NIST Quality Manual for Measurement Services

NIST-QM-I

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1. Introduction

1.1 Institutional Commitment to Quality

The provision of measurement services, which include ***calibration, certified reference material, Standard Reference Instruments, and Standard Reference Data*** related services, is an essential element of the work carried out by 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 this 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, ISO/IEC 17043 and ISO/TS 8000 as they apply to the related measurement services that NIST delivers.

Signed:

WS May Date: 12/27/16

Dr. Willie May,
Under Secretary of Commerce for Standards and Technology & Director,
National Institute of Standards and Technology

1.2 Scope

The quality management system described in this manual covers ***measurement services*** (***calibration***, ***reference material***, and ***Standard Reference Data***) provided to customers both internal and external to NIST. In general, the scope of the NIST quality management system for ***measurement services*** encompasses all services listed on the *NIST Calibrations website*, *NIST Standard Reference Materials website*, and the *NIST Standard Reference Data website*. In particular, specific services covered by the NIST QMS are those that are declared in conformity by the ***NIST Quality Manager***. For the purposes of this document, the term "reference material" refers to the entire category of NIST artifact-based services such as ***Standard Reference Materials® (SRMs®), Reference Materials (RMs), NIST Traceable Reference Materials (NTRMs),*** 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 this quality management system includes ***NIST's Calibration and Measurement Capabilities (CMCs)*** listed in Appendix C of the ***Comité International des Poids et Mesures Mutual Recognition Arrangement (CIPM MRA)***
[Calibration and Measurement Capabilities - CMCs].

1.3 Structure 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, Associate Director for Laboratory Programs, Laboratory, and Office 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 Office to meet its technical needs. The sub-level quality management systems and quality manuals vary in detail among the NIST Divisions and Offices 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 or Office 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 establishing homogeneity, stability, value assignment, and uncertainty evaluations for assigned values. For ***Standard Reference Data***, the NIST-QM-xx series addresses, in addition to the relevant above items, the quality objectives specific for integrity of data products and identifies the critical evaluation methods and techniques.

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 Directives Management System and the Administrative Manual [Standard Reference Data Program, Standard Reference Materials Program and Calibration Program], 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 Directives Management System and 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 NIST Directives Management System.

The NIST QMS does not separately address policy or procedures for environmental-, safety-, or health-related activities or compliance. These are established elsewhere within the NIST organization and are documented on NIST's Safety website. Compliance with these policies is both mandatory and essential for providing quality services safely and in an environmentally responsible manner.

2.1 Informative References

CIPM MRA "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, Technical Supplement revised in October 2003 (pages 38-41)

ISO Guide 30:2015 Reference Materials – Selected terms and definitions

ISO Guide 31:2015 Reference materials – Contents of certificates, labels and accompanying documentation

ISO Guide 33:2015 Reference materials – Good practice in using reference materials

ISO Guide 34:2009 General requirements for the competence of reference material producers

ISO Guide 35:2016 Reference materials – General and statistical principles for certification

ISO/TR 11773:2013 Global distribution of reference materials

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

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

ISO/IEC 17034:2016 General requirements for the competence of reference materials producers, published 2016-11-01

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

ISO 13528:2015 Statistical methods for use in proficiency testing by Interlaboratory comparison

ISO 8000-2:2012 Data quality – Part 2: Vocabulary

ISO/TS 8000-120:2009 Data quality – Part 120: Master data: Exchange of characteristic data: Provenance

ISO/TS 8000-150:2011 Data quality – Part 150: Master data: Quality management framework

ISO 19011:2011 The guidelines for auditing management systems

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].

JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd Edition, 2008 edition with minor corrections. [http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf]

NIST Directives Management System and the NIST Administrative Manual

NIST Ethics Rules http://www.commerce.gov/ethics

NIST Measurement Services Council [https://inet.nist.gov/nmsc]

NIST Quality Manager Handbook [https://share.nist.gov/sites/qs/assessor/default.aspx]

NIST Quality System website, (external) [http://www.nist.gov/nistqs]

NIST Quality System website, SharePoint (internal) [https://share.nist.gov/sites/qs/SitePages/Home.aspx]

NIST Special Publication 260-136 – "Definitions of Terms and Modes Used at NIST for Value-Assignment of Reference Materials for Chemical Measurements" (2000). [http://www.nist.gov/srm/upload/SP260-136.PDF]

NIST Special Publication 811 – "The NIST Guide for the Use of the International System of Units" [http://www.nist.gov/pml/pubs/sp811/index.cfm]

NIST Technical Note 1297 – "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results" [http://physics.nist.gov/Pubs/guidelines/TN1297/tn1297s.pdf]

NIST Technical Note 1900 – "Simple Guide for Evaluating and Expressing the Uncertainty of NIST Measurement Results" [http://dx.doi.org/10.6028/NIST.TN.1900]

Position Classification Manual of the NIST Alternative Personnel Management System [http://inet.nist.gov/ohrm/classification-manual.cfm]

SIM 09, SIM Procedure for Review of the Quality Management System of National Metrology Institutes and Designated Institutes [available on the NIST Quality System SharePoint site].

USPS Publication 28, Chapter 2 Postal Addressing Standards [http://pe.usps.gov/cpim/ftp/pubs/pub28/pub28.pdf]

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. Notes are included within some definitions to provide additional guidance.

ARB (Assessment Review Board)
a subcommittee of the NIST Measurement Services Council that reviews the NIST-level Assessment Reports to ensure that (1) the assessment 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 the Division Quality Manager and/or Division Chief/Office Director, who will take the actions necessary to resolve them. The ARB also reviews the completed Assessment Reports as a set to ensure that the assessment process is thorough and consistent across the NIST and to identify possible improvements in the assessment process. Following this review, the ARB reports to the ***NIST Quality Manager*** on the quality and uniformity of the assessments, and proposes changes to the assessment process, if warranted, to improve uniformity or efficiency in the next assessment cycle. ARB also reviews Corrective Actions taken that rise to the level of NIST-QM-I, provides review and feedback on draft revisions and implementation of NIST-QM-I and for the draft presentations on the NIST Quality System to be made by the NIST Quality Manager at the SIM Quality System Task Force.

A named member of the ARB serves as back-up to the NIST Quality Manager as needed.

BIPM (Bureau International des Poids et Mesures)
body established by the Convention of the Metre and headquartered near Paris, France. Its purpose 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 [http://kcdb.bipm.org/]
web application 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 200:2012, Section 2.39]

Calibration and Measurement Capabilities (CMCs)
in the context of the ***CIPM MRA*** and ***ILAC*** Arrangement, and in relation to the CIPM-ILAC Common Statement, the following shared definition is agreed upon: a CMC is a calibration and measurement capability available under normal conditions: a) as published in the BIPM key comparison database of the ***CIPM MRA***; or b) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement as defined in the CIPM MRA-D-04.

calibration method
defined technical procedure for performing a calibration.

Calibration Services (Note: use of title case is specific and intended)
name of the NIST-wide program that includes business functions and the technical functions carried out by NIST Laboratories (see description below under Physical Measurement Laboratory).

calibration services (Note: use of lower case is specific and intended)
technical functions performed by NIST 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.

Calibration Support System (CSS)
web-based database system that provides access to technical, financial, and administrative data on calibrations performed by NIST. [https://iapps.nist.gov:7300/css/home.htm]

Catalog of NIST Calibration Services
web-based publication describing the ***calibration services*** available from NIST including the technical contacts for the services, the service identification numbers, and fees/costs for the service, and provides links to publications that describe the measurement systems and measurement methods. The information contained in the ***Catalog of NIST Calibration Services*** was previously published as the NIST SP250 Users Guide.

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
document stating the intended purpose and application of an SRM, its certified property value(s) with associated uncertainty(ies), and any other technical information deemed necessary for its proper use. In accordance with ISO Guide 31:2000, 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. 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: 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***.

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

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

Comité International des Poids et Mesures (CIPM)
International Committee for Weights and Measures. The CIPM is made up of 18 individuals, each from a different country from among the 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. CCs also identify and implement ***key comparisons*** of ***calibration and measurement capabilities*** that underpin the measurement services provided by ***National Metrology Institutes (NMIs)***, called for in the ***CIPM MRA***. [CIPM: International Committee for Weights and Measures]

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

CIPM MRA
Mutual Recognition Arrangement covering national measurement standards and calibration and measurement ***certificates*** issued by ***NMIs***. Originally signed by the Directors of NMIs for the 38 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. [CIPM MRA 2003]

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)

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 qualifies as a Quality Management System concern, (See Section 4.5.2)

database
an organized collection of data that can be textual, numerical, or in image format that is accompanied by metadata.

Data Management Plans
all federally funded research data generated after October 1, 2015 is being addressed in project-level Data Management Plans. The Data Management Plans (DMP) address, among other things, the level of preservation and level of access. While measurement service data generated specifically for customers is restricted for public release, the data will be covered by a DMP. Some DMP's may refer the data control process described within the NIST Quality Management System, typically in the sub-level documents. (See section 5.7.2)

Designated Institute (DI)
entity that is formally identified by a country or economy's NMI as being responsible for a specified metrology area within the implementation of the CIPM MRA.

IEC (International Electrotechnical Commission)
the international standards and conformity assessment body for all fields of electrotechnology.

International Laboratory Accreditation Cooperation (ILAC)
international cooperation of laboratory and inspection accreditation bodies formed more than 30 years ago to help remove technical barriers to trade. ***ILAC*** has worked in cooperation with ***BIPM***, the International Organization of Legal Metrology (OIML), and ***ISO*** to a joint declaration on ***metrological traceability***. ILAC

also has established Guidance and Policy documents on topics of accreditation for ***NMIs*** and expression of ***measurement uncertainty*** for calibrations.

ISO (International Organization for Standardization)
network of national standards institutes 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.

Joint Committee of the Regional Metrology Organizations and the BIPM (JCRB)
body comprising the Regional Metrology Organizations (RMOs) along with the BIPM. It coordinates the activities among the RMOs in establishing confidence for the recognition of calibration and measurement certificates, according to the terms of the ***CIPM MRA***. ***JCRB*** makes policy suggestions to the RMOs and to the ***CIPM*** on the operation of the ***MRA***, analyzes the application by each RMO of the criteria of the MRA, analyzes and enters into Appendix C the proposals of each RMO for the ***calibration and measurement capabilities*** of their member ***NMIs*** and reports to the ***CIPM***, facilitates appropriate inter-regional supplementary comparisons, and writes an annual report on the activities of the ***JCRB*** to the ***CIPM*** and to the signatories of the ***MRA***.

key comparison is one of the set of comparisons selected by a Consultative Committee or RMO to test the principal techniques and methods in a field. Key comparisons may include comparisons of representations of multiples and sub-multiples of SI base and derived units and comparisons of artifacts. Key comparisons are also designed to test the capabilities of the participating NMIs/DIs for delivering services as described in their respective CMCs.

key comparison reference value (KCRV)
reference value qualified with an evaluation of the associated uncertainty resulting from a ***CIPM key comparison***.

Laboratory (Note: use of title case is specific and intended)
organizational layer at NIST, sometimes referred to as an organizational unit (OU). (See 4.1.3.1 Organizational Charts) [http://www.nist.gov/director/orgchart.cfm]

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

Material Measurement Laboratory
laboratory organizational unit at NIST that is responsible for policies and business, administrative, documentary, record keeping, storage and warehousing for NIST ***Standard Reference Data*** and NIST ***Standard Reference Materials*** (see below for ***ODI*** and ***ORM***).

measurement
experimental or computational process that, by comparison with a standard, produces an estimate of the true value of a property of a material or virtual object or collection of objects, or of a process, event, or series of events, together with an evaluation of the uncertainty associated with that estimate, and intended for use in support of decision-making [NIST TN 1900, Section 2]

(Note VIM definition for information purposes: the process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity. [JCGM 200:2012, Section 2.1])

Measurement Assurance Program (MAP)
typically, a stable artifact or set of artifacts that are first measured by NIST then sent to a customer's laboratory for a series of measurements. The transfer standards are then returned to NIST for re-

measurement, along with the participating laboratory's results. NIST reports its comparative findings to the customer and, when applicable, offers guidance on achieving and maintaining measurement quality.

(NIST) measurement service
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 sub-level quality documents.

measurement uncertainty
doubt about the true value of the measurand that remains after making a measurement; measurement uncertainty is described fully and quantitatively by a probability distribution on the set of values of the measurand; at a minimum, it may be described summarily and approximately by a quantitative indication of the dispersion (or scatter) of such distribution [NIST TN 1900, Section 3]

(Note VIM definition for information purposes: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. [JCGM 200:2012, Section 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 200:2012, Section 2.41]

National Metrology Institutes (NMIs)
organizations that 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.

NIST Directives Management System (DMS)
will replace the NIST Administrative Manual as the primary communication system for NIST operations and administrative documents. The purpose of the DMS is to ensure effective management and operation of NIST, to provide staff with accurate and authoritative information regarding policies, requirements, and procedures needed for the administration and operation of NIST programs and activities.

NIST Measurement Services Council (NMSC)
the NIST Measurement Services Council (NMSC) serves the ADLP in an advisory role to identify and address NIST-wide issues related to the quality, relevance, performance, operations, and resources allocated to the health and improvement of NIST measurement services; and identify and address critical NIST-wide issues affecting measurement services and the national measurement standards underpinning them. The NMSC Charter and meeting minutes are available on the website https://inet.nist.gov/nmsc

NIST Quality Manager
person responsible for the implementation and independent assessment of the NIST Quality Management System for NIST ***measurement services***.

NIST Quality Manager Handbook
internal document that provides guidance to the procedures and processes that the NIST Quality Manager uses

in the conduct of their duties. [https://share.nist.gov/sites/qs/assessor/default.aspx]

NIST Special Publication (SP) 260, Standard Reference Materials Catalog
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})
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.

Office of Data and Informatics (ODI)
entity within the Material Measurement Laboratory that provides business, administrative, and documentary support for NIST Standard Reference Data.

Office of Reference Materials (ORM)
entity within the Material Measurement Laboratory that provides business, administrative, and documentary support for NIST Standard Reference Materials (SRMs). Office of Reference Materials is also responsible for the maintenance of the ***CSS.*** ORM's quality system is based on ISO/IEC 9001.

Physical Measurement Laboratory
laboratory organizational unit at NIST that is responsible for policies and business, administrative, and record keeping support for NIST Calibration Services.

Principal Investigator
the NIST employee primarily responsible for the development and maintenance of Standard Refernce Data which is produced wholly or partially by NIST.

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.

> NOTE 1: RM is a generic term.
> NOTE 2: Properties can be quantitative or qualitative, e.g., identity of substances or species.
> NOTE 3: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.
> NOTE 4: A single RM cannot be used for both calibration and validation of results in the same measurement procedure.
> NOTE 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]

SP 250 Series publications
documentary supplements to the ***NIST Special Publication (SP) 250, NIST Calibration Services Users Guide*** 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 a characterization of all sources of uncertainty and their summarization in an 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 250s is available on the web [http://www.nist.gov/calibrations/sp250_series.cfm].

SP 260 Series publications
documentary supplements to the ***NIST Special Publication (SP) 260, Standard Reference Materials Catalog*** 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 or Certificate of*** **Analysis** or than can be found in articles in scientific journals. The complete library of published SP 260s is available on the web [http://www.nist.gov/srm/publications.cfm].

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

Standard Reference Data
quantitative information, related to a measurable physical or chemical property of a substance or system of substances of known composition and structure, which is critically evaluated as to its reliability. NIST Standard Reference Databases are copyright protected. They are produced under the authority of Public Law 90-396. See also http://www.nist.gov/srd/.

Standard Reference Instrument (SRI)
a Standard Reference Instrument (SRI) is a calibrated device provided by NIST to its customers that may be used as a link in a metrological traceability chain. The NIST Office of Reference Materials offers a variety of Standard Reference Instruments for sale. Typically, they are portable versions of instruments used at NIST to realize and disseminate a measurement unit. For some SRIs, NIST also offers optional accessories that enable customers to address specialized measurement needs.

NIST Calibration Services provides measurement traceability as an optional Special Test for each SRI purchased by a customer. Additional optional services associated with the sale of an SRI include installation at the customer site and consultation on the use of the device. Each SRI is accompanied by a Specifications Report, and by a Metrological Report listing measurement results (measured values and evaluations of the associated measurement uncertainty), and a statement of metrological traceability.

Standard Reference Material® (SRM®)
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]

Standards Information Center (formerly NCSCI)
resource offered by the NIST Standards Coordination Office, which maintains subscriptions to International and National Standards Bodies libraries of documentary standards. As a free service to NIST employees, electronic copies of documentary standards, including the referenced within NIST-QM-I are made available upon email request to StandardDocs@nist.gov. Copyright rules and regulations apply to all standards and documents provided by the Standards Information Center. https://inet.nist.gov/adlp/howdoi/request-a-standard

sub-level quality documents (NIST-QM-xx's [QM-II's, QM-III's, etc.]) NIST's quality management system is multi-level. NIST-QM-I is the NIST-level manual. Typically, QM-II is the Division-level (or Office-level) manual, and 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. The entire series comprise

the NIST quality management system for NIST's measurement services. Non-controlled copies of the Division/Office QM-II's are located on the Quality SharePoint site https://share.nist.gov/sites/qs/division_docs/default.aspx

subcontractor
(In context of NIST use of this term for activities covered in the scope of this Quality Manual)
one who would provide 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 comparisons
interlaboratory studies carried out by the RMOs to meet specific needs not covered by ***key comparisons***, including comparisons to support confidence in calibration and measurement certificates. Consultative Committees may decide to run a supplementary comparison when there are only a few participants capable of measuring the quantity, when no link can be made to an RMO comparison or when the distribution of samples to measure is a constraint (for instance: measurements of radioactive matrix reference materials).

test folder number
unique serial number issued by NIST that indicates that an official calibration or test has been requested by a Customer (external to NIST).

verification / validation
provision of objective evidence that a given item fulfils specified requirements (JCGM 200:2012, Section 2.44), with validation being a special case of verification where the specified requirements are adequacy for an intended use (JCGM 200:2012, Section 2.45). For example, the composition of a gas mixture reference material prepared gravimetrically may be verified or validated by measuring it using gas chromatography calibrated independently of the gravimetric preparation, and then ascertaining that the amount-of-substance fraction of each measurand measured gravimetrically, and the corresponding fraction measured using gas chromatography, are not statistically significantly different when they are compared taking into account their respective associated uncertainties.

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 – Updated with America COMPETES Act) that defines NIST and its functions. The legislation authorizing NIST's measurement service activities is codified in 15 USC Subtitle B Chapter II Subchapter A Part 200 [http://www.ecfr.gov/cgi-bin/textidx?SID=8c7b7e50cff24aee107c683da778f759&node=15:1.2.2.1.1&rgn=div5.] The Department of Commerce's Department Organization Orders prescribe the assignment of functions to NIST.

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 is committed to providing a safe 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 5 C.F.R Part 2635: Standards of ethical conduct for employees of the executive branch, on the NIST Ethics website [http://inet.nist.gov/ohrm/services/upload/ethicsstandards.pdf], and in Subchapter 5.06 of the NIST Administrative Manual [http://inet.nist.gov/mando/directives/506.cfm].

4.1.2 Physical Locations

Calibrations and ***reference materials certifications*** are conducted at the NIST sites [http://www.nist.gov/locations.cfm] in Gaithersburg, MD, Boulder, CO, and Charleston, SC and in some cases at special facilities away from the NIST campuses. If special facilities are used, descriptions of these facilities are documented in the NIST sub-level quality documentation.

4.1.3 Organizational Structure for the provision of *NIST measurement services*

4.1.3.1 Organization Charts

Five (5) of the major organizational units within NIST's Laboratory Programs are directly involved with the provision of the calibration reports, reports-of-test, and/or ***reference material certificates*** and are covered by this manual. Figure 4.1 provides a schematic representation of this part of the NIST organization.

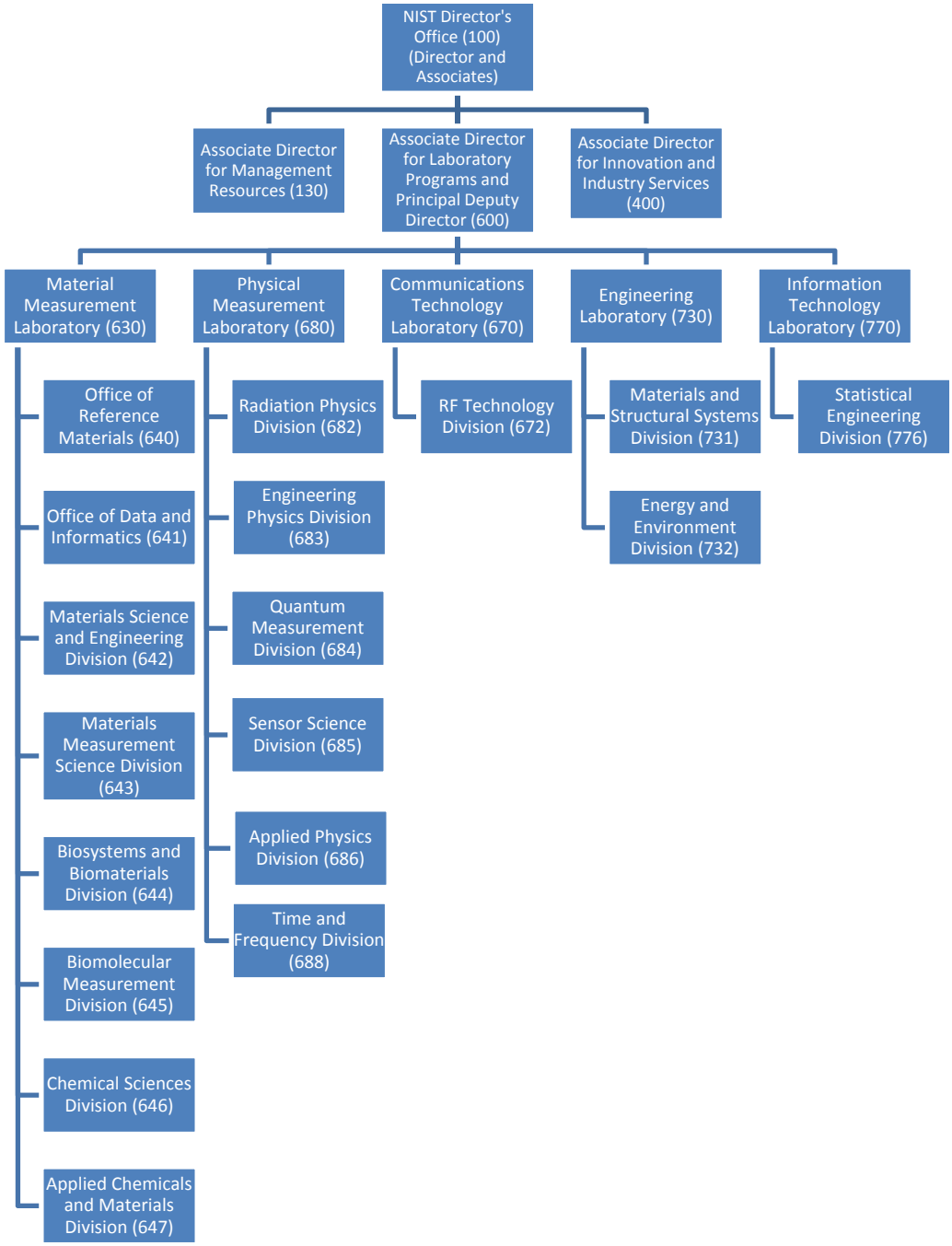

Figure 4.1 Schematic organization chart for units directly involved in provision of NIST measurement services covered by the scope of the quality management system.

The technical effort required to deliver ***NIST measurement services*** is made by scientific and technical staff within the appropriate Divisions. 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 technical Divisions and in the Laboratories. The Statistical Engineering Division of the Information Technology Laboratory supports the development of statements of ***measurement uncertainty*** for NIST calibrations, reference materials, and for measurements that NIST contributes to interlaboratory studies and to ***Key Comparisons***. ***The Material Measurement and the Physical Measurement Laboratories*** provide business, administrative, and documentary support for ***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 positions in the NIST organization are indicated in Figure 4.2. These Offices and Divisions, with examples of their functions that affect the provision of ***measurement services*** are:

Office of Financial Resource Management, which handles customer billing and payment;
Management and Organization, whose responsibilities include the maintenance of the NIST Administrative Manual and the NIST Directives Management System;
Office of Human Resources Management, which provides assistance with hiring, training, position classification, and personnel records;
Office of Acquisition and Agreements Management, which provides support for procurement of equipment and materials and shipping and receiving;
Office of Facilities and Property Management and Boulder Site Management Office, whose efforts focus on providing and maintaining the physical facilities and laboratory environments in addition to mail services and shipping and receiving of parcels and packages (including incoming customer equipment for calibration);
Office of Information Systems Management, which provide facilities and support critical to operation of all NIST's information technology infrastructure;
Fabrication Technology which provides a wide range of engineering, fabrication, and technical service to support the creation of unique measurement instruments and scientific apparatus needed by NIST scientists;
Office of Safety, Health and Environment, which plans, develops, organizes, and directs the Occupational Health, Safety, and Environmental Compliance Programs for NIST.

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/]. The functional statements that pertain to all NIST organizational units can be found at [http://inet.nist.gov/mando/services/mando_serv_funct_stmts.cfm].

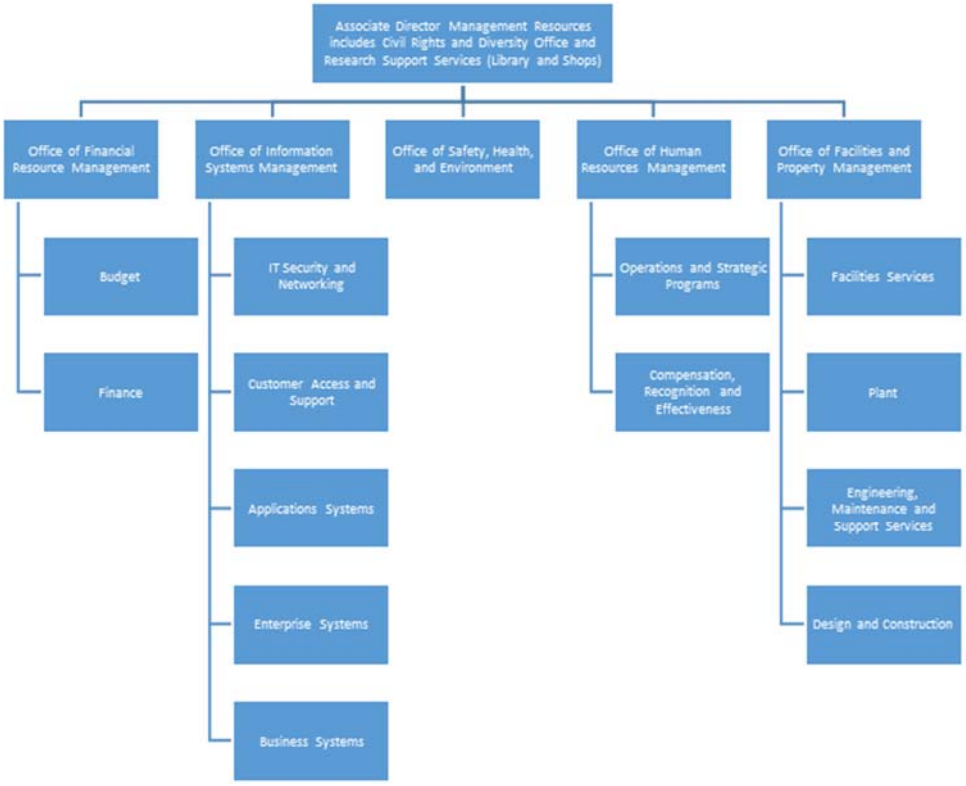

Figure 4.2 Organization chart for units that contribute support services to the provision of ***NIST measurement services***. (Laboratories and Divisions that provide direct services, (cf., Figure 4.1) are included to indicate relative positions in the organizational hierarchy.)

4.1.3.2 Responsibilities, Authorities, and Delegations

NIST provides ***measurement services*** as part of its 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, Associate Director for Laboratory Programs, Laboratory Director, and Division Chief, applies to the management activities of the ***measurement services***. 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].

The Associate Director for Laboratory Programs has ultimate line management responsibility for the provision of measurement services that meet the needs of industry, academia, and other government offices. Within the Office of the Associate Director, the NIST Quality Manager has responsibility for the quality of those ***measurement services*** by overseeing the implementation and assessment of the NIST Quality Management System. 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 approve the initiation or cessation of specific ***measurement services*** within their OU. The Physical Measurement Laboratory (PML) Director is responsible for the creation and implementation of policy affecting the provision of calibration services. The Material Measurement Laboratory (MML) Director is responsible for the creation and implementation of policy affecting the provision of ***reference materials and Standard Reference Data***.

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*** Certificates and Certificates of Analysis in the name of the NIST Director.

The responsibilities of the NIST Director, Associate Director for Laboratory Programs, and Laboratory Directors are documented in the Department of Commerce Directive DOO 30-2B. The responsibilities of all other management, administrative, support, scientific, and technical staff are documented in official Position Descriptions and individual Performance Agreements or Plans. Performance excellence is the responsibility of every NIST staff member and every level of management.

4.2 NIST Quality Management System for Measurement Services

4.2.1 NIST Policy for Measurement Quality

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 its measurement 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 producing measurement results for ***key comparisons***, 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)***. The NIST policy for measurement quality is a component of the NIST Directives Management System identified as NIST P 5400.

Further, it is NIST policy that its ultimate responsibility for providing ***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 core values include customer focus and excellence. 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) and many other practical units of measurement. 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 ***NMIs***, both as a means of assuring the quality of its ***measurement services*** and to satisfy the requirement that U.S. standards are consistent with those of other NMIs and with the SI, within stated uncertainties. Special priority is given to ***key comparisons*** conducted under the auspices of the ***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, in particular including statements of uncertainty that are fit for purpose as qualifiers of NIST calibrations, of values assigned to reference materials, and of values measured by NIST in interlaboratory studies, including key comparisons; and
  - timely and cost effective (provide real value to the customers).

- NIST provides ***Standard Reference Data*** (databases) that are customer-focused and, at a minimum, are:

  - accurate – The data must be accurately stored as finalized by the data evaluators.

  - correct – The retrieved data must be the correct data for the property and substance selected.

  - reliable – The database must be reliable, that is, it must work every time for every function.

  - provided with provenance – Sources of information provided in the database must be sufficiently documented to allow it to be reproduced.

NIST provides secure and confidential customer access to information on ***calibration*** work in progress via the NIST ***Calibration Support System (CSS)***.

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 provision of NIST measurement services.

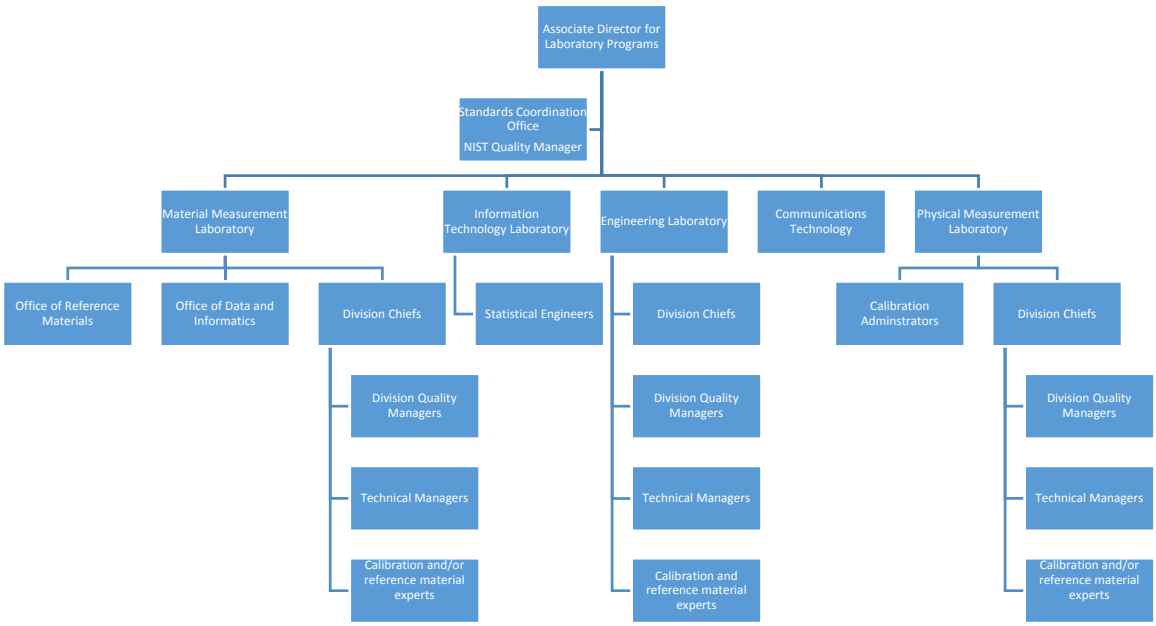

Figure 4.3 Organizational hierarchy of the management of the NIST QMS. (See the NIST organizational chart available at [http://orgchart.nist.gov/] for complete names of the listed Laboratories and Divisions.)

4.2.3.2 Responsibilities, Authorities, and Delegations

The NIST Director is ultimately responsible for the quality of ***NIST measurement services***. This responsibility is delegated to the Associate Director for Laboratory Programs, and, in turn, to the Directors of the Laboratories directly involved in providing measurement services. The responsibility for the implementation and assessment of the NIST Quality Management Systems belongs to the NIST Quality Manager. The Physical Measurement Laboratory (PML) Director is responsible for the creation and implementation of policy affecting the provision of calibration services. The Material Measurement Laboratory (MML) Director is responsible for the creation and implementation of policy affecting the provision of ***reference materials*** and ***Standard Reference Data***. The NIST Director and the ***Associate Director for Laboratory Programs*** approve the NIST-QM-I and its revision upon recommendation of the Directors of MML and PML and the NIST Quality Manager. The authority for approval of an individual Division's or Office's part of the NIST sub-level quality documentation is delegated to the Chief of that Division or Director of that Office and the NIST Quality Manager.

The ***NIST Quality Manager***

1) organizes and schedules NIST-level quality management system assessments;
2) conducts a NIST-wide evaluation of individual Division management reviews and produces a report on the health of the NIST QS;
3) serves as chair of the NIST Measurement Services Council
4) assures timely completion of any revisions of NIST-QM-I such as those required by any changes that occur in applicable international standards such as ISO 17025 and ISO Guide 34;

5) maintains document control for NIST-QM-I;
6) serves as the NIST representative to the SIM Quality System Task Force for the presentation of NIST quality systems and assessments and for the review of the quality systems of other SIM NMIs;
7) reviews the NIST quarterly quality reports and provides a cumulative summary quarterly report to the Associate Director of Laboratory Programs, the OU Directors, and the relevant Division Chiefs/Office Directors;
8) ensures that NIST assessors are trained.

The back-up for the NIST Quality Manager is a member of the Assessment Review Board. This person serves in this role in the event that the NIST Quality Manager is unavailable to fulfill their responsibilities as listed above.

The Division Chiefs and Office Directors are responsible for implementing the NIST Quality Management System for ***measurement services*** at the Division/Office level. Division Chiefs/Office Directors 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/Office Directors appoint a Division Quality Manager and ideally a Deputy Quality Manager.

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, the collection, generation, or evaluation of standard reference data,or ***reference material*** characterization are managed under Section 2.06.03b of that Subchapter and within the Comprehensive Records Schedule under Scientific and Technological Records. 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 obtained as part of a calibration procedure, SRD evaluation, or ***reference material*** characterization that are part of the sub-level quality documentation are specified therein. The policies and procedures herein are supplemental to the more general Federal and NIST requirements governing computer and information security [NIST operational information system security requirements].

4.3.2 Document Approval and Issue

The official version of NIST-QM-I is maintained on the NIST Quality System for Measurement Services (SharePoint site) [https://share.nist.gov/sites/qs/QMI/Forms/AllItems.aspx]. This site is readily available to all NIST staff. Other controlling documents such as the NIST Administrative Manual and others contained in the NIST Directives Management System are on the NIST intranet and are linked within this document. The 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 NIST servers. These servers have appropriate security and backup systems in place.

The ***NIST Quality Manager*** is responsible for assuring that the current versions of NIST-QM-I and the NIST sub-level quality documentation that are available on the internal and external websites are the official versions and copies thereof, respectively.

Appendix D contains the procedure for Revision and Document Control of NIST-QM-I.

4.3.3 Document Changes

After a revision of NIST-QM-I is approved as the official version, the ***NIST Quality Manager*** notifies all Laboratory Directors, 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 or on the NIST Quality System SharePoint site. 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 maintained by the ***Materials Measurement Laboratory (MML) and the Physical Measurement Laboratory (PML)*** and posted on the following web pages: 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 Associate Director for Laboratory Programs and the Directors of PML and MML.

The procurement of NIST calibration services can be accomplished through the Physical Measurement Laboratory's Calibration Administrators. Ordering information is available on the NIST Calibrations website.

The procurement of a NIST reference material can be accomplished through the ***Office of Reference Materials*** Sales and Customer Services Group. Orders can be placed by phone, fax, or through the SRM website. The SRM website also contains the catalog of currently available reference materials from NIST.

The procurement of NIST Standard Reference Instruments (SRI) can be accomplished through the ***Office of Reference Materials (ORM)***. Descriptions of the SRI's are available from the ORM website and potential customers are encouraged to first communicate with the NIST Technical Contact listed on the webpage for each SRI. The ORM administrative and sales staff process the orders for the physical devices of the SRI's and the Calibration Administrators process the procurements of testing and other services available in conjunction with the particular SRI as described in the Specifications Certificates.
The procurement and arrangement of use of NIST Standard Reference Data can be accomplished through the ***Office of Data and Informatics***. NIST delivers SRD using a variety of ways. Information on the access to and availability of NIST SRD and other NIST data products is found on the website, Standard Reference Data. NIST SRD is commonly distributed as web applications, direct downloads from the NIST SRD E-Commerce System, mailed as CD or DVD, or available via distributors who resell the product or that incorporate SRD into their own products. All SRD are copyrighted. Licensing and Distributor agreements are arranged through the ***Office of Data and Informatics*** and vary based on the intended use. Primary licenses available include: single users, network subscriptions, single site, and multi-site. Distributor and integrator agreements are also available. SRD available for free have copyrights on file in the ***Office of Data and Informatics.***

Additional information about the activities within this general framework and the staff responsible for various steps are presented for each Division/Office in the NIST sub-level quality documentation. Non-controlled copies of these are found on the Quality SharePoint site

https://share.nist.gov/sites/qs/division_docs/default.aspx

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 portal of the Commerce Business System [Office of Acquisition & Agreements Management Customer Support Website]. In cases where the required products and services must meet special requirements to assure the quality of a particular NIST measurement service, these requirements are authorized by the Division Chief and documented in the NIST sub-level quality documentation.

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 perform functions that affect the provision of ***NIST measurement services***. It is NIST policy that these supporting Divisions will collaborate cooperatively with the technical Divisions to provide services and facilities that allow ***NIST measurement services*** to be 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 services***. 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 the responsibility for specific 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 Policy P 5600.00 and Order O5601.00 Standard Reference Materials Program for production and control processes.

4.5 Corrective and Preventive Actions

4.5.1 Non-Conformity and Corrective Actions

4.5.1.1 Actionable Items within the activities in scope of the NIST-QM-I and the NIST Measurement Quality Policy

The Corrective Action Procedure is found in Appendix A.

4.5.1.2 Division or Office Quality Action Items

If there is evidence derived from any source, including customer feedback, that any activity supporting the provision of a ***measurement service*** is not or has not been in conformity with the requirements of the NIST QMS, management of the Division/Office 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/Office's quarterly quality report.

4.5.2 Customer Feedback and Concerns (also see Section 4.7)

All staff members are responsible for assessing the significance of complaints, with guidance from their supervisors 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 assigned to address complaint, 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/Office-maintained complaint log.

Collection and recording of this information can be facilitated by use, as appropriate, of the NIST QMS Non-conformity and Corrective Action Form (NCAF), shown as an exhibit in Appendix A, or another form as specified in the sub-level quality documentation. Complaints related to ***measurement services*** of other Divisions should be forwarded to the relevant Divisions through Division quality managers.

NIST pro-actively seeks customer feedback from its ***measurement service*** customers. Customer satisfaction surveys for Calibrations and Reference Materials are available online. The ***CSS*** also provides a link so that customers can provide feedback on the calibration services they have received from NIST https://www.surveymonkey.com/s/pml-calibrations. The NIST SRM website contains a link to their customer survey https://www.surveymonkey.com/r/nistsrm_survey. The SRM survey results are reported in the quarterly quality reports submitted by the Office of Reference Materials. Calibration survey results are reported quarterly directly to the NIST Quality Manager. SRD webpages contain a "Contact Us" email link that allows queries, comments, and feedback. Metrics and indicators from this mechanism are reported quarterly directly to the NIST Quality Manager.

4.5.3 Preventive Actions

All NIST employees are encouraged to identify needs and opportunities to improve technical and quality procedures and policies. The appropriate levels of technical and quality managers 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/Office managers, Division quality manager, and staff members review trends and analyze data in search of preventive actions that would foster continued and improved quality. Preventive actions and opportunities for improvement are acted upon and recorded within the Division/Office quality management systems. NIST-level preventive actions are recorded in the minutes of the NIST Measurement Services Council meetings.

4.6 Assessments and Management Reviews

4.6.1 NIST-Level Assessments (also known as NIST-Level Peer reviews)

Quality system reviews conducted by assessors who are external to the service-providing Division/Office are called NIST-Level Assessments. They are organized by the ***NIST Quality Manager*** and conducted in accordance with the assessment process described in Appendix B. The frequency shall be at least once every 5 years.

4.6.2 Division/Office-Level Audits (also known as internal audits) and NIST-QM-I internal audits

In addition to undergoing the assessments outlined in Appendix B, each technical Division is responsible for assuring the technical quality of its measurement results. Supporting offices are responsible for verifying the objectives of the supporting functions. At a minimum, there shall be two Division-Level audits conducted in between the NIST-Level assessments that shall address all elements of the quality management system. These internal audits shall occur at least every two years, but preferably each year. To that end, each Division shall periodically, and in accordance with their predetermined schedule and procedure, conduct internal audits that include the review of its technical procedures and/or its quality system documentation to verify that its measurement service operations, and especially the calibration and measurement capabilities, continue to be in compliance with its quality management system. Each internal audit need not cover all aspects of a Division's/Office's quality management system, but collectively the audits shall cover all aspects of the Division/Office QMS within the two-year timeframe. Because these technical reviews may vary in detail from service to service, the audit procedure and schedule are documented in the NIST sub-level quality documentation. In conducting these technical reviews, a Division may involve internal and/or external technical experts. For additional information on quality assurance practices, see Section 5.9.

In addition, NIST-QM-I will undergo an internal audit at least every two years.

4.6.3 NIST-Level Management Reviews

NIST-level management reviews are conducted on a quarterly basis by Laboratory Directors or their delegates and the ***NIST Quality Manager.*** These reviews are based on the analysis of the quarterly reports that Divisions submit to their respective Laboratories, which in turn submit them to the ***NIST Quality Manager***. Laboratory Directors or their delegates shall review the Division reports to see if there are any systemic issues that need to be addressed in any Division or in the Laboratory as a whole. Their analyses shall be included in the quarterly submission to the ***NIST Quality Manager***. The ***NIST Quality Manager*** shall:

- review all Office, Division, and Laboratory reports, assessing the implementation of the NIST QMS and conformity to ISO/IEC 17025 and ISO Guide 34, as appropriate;
- report to the NIST Associate Director for Laboratory Programs a summary of the findings, recommendations, and implementation plans, if required;
- communicate this information to Offices, Divisions, and Laboratories as appropriate;
- record this report and a report of any actions taken subsequent to the presentation to the NIST Associate Director for Laboratory Programs as part of the documentation of the NIST QMS; and

- make recommendations, if any, as to the fitness of any specific measurement service in the NIST portfolio to the Associate Director for Laboratory Programs.

Typically, management reviews will rely on information reported by the Division/Office Quality Manager and Division Chief/Office Director to his or her respective Laboratory Director or designee and then to the NIST Quality Manager. The current template for the Division reports is located on the NIST Quality System SharePoint site. These reports address the requirements found in ISO/IEC 17025 Clause 4.15 and items specific to NIST.

The management review report for the Office of Reference Materials is comprised of data from their quality event log database for the given quarter. The quality event summaries include topics of SRM sales, returns, and adjustments along with customer satisfaction survey graphs for SRMs. Quarterly the Physical Measurement Laboratory submits to the NIST Quality Manager the customer survey results for Calibrations Quarterly the Office of Data and Informatics provides the NIST Quality Manager with customer survey results for Standard Reference Data.

4.7 Service to the Client

Customer focus is a core value of NIST. We anticipate the needs of our customers and are committed to meeting or exceeding their expectations.
NIST technical representatives who provide ***measurement services*** shall maintain communication with their clients. Communication can occur through a variety of means, including phone calls and email correspondence. Such communication is especially necessary 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 meetings 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 technical staff.

Conferences and tradeshows are opportunities for NIST to showcase to a wide audience various measurement services to specific user communities, including new and existing customers, clients, and stakeholders.

NIST has also implemented the use of the ***CSS*** website to provide NIST Calibration Customers with information on the status of their calibration jobs. Other specific client service measures may be found in the NIST sub-level quality documentation.

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 NIST. All other technical requirements are located in, or referenced in, the NIST sub-level quality documentation.

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 characterization or in the collection, archival, evaluation, and production of reference data and databases must be proficient in performing the required tasks in the opinion of the NIST expert responsible for the calibration, measurement, reference material, or reference database; and
2) NIST must have on staff, or have regular advisory access to, a nationally or internationally recognized expert in the calibration, measurement, reference material, or standard reference data area.

Assuring competence is the direct responsibility of the management chain for ***measurement 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://inet.nist.gov/mando/directives/1008.cfm] 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 calibrations, ***reference materials***, SRD, and related ***measurement services*** is that of the management chain for 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 manuals. The criteria for evaluating the effectiveness of the training are found in the sub-level quality manuals.

5.2.3 Job Descriptions

Primary responsibilities, experience, and qualifications pertinent to calibrations, reference materials, and SRD 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 may support NIST in the development and characterization of a reference material or the development of a reference database. Guest researchers, CRADA partners, contractors, grantees, and informal collaborators are potential categories of collaborators. Any such collaborator will be selected by the technical Division on the basis of technical excellence with regard to the measurements and materials required. These collaborations will be carefully documented and appropriately referenced on applicable certificates. The technical Divisions are responsible for determining the extent to which collaborators must comply with this quality management system and its informative references.

NIST is solely responsible for the value assignments in all measurement services. Calibrations are performed under the CRADA authority. Only NIST employees can perform and provide calibrations and sign the calibration reports.

Another technical Divisions may collaborate in a supporting role with a SRM project lead in another technical Division to provide measurements and measurement results used and reported in the

Certificates of Analysis. In those instances, the supporting Division's measurement activities will be covered and documented in their own quality system. Should there not be an existing quality system, the supporting Division may document their role in the lead technical Division's quality system.

Note that the NIST definition and its use of collaborators is different from the definition as found in ISO/IEC 17025:2005 and ISO Guide 34, as they use the term "subcontractor" as a synonym for "collaborator."

5.3 Accommodations and Environmental Conditions

NIST recognizes the critical roles 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 offices and 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 documentation.

5.4 Measurement 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 documentation.

5.4.2 Reference Materials

When characterizing ***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 measurements 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 value-assigned, the method specific to value assignment and proper use is clearly indicated. Detailed descriptions of reference material characterization methods and procedures, methods of validation, and measurement uncertainty are documented in the sublevel quality documentation by the appropriate technical Division.

5.4.3 Evaluation of Uncertainty & Verification of Measurement Results

All reported NIST measurement results, including those in test or calibration reports for ***calibration services***,

and in ***Certificates*** and ***Certificates of Analysis*** 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 ***CIPM***, as described in the 1995 edition of the GUM (Guide to the Expression of Uncertainty of Measurement, JCGM 100:2008) and in NIST Technical Notes 1297 and 1900, all available on the NIST website This approach is described in Appendix C of this manual.

The verification of a value assigned to a property of a reference material involves measuring the value of the property independently of how it was measured for the purpose of value assignment, and ascertaining that the difference between the corresponding measured values is not statistically significant, when they are compared by application of a statistical test that takes into account their associated uncertainties. Similarly, the verification of a calibration involves performing another calibration of the same instrument or artifact, independently of the calibration being verified, and ascertaining that corresponding measured values produced as a result of the two calibrations are not statistically significantly different once their associated uncertainties are taken into account.

When a verification of a reference material is performed, and no statistically significant difference is found (that is, the reference material "passes" the verification test), and the measurement results produced during the verification are not used to update the value assigned to the reference material, then neither the originally assigned value, nor the uncertainty evaluated originally, will change: in other words, the verification does not exact a penalty in additional uncertainty. Only when the measurement results obtained for the purpose of verification are also used to update the assigned value, may the resulting assigned value and associated uncertainty change. And in such case, the resulting uncertainty may be larger or smaller than the uncertainty originally associated with the originally assigned value, depending on the measurement results being combined and on the procedure used to combine them. Similar provisions apply to calibrations.

5.4.4 Control of Data generated during the provision of NIST Measurement Services

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 documentation.

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. Various data backup methods are available from OISM including Tier 1 and Tier 2 level services. The default sensitivity rating for information technology (IT) systems in the technical laboratories and offices will be maintained at a level of Low, Low, Low, respectively, as a minimum. The calibration business system has a sensitivity rating of Medium, Medium, Low. See the inventory of NIST Information System Security Requirements for further information about information technology security policies at NIST.

5.4.5 Evaluation of NIST Standard Reference Data

The critical evaluation techniques, methods, and procedures employed by the NIST technical divisions shall be documented in the sub-level quality manuals. The Division chiefs have the responsibility to ensure that the evaluations of NIST data products are documented in sufficient detail and that the documentation addresses data accuracy, reliability, correctness, and provenance. Publications that explain SRD or support SRD are considered technical publications therefore they undergo the NIST Editorial Review Board's process of review and approval per NIST Administrative Manual Section 4.09 NIST Technical Communications.

5.5 Equipment

NIST recognizes the critical role that well-maintained, state-of-the-art equipment plays in the provision of measurements, ***calibrations***, ***standard reference data***, and ***reference materials*** 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 management. The technical Divisions determine the requisite equipment needs and, for consideration by their Laboratory Directors, provide prioritized requests for funds to develop or purchase equipment. The technical Divisions are also responsible for the maintenance, calibration, storage, safe and proficient operation, quality assurance, and documentation of all equipment supporting ***calibration***, ***standard reference data***, and ***reference material*** services. This includes software validation and data storage. The details of the Division processes for selection, handling, and maintenance of equipment are documented in the NIST sub-level quality documentation.

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 ***VIM*** (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 documentation and other documents referenced therein. Rigorous traceability is a core competency of NIST.

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

Within NIST, internal calibrations across Divisions and organization structure are encouraged for maintaining the metrological traceability for the measurement services. When practical, time and cost constraints should be minimized.

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

[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.

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 ***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 documentation.

5.7.2 Characterization of Reference Materials

For reference materials, when samples of in-process material and/or of process material are required for characterization 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). ***The Office of Reference Materials*** staff may perform sampling operations with guidance and specifications from the technical Division.

Preparation, homogeneity, and stability assessment are specific to each ***reference material*** characterized. 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 documentation.

Data plans that are aimed towards the ability to reproduce the Reference Materials need to address Discoverability and Preservation. The data plans are documented in the NIST sub-level quality documentation of the technical Divisions.

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 documentation and/or the ***reference material*** project completion memo.

5.9 Quality Assurance Practices

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

- repeat measurements/calibrations compared over many time intervals;
- stability testing of reference materials;
- comparison of results obtained using multiple reference standards;
- use of check standards and control charts;
- consistency checks, review, and verification of data;
- critical evaluation of data;
- 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, conform to ISO/IEC 17025:2005 and at a minimum, contain or address 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, and service id number;
- if required, the complete specification of a special test, either explicitly or by reference;
- the Test Folder number;
- page numbers, with the last page designated as the end of the report;
- the name and address of the client (refer to USPS Publication 28, Postal Addressing Standards);
- 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;
- an evaluation of the measurement uncertainty associated with each measured value;
- 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;
- statement of traceability;
- methods used to obtain property values (when method dependent); and
- period of validity.

Further details and descriptions of specific types of certificates, if relevant, are found in the sublevel quality documentation.

5.10.3 Distribution of Standard Reference Data

The distribution of SRD shall include or address the following:

- SRD identifier
- name of database
- intended use
- instructions for use
- NIST name and/or logo
- NIST point of contact name (principal investigator) and their contact information (example; email address and phone number)
- disclaimer or warrantee statement (if not addressed by the license agreement)

Divisions that provide SRD on their hosted websites for free are responsible for identifying the point of contact for that product. The PI is responsible for responding promptly to customer surveys and public inquiries. The Division will need to ensure the site is maintained with adequate reliability and uptime, and to devote resources to the NIST quarterly and annual security assessment and authorization IT processes.

Websites that contain NIST Standard Reference Data products shall conform to the DOC and NIST web policies, incorporate the feature to collect usage statistics, contain links to copyright (if applicable) and to the SRD feedback form.

5.10.4 Signatory Authority

All Reports of Calibration and Reports of Special Test shall be signed by personnel explicitly authorized to do so. It will also include the phrase, “For the Director of the National Institute of Standards and Technology” under the signature.

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(s) of the NIST officer(s) authorized to accept responsibility for their contents.

Appendix A. Corrective Action Procedure

1 PURPOSE AND SCOPE

The purpose of this procedure is to specify how NIST identifies and manages nonconformities found in its provision of Measurement Services, its quality management system, within the scope of the NIST-QM-I and the NIST Measurement Quality Policy. The procedure describes the processes for actions to eliminate the causes of nonconformities in order to prevent their recurrence (corrective actions).

2 REFERENCES

2.1 *NIST-QM-I, the NIST quality manual for measurement services*

2.2 NIST Policy for Measurement Quality

3 DEFINITIONS

There are no definitions that are specific to this procedure. See *NIST-QM-I.*

4 RESPONSIBILITIES

The following positions and groups have responsibilities that are described in this procedure:

a) Assessment Review Board (ARB);

b) Quality Manager;

c) ADLP;

e) all NIST staff who measurement services in an administrative or technical capacity.

5 PROCEDURE

5.1 Identifying nonconformities

Nonconformities are identified by, but not limited to, the following activities:

a) internal audits;

b) NIST assessments; including continuing after actions following ARB reviews of the NIST assessments;

c) complaints;

d) quarterly quality reports/management reviews;

e) staff observations.

5.2 Determining the causes of and correcting nonconformities

5.2.1 An identified nonconformity is handled to a degree commensurate with the magnitude of the problem, the potential consequences, and the level of risk involved. Some nonconformities may require the use of the formal corrective action process (see 5.3); others may have simpler remedies.

5.2.2 The NIST Quality Manager reviews the inputs from the activities listed in 5.1. If a nonconformity is identified, the corrective action process is initiated.

5.2.3 The ARB, chaired by the Quality Manager, may also initiate formal corrective action for nonconformities they detect arising from after actions following reviews of NIST assessments.

5.3 Formal corrective action process

5.3.1 The ARB is responsible for reviewing requests for corrective actions.

5.3.2 If the committee identifies a need for formal corrective action, it issues a corrective action request (CAR) to the staff member responsible for the area where the problem exists (hereinafter called the "CAR owner").

5.3.3 The Quality Manager assigns a reference number to the CAR and completes the form shown in Exhibit 1, ensuring that the nonconformity statement is clearly written and references the requirement that is not in conformance. The "reply requested by date" is normally 30 days from the issue date of the request; however, the date may vary depending upon the severity and/or complexity of the required action.

5.3.4 The Quality Manager forwards a copy of the form to CAR owner and creates a case file for the quality records.

5.3.5 The CAR owner investigates the extent of the problem and determines the root cause(s) of the nonconformity. He/she enters the root cause, corrective action to be taken, and expected completion date on the CAR form, and signs and dates the form to indicate endorsement of and commitment to the corrective action plan. A copy of the form (the reply) is returned to the Quality Manager.

a) If the CAR owner belongs to a Division having an implemented quality system, the corrective action will be processed according to that Division's quality management system's corrective action procedures.

b) Copies of records of closed corrective actions taken by the Divisions that were initiated by the NIST Quality Manager or Assessment Review Board will be forwarded to the NIST Quality Manager upon their closure.

5.3.6 If the root cause(s) is determined to be outside the CAR owner's area of responsibility, the CAR form, including the description of the root cause, is returned to the Quality Manager for reassignment.

5.3.7 The ARB conducts timely reviews of all CAR replies and takes one of the following actions.

a) If the action to be taken and expected completion date are acceptable to the committee, the Quality Manager signs the CAR form and notifies the CAR owner to proceed with implementation.

b) If the action to be taken and/or expected completion date are not acceptable, the CAR form is returned to the owner for revisions, along with the committee's comments.

c) If a disagreement exists as to the acceptability of the action plan and date, the CAR form and any related documentation are forwarded to the ADLP, who will do what is necessary to establish resolution.

5.3.8 The CAR owner ensures that the corrective actions are carried out according to the plan and notifies the Quality Manager when all actions are completed.

5.3.9 If a CAR remains open after its estimated completion date, the Quality Manager will request its status from the owner and extend the date, if needed. If there is no response to the status request, the Quality Manager will notify the ADLP, who will take action to foster the successful completion of the CAR.

5.3.10 The completed corrective actions are reviewed by the ARB. If the board considers the action(s) to be satisfactory, the Quality Manager indicates that on the CAR form and enters the date the action(s) was completed.

5.3.11 The Quality Manager enters the date the CAR was closed after all affected procedures, instructions, and forms are revised and reissued, as needed.

5.4 Corrective action follow-up

5.4.1 The status and results of open CARs and CARs recently closed are considered as inputs to management reviews for the ADLP.

5.4.2 Closed CARs will be reviewed and verified for effectiveness at the internal audit following their closure.

5.5 Records

The completed CAR form and supporting documentation are filed and maintained by the Quality Manager for at least five years. These records may be saved in either electronic or hard copy format.

Exhibit 1. NIST Non-conformity and Corrective Actions Form

Non-conformity and Corrective Actions Form FRM-01-NCAF

FY: ____ **CAR Log No.: __**

NIST QMS or Measurement Service: _____ **Forwarded to Measurement Service: __**

Initiator: _____ **Date Received: ------**

Quality Manager (QM): _____ **Date Received: ------**

Assessment Review Board Member: _____ **Date Received: ------**

Forwarded to CAR Owner: _____ **Date Received: ------**

COMPLAINT

Does this qualify as a complaint? ☐ Yes ☐ No. If Yes, complete this subsection.

Customer: _____ **Phone Number: _____**

Point-of-Contact: _____ **Email: _____**

Folder Number: _____ **SRM Number: _____** **SRD Number: _____**

NON-CONFORMITY

Request as a result of Nonconforming work [ ] **Internal Audit [ ]**

Management Concern [ ] **NIST Assessment [ ]**

Customer Advisory [ ] **ARB Concern [ ]**

Other:

Concern:

Initial Response:

CAR Owner Initials: _____ **Date: ------**

NIST QM Initials: _____ **Date: ------**

Cause Analysis:

CAR Owner Initials: _____ **Date: ------**

NIST QM Initials: _____ **Date: ------**

CORRECTIVE ACTION

Does this non-conformity require a corrective action? ☐ Yes ☐ No. If Yes, complete this subsection.

Corrective Actions:

POC Initials: _____ **Date: ------** **ARB member Initials: _____** **Date: ------**

FOR QM ONLY

Follow-up with Customer:

QM Initials: _____ **Date: ------**

Date Closed: -----

Appendix B. Process for NIST-Level Assessments of the Quality Management System that Supports the Delivery of the Measurement Services and Provides Confidence in the NIST *CMCs* According to the *CIPM MRA*

B1. Assessment

The purpose of the NIST-Level Assessment is to determine the compliance of the implementation of the NIST Quality System within the Divisions providing NIST *measurement services*. The scope of the assessment is the portfolio of services offered by the Divisions with particular attention to the declared *CMCs* in the *CIPM MRA*. The assessment will include all requirements of the NIST QM-I. This is ensured by the use of the NIST QM-I checklist by the NIST assessors.

a. It is the responsibility of the NIST Quality Manager to select the assessment teams. The NIST Quality Manager will consider Division Chief/Office Director input in that decision. The goal in team selection will be to have the strongest possible team composition having specific technical expertise and no line management reporting with the specific measurement area under assessment thereby eliminating the possibility of undue pressure from management. The NIST Quality Manager will serve as an administrative resource to the assessment team. The NIST Quality Manager can elect to observe any or all aspects of the assessment process.

   The criteria for selection of assessment team members must meet the following requirements (SIM 09):

   - experience in assessing Quality Management Systems of NMIs
   - knowledge and experience assessing the management requirements of ISO/IEC 17025 and/or ISO Guide 34 and/or the NIST Quality System including but not limited to ensuring appropriate policies regarding qualifications and neutrality of personnel, provision of appropriate supervision, ensuring confidentiality of results and impartiality of staff, policies regarding document and records control, demonstration of a commitment to customer service, appropriate handling of complaints, policy for addressing nonconforming work and corrective actions, procedure for regular internal audits and management reviews
   - knowledge and experience assessing the technical requirements of ISO/IEC 17025 and/or ISO Guide 34 relevant to the field of the CMCs supported by the QMS, including test and calibration methods, measurement uncertainty assessments, and method validation

b. Each team will consist of at least two (preferably three or more) qualified assessors including one team leader. The assessors, including the team leader, shall be from outside the Division/Office being assessed with at least one member 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, NIST retirees maybe used via a CRADA with the Standards Alumni Association, and 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 NIST Measurement Services Council.
c. The Laboratory Director must concur with the assessment team selected by the NIST Quality Manager 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 NIST Quality Manager finds it necessary to make such a change, the Laboratory Director must concur with the change proposed by the NIST Quality Manager.
d. The Division Chief/Office Director, along with the Division/Office quality manager will work in

collaboration with the NIST Quality Manager, regarding the specific dates and logistics of the assessment. The NIST Quality Manager will maintain the overall schedule of assessments, in particular with regard to the deadlines of *RMO* review. See B3 below. Exact assessment dates will depend upon availability of assessors. The NIST Quality Manager will work with the Division/Office management and the assessors to determine a mutually agreeable schedule.

e. At the beginning of the assessment, the assessment team will conduct an opening meeting with Division/Office management (technical and quality) and the measurement service staff. The purpose will be to articulate the scope and objectives of the assessment. Last-minute changes to schedules may occur. The assessment team will conduct both a documentation and a conformity assessment. The assessment activity will determine if the Division/Office quality system documentation addresses the requirements of NIST QM-I. It will further identify through collection of evidence, if there is compliance by the Division/Office that the NIST quality system is being followed – and that the practices of the laboratories congruent with its quality system. The assessment will also include a review of the technical competency with emphasis on quality assurance practices and evidence thereof.
f. The team leader will prepare a written Assessment Report using the template provided by the NIST Quality Manager, to be signed by both the team leader and the Division Chief/Office Director, listing all fully conforming services, and all nonconforming services with a list of the nonconformities that must be resolved. A spreadsheet (template provided by the NIST Quality Manager) of the findings, which will serve as a data record for the remainder of the assessment review process, will also be presented to the Division/Office, At the conclusion of the assessment, the assessors led by their team leader, will conduct a closing meeting with the Division Chief/Office Director, quality management team and all measurement service staff, as appropriate, to report findings.
g. The team leader will provide copies of the final report to the Laboratory Director, Division Chief/Office Director, Division quality manager, and the NIST Quality Manager (who also serves as 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 NIST Quality Manager, who, after discussing the issue with the Laboratory Director, 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/Office Director working with the Division/Office quality manager has 90 calendar days from receipt of the assessment findings report memo to respond in writing to the assessment team report by demonstrating evidence of corrective actions to the nonconformities. These will be recorded in the findings/corrective action spreadsheet (see item f above). Failure to close out the findings and take proper timely corrective action may result in *the NIST Quality Manager* requiring that a new assessment 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/Office Director, 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 and the *NIST Quality Manager* who serves as the Chair of the Assessment Review Board (ARB).

B2. Assessment Review

a. A small group of experienced NIST assessors (who are NIST employees) – the ARB – will review the Assessment Report, Findings with corrective actions, along with the quality manuals 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/Office Director, who will take the actions necessary to resolve them.
b. The ARB will comprise five (5) staff members selected from MML (2), PML (2), and EL (1). The *NIST Quality Manager* serves as the nonvoting Chair.
c. The ARB can conduct its review after the team leader and Division Chief/Office Director submit the Final Report certifying that all nonconformities have been resolved. At this point a recommendation can be made that all services within the Division/Office are in conformity with the NIST Quality Management System.
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 *NIST Quality Manager* 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/Office Director cannot reach agreement on an outstanding issue, the issue will be presented to the NIST Quality Manager, who, after discussing the issue with the Laboratory Director, 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 the Assessment and Final Reports to the *NIST Quality Manager* with its recommendation that the *NIST Quality Manager* find the specified services or reference material certification laboratories of the Division/Office to be in conformity with the NIST QMS.
g. The *NIST Quality Manager* 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/Office Director and other parties, as appropriate.
h. Any given declaration of conformity may apply to all services or reference material certification laboratories within a Division/Office at one time or only for selected services or reference material certification laboratories or SRD curators as specified by the Division Chief/Office Director and documented in the Assessment and Final Reports submitted for review. If reports are submitted only for selected services or reference material certification laboratories or SRD curators within a Division/Office, it will be the responsibility of the Division Chief/Office Director and the team leader to assure that Final Reports for all services or reference material certification laboratories or SRD curators within the Division/Office are submitted according to the schedule established by the *NIST Quality Manager*.

The *NIST Quality Manager* will provide secure storage for the assessment records, which the NIST Quality Manager will retain for future reference.

B3. 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 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 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). The SIM Council also agreed in 2005 to the following general guidelines:

- any SIM Member NMI can request the review of its quality management system, even if it is not yet a signatory of the MRA;
- a meeting to review the QMS of NMIs will be held at least once a year. The meeting will be open to all SIM members and observers from other RMOs, and will provide the opportunity for discussion and comments. SIM QSTF decisions will be made by the representatives of the SIM signatories to the CIPM MRA;
- the Task Force will assess whether or not the quality management system of each NMI complies with the requirements of the CIPM MRA. If it does not comply, the SIM QSTF will ask for additional information and/or corrective actions;
- NMIs may choose to present their quality management system in parts, covering different calibration and measurement services; and
- the quality management system review procedure will also apply to designated institutes (who must make the request for a review through their SIM Member NMI).

The SIM QSTF usually meets twice a year: once during the SIM General Assembly Week in the Fall and once during the Spring. The SIM Procedure for Review of the Quality Management System of National Metrology Institutes and Designated Institutes, known as SIM 09, describes the requirements for quality management system reviews including the quality manual and description of the QMS for its calibration and measurement capabilities.

SIM 09 is found on the following website SIM Quality System Documentation: The Quality System Task Force (QSTF) of the Inter-american Metrology System (SIM)[https://www.nist.gov/pml/sim-quality-system-documentation].

Appendix C. Evaluating and Expressing the Uncertainty Associated with Measured Values

A measurement result consists of an estimate of the measurand qualified with the associated measurement uncertainty evaluated and expressed according to NIST Technical Notes 1297 or 1900.

C1. Background

NIST Technical Note 1297, first published in January of 1993 [1], defined a uniform approach to express the uncertainty of NIST measurement results. This Technical Note was revised to recognize the official publication in October 1993 of the ISO *Guide to the Expression of Uncertainty in Measurement.* The second edition of NIST Technical Note 1297 was published in September of 1994 [2]. These developments were motivated in part by the emerging international consensus on the approach to expressing uncertainty in measurement recommended by the International Committee for Weights and Measures (CIPM) in 1980-81 [3-4]. The overarching goal was to ensure the comparability of measurements made in different countries at different times, to facilitate commerce and trade, and the exchange, interpretation, and comparison of measurement results obtained in all sectors of science and technology.

NIST Technical Note 1900 expands the scope of uncertainty evaluations to all properties measured by NIST, and introduces models and methods for uncertainty evaluation that are not described in NIST Technical Note 1297. However, NIST Technical Note 1900 does not replace NIST Technical Note 1297: the guidance provided in the latter may continue to be used when it is deemed fit for purpose and there is no compelling reason to question its underlying assumptions.

C2. Policy

Every value measured by NIST must be qualified with an evaluation of measurement uncertainty, expressed in a manner that is fit for purpose, and evaluated consistently with the guidance provided in the GUM (*Guide to the Expression of Uncertainty in Measurement*) [5], and in NIST Technical Notes 1297 [2] and 1900 [6], in particular as illustrated in the examples included in these documents.

In many cases, a set of values of the measurand believed to include its true value with 95 % probability (*95 % coverage region*) suffices and is fit for purpose as expression of measurement uncertainty. When the result of an evaluation of measurement uncertainty is intended for use in subsequent uncertainty propagation exercises involving Monte Carlo methods, then the expression of measurement uncertainty should be a fully specified probability distribution for the measurand, or a sufficiently large sample drawn from a probability distribution that describes the state of knowledge about the measurand.

Uncertainty evaluations for measurands defined by the measurement model contemplated in the GUM, in NIST Technical Note 1297, and in (4a) of NIST Technical Note 1900, may be performed using the NIST Uncertainty Machine, available at https://uncertainty.nist.gov [7].

C3. Responsibilities

Laboratory Directors are responsible for conformity with this policy.

a. 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.
b. 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.
c. The ***Chiefs of the Divisions that provide measurement services*** are responsible for ensuring that calibration and test reports, SRM certificates and RM reports, and other technical outputs under their jurisdiction are in conformity with this policy.
d. ***The Office of Data and Informatics*** is responsible for ensuring that technical outputs under their

jurisdiction are in conformity with this policy.

e. 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.

C4. Exceptions

Any statistical method that the Chief Statistician for NIST (or, in his absence, the Chief of the Statistical Engineering Division) determines to be valid for the assessment of measurement uncertainty in the particular situation, may be employed to determine the equivalent of standard uncertainty, combined uncertainty, or expanded uncertainty, or of other expression of 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.

C5. References Cited

[1] 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), URL http://dx.doi.org/10.6028/NIST.TN.12971297.

[2] B. N. Taylor and C. E. Kuyatt, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, NIST Technical Note 1297 (2nd edition), National Institute of Standards and Technology, U.S. Department of Commerce, Gaithersburg, Maryland, 1994, URL http://physics.nist.gov/Pubs/guidelines/TN1297/tn1297s.pdf

[3] 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).

[4] 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).

[5] Joint Committee for Guides in Metrology. *Evaluation of measurement data — Guide to the expression of uncertainty in measurement*. International Bureau of Weights and Measures (BIPM), Sèvres, France, 2008. URL http://www.bipm.org/en/publications/guides/gum.html. BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML, JCGM 100:2008, GUM 1995 with minor corrections.

[6] A. Possolo, *Simple Guide for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, NIST Technical Note 1900, National Institute of Standards and Technology, U.S. Department of Commerce, Gaithersburg, Maryland, 2015, URL http://dx.doi.org/10.6028/NIST.TN.1900.

[7] T. Lafarge and A. Possolo (2015) The NIST Uncertainty Machine, NCSLI Measure Journal of Measurement Science, 10(3): 20-27.

Appendix D. Procedure for NIST-QM-I Revision and Document Control

1 PURPOSE

The purpose of this procedure is to describe the process for reviewing, revising, vetting and issuing a revised version of the NIST Quality Manual (NIST-QM-I), and the procedure document control throughout the process. This procedure includes requirements for communicating changes in NIST-QM-I to affected parties.

2 REFERENCES

NIST-QM-I Sections: 2.; 4.2.3.2 (3), (4); 4.3.2; and 4.3.3

3 DEFINITIONS

4 RESPONSIBILITIES

The NIST Quality Manager is responsible maintaining NIST-QM-I and as such is responsible for ensuring timely review, revision, document issue and communication of changes to affected parties. The NIST Quality Manager is also responsible for ensuring that previous versions are marked as obsolete and archived.

5 PROCEDURE

5.1 Review

NIST-QM-I may be revised to address any of the following:

- Results of routinely conducted self-assessments;
- Identified opportunities for improvements;
- Corrective actions developed in response to customer feedback; and
- Changes to relevant informative references or international standards.

5.2 Revision

When revisions to NIST-QM-I are needed, the changes are made to a copy of the current NIST-QM-I document. The revised NIST-QM-I document is watermarked DRAFT and the Version of the Draft is "Proposed Version X Draft X". An electronic copy of the draft is posted NIST Quality System SharePoint website, and distributed to the NIST Associate Director for Laboratory Programs, the Associate Director of Measurement Services PML, the Director of Office of Reference Materials, the Director of the Office Data and Informatics, the NMSC, the NIST WERB Chair, NIST Management and Organization's Directives Program contact, and Assessment Review Board (ARB) for comment. This communication specifies a deadline by which comments are due to the NIST Quality Manager. The comments are reviewed and incorporated as appropriate.

The NIST Quality Manager determines whether and how to incorporate comments. The NIST Quality Manager may enlist the NMSC to serve as arbiter of conflicting comments. The revised draft is routed to the NIST Director following NIST procedure for review and approval at this level. This process is defined by the instructions that accompany form CD-15.[2]

[1] The routing of the CD 15 includes: the NIST Director and Chief of Staff, the ADLP and SCO Director.

5.3 Communication

Upon approval by the NIST Director, the new approved version of NIST-QM-I is posted on the NIST Quality System SharePoint website, with the new version number and effective date. An uncontrolled copy is posted to the NIST Quality System webpage for availability on the www at http://www.nist.gov/qualitysystem/ The NMSC, ARB, NIST QMS sublevel document owners, and all affected DCs and DQMs are notified that the new version is available in a communication that includes a summary of the changes.

Every effort is made to ensure that proposed changes do not conflict with existing NIST Policies, Orders and Procedures. The NIST Quality Manager is responsible for evaluating proposed changes to determine if there are implications for existing NIST directives documents, and notifying the affected directive owners.

5.4 Document Control

The NIST Quality Manager procedure for document control is outlined below.

- Proposed new NIST-QM-I version is marked with DRAFT, Version ____; posted _____.
- Upon approval of the new version, the previous version is marked as obsolete.
- The approved version is marked with the appropriate version number and effective date and posted.
- Once posted, affected parties are notified via email.
- *Update the version-tracking table.*

Table. NIST-QM-I Document Tracking

Effective Date	Version	Date Obsolete
4-Mar-2003	NIST-QM-I Version 1	3-Mar-2004
4-Mar-2004	NIST-QM-I Version 2	19-Mar-2006
20-Mar-2006	NIST-QM-I Version 3	18-Aug-2008
19-Aug-2008	NIST-QM-I Version 4	2-Sep-2009
3-Sep-2009	NIST-QM-I Version 5	31-July-2010
1-Aug-2010	NIST-QM-I Version 6	8-Aug-2011
9-Aug-2011	NIST-QM-I Version 7	6-May-2013
7-May-2013	NIST-QM-I Version 8	12-Nov-2015
13-Nov-2015	NIST-QM-I Version 9	27-Dec-2016