately documented in sub-level documentation for each person involved in managing or conducting such work (See Sections 4.1.3.2 and 4.2.3.2).

5.2.4 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 technical division on the basis of technical excellence with regard to the measurements and materials required. Their collaboration will be carefully documented and appropriately referenced on applicable certificates.

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

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 ***reference materials*** 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 NIST'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 for assuring that environmental conditions do not adversely affect the quality of ***measurement services***.

Specific requirements and methods for achieving, monitoring, and controlling accommodations and environmental conditions are detailed in ***sub-level quality document***s.

5.4 Test and Calibration Procedures and Procedure Validation

5.4.1 Calibrations and Special Tests

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. These calibrations are assigned a distinct number and name. To meet customer needs, the technical divisions may agree to perform a ***Special Test***. These are so designated for one or more of the following reasons: (1) the specific type of calibration is seldom requested, thus precluding the maintenance of a large statistical base for characterizing the measurement process; (2) the test requested is unique; or (3) the service is still under development - meaning the measurement or ***calibration methods*** are still being perfected, or all the quality-assurance steps have not been completed. Detailed descriptions of the calibrations and tests offered, and the associated procedures, methods of validation, and ***measurement uncertainty***, are documented in the NIST ***sub-level quality document***s.

5.4.2 Reference Materials

When certifying ***reference materials***, NIST uses 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. As needed, new measurement methods are developed and validated by the staff members of a technical division. 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. Detailed descriptions of ***reference material certification*** methods and procedures, methods of validation, and ***measurement uncertainty*** are documented in the ***sub-level quality document***s by the appropriate technical division.

5.4.3 Estimation of Uncertainty

All reported NIST measurement results, including those in test reports for ***calibration services***, and in ***certificates*** for ***reference materials***, and those that are produced in relation with interlaboratory studies and ***key comparisons***, are 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 this manual and made available to stakeholders on the NIST external website [http://ts.nist.gov/MeasurementServices/Calibrations/policy.cfm#uncertain].

5.4.4 Evaluation and Control of Data

Procedures for checking calculations, data transfer, and associated data processing software are the responsibility of the performing technical division and are documented in the ***sub-level quality document***s.

All computer systems involved in the technical portion of providing ***measurement services***, such as data acquisition and analysis, will be appropriately protected to prevent compromises in confidentiality, integrity, and availability. The default sensitivity rating will be maintained at a level of Low, Low, Low as a minimum. See Chapter 11.02 of the Administrative Manual http://www-i.nist.gov/admin/mo/adman/1102.HTM for further information about information technology security policies at NIST.

5.5 Equipment

NIST recognizes the critical role that well-maintained, state-of-the-art equipment plays in the provision of the measurements, calibration and reference materials, and standards required by U.S. industry and the scientific and engineering communities. Assuring the quality and adequacy of the ***laboratory*** equipment is another key responsibility of NIST's executive management. The technical divisions determine the requisite equipment needs and provide prioritized requests for funds to develop or purchase equipment for consideration by their ***Laboratory*** Directors. The technical divisions are also responsible for the maintenance, calibration, storage, safe and proficient operation, quality-assurance, and documentation of all equipment supporting calibration and reference material services. This includes software validation. The details of the division processes for equipment are documented in the NIST ***sub-level quality document***s.

5.6 Measurement Traceability

NIST adopts for its own use and recommends for use by others the definition of ***metrological traceability***[1] provided in the most recent version of the International vocabulary of metrology (see Section 3. Definitions and the NIST traceability site at http://www.nist.gov/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 document***s 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

[1] The full term, "metrological traceability" is preferred when there is a risk of confusion with other meanings of the abbreviated term "traceability", which is sometimes used to refer to the "history" or "trace" of an item. The abbreviated term is also used in this document to improve readability, since it is clear that "metrological traceability" is meant in every case.

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.

NIST policy also asserts that providing support for a claim of traceability of the result of a measurement or value of a standard is the responsibility of the provider — whether NIST or another organization — of that result or value, and that assessing the validity of such a claim is the responsibility of the user of that result or value. The NIST policy on traceability is made available to stakeholders on the NIST external website [http://www.nist.gov/traceability/].

5.7 Sampling, Preparation, Homogeneity, and Stability

5.7.1 Calibration of Individual Instruments

NIST normally calibrates individual instruments and explicitly states that the measurement results apply only to that specific instrument. Generally, NIST ***calibrations*** and ***special tests*** do not rely on sampling. In those cases where sampling is required for any application, such as for the characterization of certain types of ***certified reference materials***, it is the responsibility of the technical division to ensure its validity. Details of this process can be found in the respective NIST ***sub-level quality document***s.

5.7.2 Certification of Reference Materials

For ***reference materials***, when samples of in-process material and/or of process material are required for certification measurements, the technical division(s) develops a sampling plan in cooperation with the Statistical Engineering Division. The responsibility for conducting sampling operations is that of the technical division(s). ***Measurement Services Division*** staff may perform sampling operations with guidance and specifications from the technical division.

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 NIST ***sub-level quality document***s.

5.8 Handling of Test and Calibration Items

Chiefs of the technical and support divisions must assure that staff members understand the importance of proper handling, are properly trained, and consistently handle test and ***calibration*** items and reference materials appropriately. If specific procedures for identifying, preparing, packaging, handling, storing, and shipping of ***calibration*** items and ***reference materials*** are required, these are documented in the ***sub-level quality document***s.

5.9 Quality Assurance Practices

NIST measurement services make use of quality assurance practices to ensure the validity of ***calibration*** and ***reference material*** results and their uncertainties. Such practices can include:

- repeat measurements/calibrations compared over many time intervals
- comparison of results obtained using multiple reference standards
- use of check standards and control charts
- use of redundant experimental designs
- comparison of results obtained using two or more differing measurement approaches
- results of national and international comparisons, including ***CIPM key comparisons***
- results of proficiency tests
- correlation of results for different characteristics of an item.

The NIST ***sub-level quality documentation*** details the quality assurance practices for specific ***measurement services***.

5.10 Reporting Results

5.10.1 Reports of Calibrations and Special Test

Reports of Test or Calibration shall, at a minimum, contain or be in accordance with the following:

- a title (e.g., "Report of Test/Calibration");
- the first page shall be on NIST letter head or be equivalently identified as originating from NIST;
- the NIST ***Calibration Services*** test or calibration number, service id number [http:/www.nist.gov/calibrations/]
- if required, the complete specification of a special test, either explicitly or by reference;
- the ***Test Folder Number***;
- all pages shall be numbered and the last page designated as the end of the report;
- the name and address of the client;
- a description and identification of the item(s) tested or calibrated;
- a description of the ***calibration method***;
- the date(s) of performance of the test or ***calibration***;
- the test or ***calibration*** results with, where appropriate, the units of ***measurement***;
- a statement of uncertainty of each ***measurement*** result;
- the conditions (e.g. environmental) under which the ***calibrations*** were made that have an influence on the ***measurement*** results;
- evidence that the ***measurements*** are traceable;
- the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the report;
- when necessary, a statement that the results apply only to the items tested or calibrated;
- the name of the person(s) performing the ***measurements*** and analyses; and
- an explanation of the proper use and interpretation of the reported results, as necessary (this can be in the form of an addendum).

5.10.2 Certificates for Reference Materials

Certificates for Standard Reference Materials (SRMs) and Reports of Investigation for NIST Reference Materials (RMs) shall conform to ISO Guide 31, and at a minimum, contain or address the following:

- name of material;
- ***reference material*** code and batch number;
- description of the SRM;
- intended use;
- instructions for the correct use of the material;
- certified or reference values and their uncertainties;
- methods used to obtain property values; and
- period of validity.

Further details and descriptions of specific types of certificates, if relevant, are found in the ***sub-level quality document***s.

5.10.3 Signatory Authority

All Reports of Calibration and Reports of Special Test shall be signed "For the Director of the National Institute of Standards and Technology" by personnel explicitly authorized to do so.

SRM certificates and RM Reports bear the logo of the U.S. Department of Commerce, the name of NIST as the certifying body, and the name(s) and title of the NIST officer(s) authorized to accept responsibility for their contents.

Appendix A. Sample Customer Concerns Form

Division Log Number:_____

Measurement Service Area Log Number:_____

Person Receiving the Communication: _____ Date Received:_____

Ext.:_____

Project Leader: _____ Date Forwarded: _____

Ext.:_____

Forwarded To: _____ Date Forwarded: _____

Ext.:_____

Customer:_____ **Phone Number: _____**

Point of Contact:_____ **FAX Number: _____**

Describe the Concern:

Action Taken:

Date Closed: _____ Project Leader Initials: _____

Technical Manager Initials: _____ Quality Manager Initials: _____

Appendix B. Assessment Process for SP 250 Calibration and SP 260 Standard Reference Material Services, and Approval Process of the Quality Management Systems that Support the Delivery of the Measurement Services

1. Assessment

a. Each Division Chief and Chief of ***NVLAP*** will jointly recommend an assessment team for his/her division.
b. Each team will consist of at least two (preferably three or more) qualified assessors including one team leader. The majority of the assessors, including the team leader, should be from outside the local ***Laboratory*** (organizational unit). The assessment team should have technical knowledge of the area being assessed and documented training in ISO/IEC 17025 and ISO Guide 34 where applicable. While most or all of the assessors will be NIST staff members or NIST retirees, outside assessors (peers from other NMIs from SIM or elsewhere around the world) may be invited to either participate in or observe the assessment when it is needed and appropriate. The use of outside participants must be approved by the ***Laboratory*** Director with ***MSAG*** concurrence. Team members will not be from the Division being assessed.
c. The ***Laboratory*** Director and the Chair of the ***MSAG*** will approve the recommended team members prior to the start of the assessment. Because of unforeseen circumstances, membership of the assessment team may need to be changed either immediately before or during the scheduled assessment. If the Division Chief and Chief of ***NVLAP*** find it necessary to make such a change, the ***Laboratory*** Director and the Chair of the ***MSAG*** must approve the change as soon thereafter as possible. If the Laboratory Director and the Chair of the ***MSAG*** disapprove the change, the assessment, or affected parts thereof, must be conducted again with an approved assessment team.
d. The Division Chief will convey the dates of the assessment to ***NVLAP***, which will maintain the overall schedule of assessments. (Dates will depend upon availability of assessors. ***NVLAP*** will work with the Division and the assessors to determine a mutually agreeable schedule.)
e. The assessment team will conduct both a documentation assessment and a conformity assessment.
f. At the conclusion of the assessment, the assessment team leader will meet with the Division Chief and other staff, as appropriate, to report findings, to cover any nonconformity issues, and to discuss how the nonconformity issues will be addressed. This will be primarily a verbal interaction supported by assessment notes, annotated checklists, etc.
g. The team leader will prepare a written Assessment Report, to be signed by both the team leader and the Division Chief, listing all fully conforming services, and all nonconforming services with the nonconformities that must be resolved and the schedule for resolving them. The team leader will provide copies of this report to the ***Laboratory*** Director, the Chair of the ***MSAG***, and the Chair of the Assessment Review Board (ARB).
h. If the team leader and the Division Chief cannot reach agreement upon a nonconformity issue or upon a remedy for a nonconformity issue, the issue will be presented to the ***Laboratory*** Director and the Chair of the ***MSAG***, who together will determine an appropriate course of action. This extreme case should be rare, occurring only in cases of significant and dramatic differences of opinion on important matters.
i. The ARB will confirm its receipt of the Assessment Report to the team leader and begin the

review process as described under "2) Assessment Review."

j. The Division Chief has 90 calendar days to respond in writing to the assessment team report. Failure to do so may result in ***MSAG*** requiring that a new review be initiated.

k. Once the nonconformities have been resolved, the team leader will prepare a written Final Report, signed by both the team leader and the Division Chief, indicating that the specified services or reference material certification laboratories are in conformity with the NIST QMS, and listing the actions taken to resolve the nonconformities identified in the Assessment Report. The team leader will send the Final Report to the ***Laboratory*** Director, the Chair of the ***MSAG,*** and the Chair of the Assessment Review Board (ARB)**.**

2. Assessment Review

a. A small board of experienced assessors – the ARB – will review the Assessment Report and Final Report to ensure that (1) the team conducted the assessment properly, (2) the nonconformities noted were valid, and (3) the responses to the nonconformities resolved the nonconformities. The ARB will discuss outstanding issues, if any, with the team leader and Division Chief, who will take the actions necessary to resolve them.

b. The ARB will comprise six (6) staff members, one each from EEEL, MEL, CSTL, MSEL, PL, and ***NVLAP***. The ***NVLAP*** representative will serve as Chair. A representative from the Statistical Engineering Division will serve as a resource to the ARB as needed.

c. The ARB will conduct its reviews in two stages. First, the Assessment Report, including the proposed schedule for resolution of any noted nonconformities will be reviewed per clauses 2.a.(1) and 2.a.(2), above. For services that have no reported nonconformities, a recommendation can be made to the ***MSAG*** that these specific services be declared in conformity with the NIST Quality Management System. The second stage review will be conducted after the team leader and Division Chief submit the Final Report certifying that all remaining nonconformities have been resolved. This review will address clause 2.a.(3). At this point a recommendation can be made that all services within the Division are in conformity with the NIST Quality Management System. If there are no nonconformities declared in the Assessment Report, both stages of the review process can be completed at once.

d. The ARB will also review the completed Assessment and Final Reports as a set to ensure that the assessment process is consistent across the NIST ***Laboratories*** and to identify possible improvements in the assessment process. Following this review, the ARB will report to the ***MSAG*** on the quality and uniformity of the assessments, and propose changes to the assessment process, if warranted, to improve uniformity or efficiency in the next assessment cycle.

e. If the ARB, team leader, and Division Chief cannot reach agreement on an outstanding issue, the issue will be presented to the ***Laboratory*** Director and the Chair of the ***MSAG***, who together will determine an appropriate course of action. As above, this extreme case should be rare, occurring only in cases of significant differences of opinion.

f. The ARB will forward Assessment and Final Reports to the ***MSAG*** with its recommendation that the ***MSAG*** find the specified services or reference material certification laboratories of the Division to be in conformity with the NIST QMS.

g. The ***MSAG*** will declare the specified services or reference material certification laboratories of the Division to be in conformity with the NIST QMS via memorandum to the Division Chief and other parties, as appropriate.

h. Any given declaration of conformity may apply to all services or reference material

certification laboratories within a Division at one time or only for selected services or reference material certification laboratories as specified by the Division Chief and documented in the Assessment and Final Reports submitted for review. If reports are submitted only for selected services or reference material certification laboratories within a Division, it will be the responsibility of the Division Chief and the team leader to assure that Final Reports for all services or reference material certification laboratories within the Division are submitted according to the schedule established by the ***MSAG***.

The ***MSAG*** will provide ***NVLAP*** with a copy of the final memorandum and assessment report, which ***NVLAP*** will retain for future reference.

3. Approval of the quality management systems in support of the CMCs: SIM review of the NIST Quality Management System

In the fulfillment of the ***CIPM MRA***, an ***NMI*** is required to have its quality management system reviewed and approved by its Regional Metrology Organization (RMO). The RMO of which NIST is a member is the Inter-American Metrology System (SIM). SIM representation includes the 34 member countries of the Organization of American States (OAS).

The CIPM MRA provides for the following approaches for the approval of an NMI quality management system:

a) an ***NMI*** that chooses for its ***calibration*** and ***measurement services*** a quality system that meets the requirements of ISO/IEC 17025 or equivalent for an ***NMI***, assessed by an accreditation body fulfilling the requirements of ISO 17011, declares its ***calibration measurement capabilities*** and submits them to the local RMO for review and transmission to the Joint Committee of the RMOs and the BIPM (JCRB) for analysis and inclusion in Appendix C of the ***CIPM MRA***.

b) an ***NMI*** that chooses to use a different way of assuring quality or chooses a different quality system, or ISO/IEC 17025 without third-party assessment, for its ***calibration*** and ***measurement services*** declares its ***Calibration and Measurement Capabilities*** and submits them to the local RMO for review and transmission to the JCRB for analysis and inclusion in Appendix C.

Demonstration of competence and capability may require visits and examination of procedures by an ***NMI*** and/or by peers selected by the local RMO.

SIM is responsible for reviewing the quality management systems submitted by its member ***NMIs*** and reporting on their acceptance or rejection. SIM reports to the JCRB, which in turn uses this process to help build confidence among the ***NMIs*** by establishing a transparent QMS review process, which is mutually acceptable among all RMOs.

In 2002, the SIM Council approved the creation of a task force for reviewing the QMS of SIM ***CIPM MRA*** signatories. The SIM ***CIPM MRA*** signatories comprise the ***NMIs*** in Argentina, Bolivia, Brazil, Canada, Chile, Costa Rica, Ecuador, Jamaica, Mexico, Panama, Paraguay, Peru, United States, and Uruguay. In addition, in October 2004, a block of Caribbean nations (CARICOM/CARIQ) signed the

MRA. The SIM associate representative to the JCRB coordinates the task force work. The task force is referred to as the SIM Quality System Task Force (SIM QSTF).

NIST has a self-declared quality management system using the NIST assessment process described previously. After the ***MSAG*** approves the NIST quality management system for a given measurement service area, the quality management system is presented to the SIM QSTF for review at their meetings. Several weeks prior to the SIM QSTF meetings, the following evidence is presented to the task force members for their review along with the quality manuals in the following format:

Section 1: Quality Management System Structure

The quality policy statement, the organization chart of the ***NMI*** (as it pertains to the delivery of ***measurement and calibration services***), and quality management policies and procedures (including identification of Quality Manager roles and responsibilities).

Section 2: Quality Manual Components

The table of contents, a cross-walk between the sections of the Quality Manual and the ISO/IEC 17025 and/or ISO Guide 34 sections, a listing of relevant ***CMCs***, and a list of technical procedures.

Section 3: Quality Management System Implementation

- Statistics on customer complaints, nonconforming work, and corrective actions
- Quality Management philosophy and process of handling the above listed items
- Internal Audits
- Qualifications of the assessor team
- Management reviews
- External reviews (if applicable)

Section 4: Assessment Process

Accredited ***NMIs*** need to show the following:

- **CMC** uncertainties are not smaller than the uncertainties listed in the scope
- Accreditation body is a signatory to the ***ILAC*** MRA
- Name of the Accreditation body and the names of the technical assessors
- Copy of the Accreditation Certificate

Self-declared and Peer Reviewed ***NMIs*** need to show the following:

- Description of the Assessment Process
- Executive Summary of the Report
- Copy of the Report for Peer reviewed ***NMIs***

In addition, SIM requires that all ***NMIs*** with ***CMCs*** provide an annual report to the SIM QSTF that describes participation in ***Key Comparisons*** and any changes in the ***NMI*** that would affect the delivery of the ***CMCs***.

In order for an ***NMI*** to retain its ***CMCs*** in the ***CIPM MRA*** Appendix C listing, the re-assessment process including RMO approval needs to be completed within 5 years of the previous approval.

Appendix C. Statements of Uncertainty Associated with Measurement Results

A measurement result is complete only when accompanied by a quantitative statement of its uncertainty. This policy requires that NIST measurement results be accompanied by such statements and that a uniform approach to expressing measurement uncertainty be followed.

1. Background

Since the early 1980s, an international consensus has been developing on a uniform approach to the expression of uncertainty in measurement. Many of NIST's sister ***NMIs*** as well as several important metrological organizations, including the Western European Calibration Cooperation (WECC) and the European Association of National Metrology Institutes (EURAMET), have adopted the approach recommended by the International Committee for Weights and Measures ***(CIPM)*** in 1981 [1] and reaffirmed by the ***CIPM*** in 1986 [2].

Equally important, the ***CIPM*** approach is now widely used throughout NIST, and is also becoming accepted in U.S. industry. For example, the National Conference of Standards Laboratories International (NCSLI) is using it to develop a Recommended Practice on measurement uncertainty for NCSLI member laboratories.

The responsibility for maintaining, developing, and disseminating the ***CIPM*** approach to measurement uncertainty rests with the ***BIPM***'s Joint Committee for Guides in Metrology (JCGM). This Committee promotes the use of the *Guide to the Expression of Uncertainty in Measurement* (known as the *GUM*) [3], prepares supplemental guides for its broad application, and revises and promotes the use of the *International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (**VIM**)* [JCGM 200:2008].

2. Policy

All NIST measurement results are to be accompanied by quantitative statements of uncertainty. To ensure that such statements are consistent with each other and with present international practice, this NIST policy adopts in substance the approach to expressing measurement uncertainty recommended by the ***CIPM***. The ***CIPM*** approach as adapted for use by NIST is:

a. *Standard Uncertainty*: The standard measurement uncertainty of a measurement x of a scalar measurand is the expression of measurement uncertainty in terms of a standard deviation $u(x)$ (the square root of the mean squared difference between the measurement and its expected value, corresponding to the probability distribution that encapsulates such measurement uncertainty).

b. *Combined Standard Uncertainty:* For a measurement $y = f(x_1,\ldots,x_n)$ of a scalar measurand that is a function of input quantities $x_1,\ldots,x_n$, it is y's standard measurement uncertainty $u_c(y)$, which results from the propagation of the standard uncertainties $u(x_1),\ldots,u(x_n)$ of the input quantities, and may be obtained either approximately, using the GUM's *law of propagation of uncertainty*, or exactly by application of suitable analytical or simulation methods.

c. *Expanded Uncertainty:* For a measurement y of a scalar measurand, it is $U(y) = ku_c(y)$, the product of y's combined standard uncertainty $u_c(y)$ and a factor $k > 1$ that depends on the probability distribution of the output quantity y, and on the choice of probability with which the interval from $y - U(y)$ to $y + U(y)$ (commonly written $y \pm U(y)$) should include the measurand's true value.

   Expanded uncertainty $U(y)$ is used to report the results of all NIST measurements other than those for which $u_c(y)$ has traditionally been employed. The value $k = 2$ is conventionally used at NIST unless specific measurement situations or applications require otherwise. Under particular assumptions, the choice $k = 2$ ensures that $y \pm U(y)$ covers the measurand with 95% probability.

d. *Reporting Uncertainty:* Report U together with the coverage factor k used to obtain it, or report u_c. When reporting a measurement result and its uncertainty, include the following information in the report itself or by referring to a published document:

   - A list of all components of standard uncertainty, together with their degrees of freedom where appropriate, and the resulting value of u_c. The components should be identified according to how they are evaluated:
     - Type A evaluation of a component of measurement uncertainty is by a statistical analysis of measured quantity values obtained under defined measurement conditions;
     - Type B evaluation of a component of measurement uncertainty is determined by means other than a Type A evaluation of measurement uncertainty: for example, evaluation based on information associated with published quantity values, or with the quantity value of a certified reference material, or obtained from a calibration certificate, or inferred from the accuracy class of a verified measuring instrument, or corresponding to limits deduced through personal experience.
   - A detailed description of how each component of standard uncertainty was evaluated.
   - A description of how k was chosen when k is not taken equal to 2.
   - When a probabilistic interpretation is assigned to $y \pm u_c(y)$ or to $y \pm U(y)$, for example by regarding these as intervals that include the measurand with specific probabilities, then the basis for such interpretation also must be given.

Additional guidance on the use of the ***CIPM*** approach at NIST may be found in *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results* [4]. A more detailed discussion of the ***CIPM*** approach is given in the *Guide to the Expression of Uncertainty in Measurement* [3]. Classic expositions of the statistical evaluation of measurement processes are given in references [5-7].

3. Responsibilities

a. Operating Unit Directors are responsible for conformity with this policy.
b. The Statistical Engineering Division of the Information Technology Laboratory is responsible for providing technical advice and concurrence on statistical methods for evaluating and expressing the uncertainty of NIST measurement results, including those that pertain to SRMs, calibrations, interlaboratory studies, and key comparisons.

c. NIST Editorial Review Boards are responsible for ensuring that statements of measurement uncertainty are included in NIST publications and other technical outputs under their jurisdiction, which report measurement results, and that such statements are in conformity with this policy.
d. The ***Measurement Services Advisory Group*** is responsible for ensuring that calibration and test reports, other technical outputs under its jurisdiction are in conformity with this policy.
e. The groups within the ***Measurement Services Division*** are responsible for ensuring that technical outputs under their jurisdiction are in conformity with this policy.
f. Authors, as part of the process of preparing manuscripts and other technical outputs, are responsible for formulating measurement uncertainty statements consistent with this policy. These statements must be present in drafts submitted for NIST review and approval.

4. Exceptions

Any statistical method that the Statistical Engineering Division determines to be valid for the assessment of measurement uncertainty in the particular circumstances of each measurement situation may be employed to determine the equivalent of standard, combined, or expanded uncertainty, or otherwise to represent measurement uncertainty. It is also recognized that international, national, or contractual agreements to which NIST is a party may occasionally require deviation from this policy. In both cases, the uncertainty report must document what was done and why.

5. References Cited

[1] CIPM, *BIPM Proc.-Verb. Com. Int. Poids et Mesures* **49**, 8-9, 26 (1981) (in French); P. Giacomo, "News from the BIPM," *Metrologia* **18**, 41-44 (1982).

[2] CIPM, *BIPM Proc.-Verb. Com. Int. Poids et Mesures* **54**, 14, 35 (1986) (in French); P. Giacomo, "News from the BIPM," *Metrologia* **24**, 45-51 (1987).

[3] ISO, *Guide to the Expression of Uncertainty in Measurement*, prepared by ISO Technical Advisory Group 4 (TAG 4), Working Group 3 (WG 3), October 1993. ISO/TAG 4 has as its sponsors the BIPM, IEC, IFCC (International Federation of Clinical Chemistry), ISO, IUPAC (International Union of Pure and Applied Chemistry), IUPAP (International Union of Pure and Applied Physics), and OIML. Although the individual members of WG 3 were nominated by the BIPM, IEC, ISO, or OIML, the *Guide* is published by ISO in the name of all seven organizations. NIST staff members may obtain a single copy of the *Guide* from the Measurement Services Division.

[4] B. N. Taylor and C. E. Kuyatt, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, NIST Technical Note 1297, prepared under the auspices of the NIST Ad Hoc Committee on Uncertainty Statements (U.S. Government Printing Office, Washington, DC, January 1993).

[5] C. Eisenhart, "Realistic Evaluation of the Precision and Accuracy of Instrument Calibration Systems," *J. Res. Natl. Bur. Stand.* (U.S.) **67C**, 161-187 (1963). Reprinted, with corrections, in *Precision Measurement and Calibration: Statistical Concepts and Procedures*, NBS Special Publication 300, Vol. I, H. H. Ku, Editor (U.S. Government Printing Office, Washington, DC, 1969), pp. 21-48.

[6] J. Mandel, *The Statistical Analysis of Experimental Data* (Interscience-Wiley Publishers, New York, NY, 1964, out of print; corrected and reprinted, Dover Publishers, New York, NY, 1984).

[7] M. G. Natrella, *Experimental Statistics*, NBS Handbook 91 (U.S. Government Printing Office, Washington, DC, 1963; reprinted October 1966 with corrections).

This policy is included in the Administrative Manual, Appendix E of Subchapter 4.09 titled Statements of Uncertainty Associated with Measurement Results [http://www-i.nist.gov/admin/mo/adman/409appe.htm#Appendix%20E] with the following updates under "responsibilities" - "The Standard Reference Materials and Standard Reference Data programs" was updated to "The groups within Measurement Services Division" and "Calibration Advisory Group" was updated to "Measurement Services Advisory Group."