NIST Quality Manual for Measurement Services

NIST-QM-I

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Introduction

The provision of measurement services, which include ***calibrations***, ***special tests***, ***measurement assurance programs***, ***Standard Reference Materials***, ***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 the performance excellence that is 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 Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) standard *ISO/IEC 17025* and the relevant requirements of *ISO/IEC 17034*, *ISO/IEC 17043* and Technical Specification (TS) *ISO/TS 8000* as they apply to the related measurement services that NIST delivers.

Signed:

Date: 3/29/19

Dr. Walter G. Copan,
Under Secretary of Commerce for Standards and Technology & Director,
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1 Scope

The quality management system (QMS) described in this manual covers ***measurement services*** (***calibrations, special tests, measurement assurance programs, Standard Reference Instruments, Standard Reference Material, and Standard Reference Data***) provided to customers both internal and external to NIST. 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/IEC 17034:2016* (see Appendix E), *ISO/IEC 17043:2010* (see Appendix F) and *ISO/TS 8000* (see Appendix G), as they apply to the related ***measurement services*** that NIST delivers. In general, the scope of the NIST QMS 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 to be 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®), Certified Reference Materials, Reference Materials (RMs), NIST Traceable Reference Materials (NTRMs^{CM})***, ***Standard Reference Instruments***, 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 QMS 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].

This document is organized as follows:

- Sections 2 to 8 and Appendixes A to D address the requirements of testing and ***calibration*** laboratories in accordance with *ISO 17025:2017*;
- Appendix E addresses the additional requirements of reference material producers in accordance with *ISO/IEC 17034:2016*;
- Appendix F addresses the additional requirements of proficiency testing in accordance with *ISO 17043:2010*;
- Appendix G addresses the additional requirements of providers of NIST ***Standard Reference Data (SRD)***.

2 References

2.1 NIST Directives

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 ***NIST 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 QMS for Measurement Services as documented in this NIST-QM-I are controlling. They may be included either 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 5.5 **b)** below) will notify the NIST Management and Organization Division (cf., Section 5.5 **a)** below), which is responsible for their inclusion in the ***NIST Directives Management System***.

The NIST QMS also helps to further the purposes of NIST Policy 5100.00, Scientific Integrity; NIST Order 5101.00, Scientific Integrity; and NIST Procedure 5101.01, as well as NIST Policy 5200, Responsible Conduct of Research; NIST Order 5201.00, Responsible Conduct of Research Order; and NIST Procedure 5201.01, Procedures in Response to Allegations of Research Misconduct. 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.

2.2 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 35:2017 Reference materials – Guidance for characterization and assessment of homogeneity and stability

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 17025:2017 General requirements for the competence of testing and calibration laboratories

ISO/IEC 17034:2016 General requirements for the competence of reference materials producers

ISO/IEC 17043:2010 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]

Measurement Uncertainty, information and resource knowledge made available by the Statistical Engineering Division at NIST https://www.nist.gov/information-technology-laboratory/sed/topic-areas/measurement-uncertainty

NIST Directives Management System and the NIST Administrative Manual

NIST Calibration Services Policy [https://inet.nist.gov/directives/calibration-services]

NIST Calibration Services Order [https://inet.nist.gov/directives/calibration-services-order]

NIST Calibration Services Suborders: Establishment of Calibration Services, Determining and Setting Calibration Fees, Significant Changes to a NIST Calibration Service, Termination of a Calibration Service, Guidance on Software Supporting NIST Calibration Services [https://inet.nist.gov/mando/directives/directives-home?page=1]

NIST Standard Reference Materials Program Policy [https://inet.nist.gov/adlp/directives/standard-reference-materials-program]

NIST Standard Reference Material Order [https://inet.nist.gov/adlp/directives/standard-reference-materials-program-0]

NIST Standard Reference Data Program Policy [https://inet.nist.gov/directives/standard-reference-data-program-0]

NIST Standard Reference Data Program Order [https://inet.nist.gov/directives/standard-reference-data-program]

NIST Standard Reference Instruments Policy [https://inet.nist.gov/directives/standard-reference-instruments-0]

NIST Standard Reference Instruments Order [https://inet.nist.gov/directives/standard-reference-instruments]

NIST Administrative Manual Section 14.05 Standard Reference Data Program [https://inet.nist.gov/mando/directives/1405]

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

Definitions for all terms, indicated by ***bold italics***, 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 (SIM QSTF).

A named member, or former member, of the ***ARB*** can serve 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] This system will be retired after the new E-commerce solution is released for use in Fiscal Year 2019.

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/IEC 17034* and *Guide 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 Metre 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 Section **6.2.6.3**)

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 **7.10.1**)

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

Data Management Plans (DMP)
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 from public release, the data will be covered by a ***DMP***. Some ***DMP's*** may refer the data control process described within the NIST QMS, typically in the ***sub-level quality documents***. (See section **7.2.1.1**, ***Reference materials***)

Designated Institute (DI)
entity that is formally identified by a country's or economy's NMI as being responsible for a specified metrology area within the implementation of the ***CIPM MRA***. NIST can Designate an Institute within the United States to be responsible for providing a specific metrology area and to participate in the CIPM MRA. See NIST P 5810.00 for details.

discoverability
the degree to which of something, especially a piece of content or information, can be found in a search of a file, database, or other information system.

E-commerce
The platform that allows measurement services customers to place online orders. It implements fulfillment practices and manages invoicing and payment processes. The E-commerce solution is being rolled out in Fiscal Year 2019, first to the Calibration Services followed by ***SRD***, ***SRM***, and ***SRI***.

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

impartiality
presence of objectivity.

NOTE 1: Objectivity means that either conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the ***laboratory***.

NOTE 2: Other terms that are useful in conveying the element of impartiality include "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "evenhandedness", "detachment", "balance".

[Source: *ISO/IEC 17025:2017*]

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***. The ***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 **5.5** 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 (MML)
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 1: 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]

NOTE 2: The NIST Measurement Services Council (NMSC) approved the expanded interpretation of the definition of measurement to include value assignments of properties using qualitative techniques. [July 3, 2017 NMSC] https://inet.nist.gov/sites/default/files/documents/2017/08/01//memo_on_nsmc_approval_for_qualitative_measurement.pdf

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** (*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)
replaces 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 Associate Director for Laboratory Programs (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 Reference Material
material issued by NIST with a report of investigation instead of a ***certificate*** to: (1) further scientific or technical research; (2) determine the efficacy of a prototype reference material; (3) provide a homogeneous and stable material so that investigators in different laboratories can be ensured that they are investigating the same material; and (4) ensure availability when a material produced and certified by an organization other than NIST is defined to be in the public interest or when an alternate means of national distribution does not exist. A NIST RM meets the ISO definition for a RM and may meet the ISO definition for a ***CRM*** (depending on the organization that produced it). [https://www.nist.gov/srm/srm-definitions]

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*.

Order number
previously known as test folder number, starting with the letter "O" this is a unique 10-digit number that is issued by NIST that indicates that an official calibration or test has been requested by a customer.

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

preservation
refers to the set of activities that aims to prolong the life of a record with as little changes to the original record as possible.

Principal Investigator (PI)
the NIST employee primarily responsible for the development and maintenance of ***Standard Reference 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 200:2012*, 5.13), but restricts the term "measurement" to apply to quantitative values and not to qualitative properties. However, Note 3 of *JCGM 200:2012*, 5.13 specifically includes the concept of qualitative attributes, called "nominal properties".

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

SIM
the Regional Metrology Organization of the Americas is the Inter-american Metrology System, Sistema Interamericano de Metrologia.

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 (SRD)
NIST provides Standard Reference Data to customers through downloads, shipments, instruments and software sold by SRD distributors. SRD products come with varying level of support ranging from installation support to individuals, to integration support for instrument and software manufactures.

SRD is data that is-

a. either-
   i. quantitative information related to a measurable physical, or chemical, or biological property of a substance or system of substances of known composition and structure;
   ii. measurable characteristics of a physical artifact or artifacts;
   iii. engineering properties or performance characteristics of a system; or
   iv. one or more digital data objects that serve–
      a) to calibrate or characterize the performance of a detection or measurement system; or
      b) to interpolate or extrapolate, or both, data described in (i)-(iii); and
b. that is critically evaluated as to its reliability

[from 2017 SRD Act Update, Section 108, Standard Reference Data Act Update, in Public Law No. 114-329, American Innovation and Competitiveness Act. 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 a ***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 (QM-IIs, QM-IIIs, etc.)
NIST's QMS 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, records, procedures, and quality manuals that are not included specifically in NIST-QM-I. The entire series comprise the NIST QMS 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 servic***e to a NIST customer, for NIST, without participation by NIST. NIST does not subcontract ***measurement services*** in this manner. (See Section **6.2.6.2**)

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). These are being phased out for the implementation of unique order numbers in the ***E-commerce*** system.

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 was measured gravimetrically, and that the corresponding fractions measured using gas chromatography are not statistically significantly different when they are compared (taking into account their respective associated uncertainties).

4 General requirements

4.1 Impartiality

4.1.1 NIST conducts its ***measurement services*** in a fair and open-minded manner that is free of conflict of interests, bias or prejudice ensuring impartiality in the operations and measurements of the laboratory.

4.1.2 High standards of ethical conduct, impartiality and objectivity are vital to the success of NIST programs and required of all employees (see **6.2.1** *Competence and impartiality*).

4.1.3 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.

4.1.4 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, and on the NIST Ethics website [http://inet.nist.gov/ohrm/services/upload/ethicsstandards.pdf]. NIST provides triennial ethics training to all employees. Additional ethics policies and training related to impartiality, specific to a ***measurement service***, are provided by the responsible NIST Division or Office to address its needs as described in ***sub-level quality documents***. Perceived risks to impartiality are addressed during the Management Review and Internal Audit processes as described in ***sub-level quality documents***.

4.1.5 NIST expects that all perceived or actual risks to impartiality be eliminated or minimized as an essential obligation to its customers. The management of each ***measurement service*** addresses any identified risk to impartiality as described in ***sub-level quality documents***.

4.2 Confidentiality

4.2.1 NIST is legally obligated to provide protection of confidential or proprietary information obtained or created during the performance of laboratory measurement services activities. The NIST policy and procedures for protecting proprietary information received by NIST, is provided to all employees in Subchapter 5.06 of the NIST Administrative Manual [http://inet.nist.gov/mando/directives/506.cfm]. Proprietary information includes trade secrets, commercial, and financial information submitted to NIST. Divulging or improperly using such information without the express permission of the owner is a violation of the Trade Secrets Act (18 U.S.C. 1905). If proprietary information is necessary for the measurement service, parties must implement a Cooperative Research and Development Agreement (CRADA) or a Non-disclosure Agreement before proprietary information can be received.

To obtain a NIST Calibration Service, a Calibration Cooperative Research and Development Agreement (C-CRADA) is entered into between the customer and NIST pursuant to 15 USC 3710a and 15 USC 272(b)(6) and (c)(2). These statutes give NIST the authority to enter into CRADAs in order to assist industry in the development of measurements, measurement methods, and basic measurement technology by testing or calibrating standards and standard measuring apparatus. All NIST Calibration Services are provided under the C-CRADA, and therefore must have a signed Calibration Service Pro Forma Invoice (PFI) in place prior to the work commencing. For U.S. government agencies, a memorandum of understanding is required in lieu of the Calibration Service PFI. Only NIST employees can perform and provide measurement services, including the signing of a Pro Forma Invoice or memorandum of understanding. C-CRADA Protected Information means the data and the Report of Calibration or Test issued by NIST will be protected from disclosure for a minimum of five (5) years. Permanent retention may be selected by the U.S. National Archives and Records Administration if the calibration service (i) becomes the subject of a Congressional investigation or comes under intensive public scrutiny or (ii) becomes involved in court decisions or legislative actions affecting the functions and activities of NIST. These requirements and responsibilities are provided in NIST Order 5901.00 for Calibration Services.
[https://inet.nist.gov/sites/default/files/documents/2018/03/09//Final%20O%205901%20ver%201_0.pdf].

4.2.2 NIST policy is that reports on NIST ***calibrations*** or other ***measurement services*** are the property of the customer. Copies are supplied to other parties only as required by federal law or requested in writing by the customer [https://www.nist.gov/calibrations/policies].

4.2.3 The NIST policy and procedures for protecting proprietary information received by NIST from external organizations or persons is provided to all employees in Subchapter 5.06 of the NIST Administrative Manual [http://inet.nist.gov/mando/directives/506.cfm] (see **4.2.1)**.

4.2.4 The NIST policy and procedures for protecting proprietary information (see **4.2.1**) received by NIST from external organizations or persons, or obtained or created during the performance of ***laboratory*** activities, applies to all personnel working at NIST including any committee members, contractors, personnel of external bodies, or individuals acting on the NIST's behalf.

5 Structural requirements

5.1 The National Institute of Standards and Technology

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 [https://www.ecfr.gov/cgi-bin/text-idx?SID=80b14041330edac02df5929571828db2&mc=true&node=pt15.1.200&rgn=div5]. The Department of Commerce's Department Organization Orders prescribe the assignment of functions to NIST.

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.

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.

Reference Materials Production: The legal authorities and the requirements, roles and responsibilities for producing, certifying, and distributing NIST ***reference materials*** are listed in NIST directives Policy P 5600.00 and Order O5601.00 Standard Reference Materials Program.

Standard Reference Data databases are copyrighted by the U.S. Secretary of Commerce on behalf of the United States of America. The legal authorities to provide for the collection, compilation, critical evaluation, publication and sale of ***standard reference data*** are the Standard Reference Data Act: Public Law 90-396, July 11, 1968, and the American Innovation and Competitiveness Act, Section 108, Standard Reference Data Act Update: Public Law 114-329, January 6, 2017, S. 3084.

5.2 Laboratory management responsibility

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. Figure 1, provides the organization chart for those units responsible for the provision of NIST measurement services. Each box indicates a Director, an Associate Director, Laboratory Director, and Division Chief, these are the roles that apply 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.

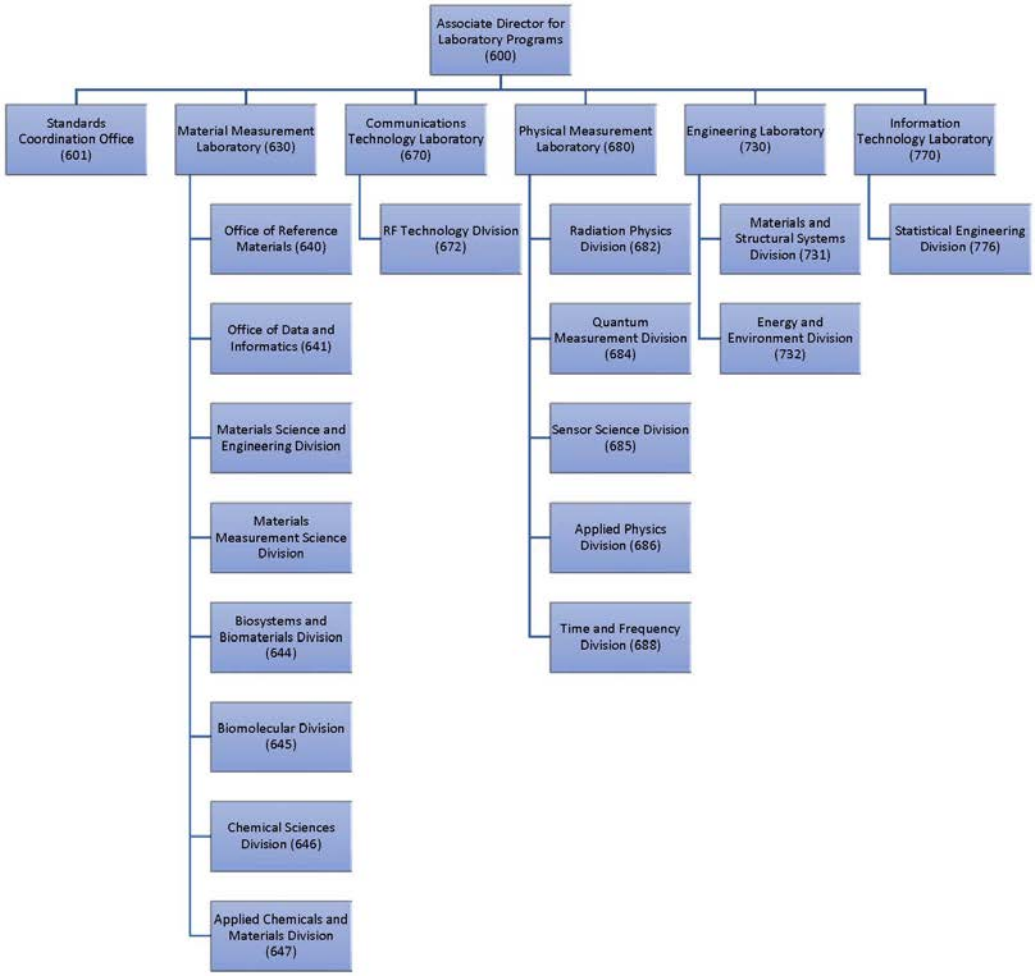

Figure 1 Organization chart of the units involved with the provision of ***NIST Measurement Services***.

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 ADLP 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 QMS. ***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***.

The responsibilities of the NIST Director, ADLP, 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.

5.3 NIST *measurement services*

The NIST QMS 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***.

5.3.1 Types of NIST Calibration Services

- **Calibration Services** are provided by NIST using well-characterized, stable and predictable measurement processes. NIST calibrates instruments and devices that are metrologically suitable as reference or transfer standards.
- **Special Tests** 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-control documentation has not been completed. Also see **NIST *Standard Reference Instrument* (*SRI*)** below**.**
- ***Measurement Assurance Program* (*MAP*)** is a quality control program for calibrating a customer's entire measurement system. In a typical ***MAP***, a stable artifact or set of artifacts called transfer standards are first measured by NIST and 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 necessary, offers guidance on achieving and maintaining measurement quality.
- **NIST *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. NIST ***Calibration Services*** provides measurement traceability as an optional ***Special Test*** for each ***SRI*** purchased by a customer.

5.3.2 Types of NIST reference materials

- **NIST Standard Reference Material® (SRM)** - A ***Certified Reference Material (CRM)*** issued by NIST that also meets additional NIST-specific certification criteria and is issued with a ***certificate*** or ***certificate*** of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material (*NIST SP 260-136*).

  Note: An ***SRM*** is prepared and used for three main purposes: (1) to help develop accurate methods of analysis; (2) to calibrate measurement systems used to facilitate exchange of goods, institute quality control, determine performance characteristics, or measure a property at the state-of-the-art limit; and (3) to ensure the long-term adequacy and integrity of measurement quality assurance programs. The terms "***Standard Reference Material***" and the diamond-shaped logo which contains the term "***SRM***," are registered with the United States Patent and Trademark Office.
- **NIST Reference Material (RM)** - Material issued by NIST with a report of investigation instead of a ***certificate*** to: (1) further scientific or technical research; (2) determine the efficacy of a prototype ***reference material***; (3) provide a homogeneous and stable material so that investigators in different laboratories can be ensured that they are investigating the same material; and (4) ensure availability when a material produced and certified by an organization other than NIST is defined to be in the public interest or when an alternate means of national distribution does not exist. A NIST RM meets the ISO definition for a RM and may meet the ISO definition for a ***CRM*** (depending on the organization that produced it).
- ***NIST Traceable Reference Material*^CM^ (*NTRM*^CM^)** - A commercially-produced ***reference material*** with a well-defined traceability linkage to existing NIST standards for chemical measurements. This traceability linkage is established via criteria and protocols defined by NIST to meet the needs of the metrological community to be served (*NIST SP 260-136*). ***Reference material***s producers adhering to these requirements are allowed use of the NTRM

trademark. A NIST NTRM may be recognized by a regulatory authority as being equivalent to a ***CRM***.

5.3.3 ***Standard Reference Data (SRD)*** - NIST develops and produces free, web interface ***SRD databases*** and develops and sells fee-based ***SRDs***. These ***databases*** may include data from the literature, NIST research, or both, all critically evaluated by NIST. Some of the ***databases*** have been developed in partnership with other organizations. NIST Standard Reference Data Products include web sites, individual licenses, subscriptions for online access by individuals and sites, and distributor relationships to embed SRD files directly into instruments by their manufacturer.

The American Innovation and Competitiveness Act, Section 108, the Standard Reference Data Act Update: Public Law 114-329, January 6, 2017, S. 3084 defines ***SRD*** as data that are-

(A) either-
  (i) quantitative information related to a measurable physical, or chemical, or biological property of a substance or system of substances of known composition and structure;
  (ii) measurable characteristics of a physical artifact or artifacts;
  (iii) engineering properties or performance characteristics of a system; or
  (iv) one or more digital data objects that serve-
    (I) to calibrate or characterize the performance of a detection or measurement system; or
    (II) to interpolate or extrapolate, or both, data described in (i)-(iii); and

(B) that is critically evaluated as to its reliability under section 290b of this title.

§290b. Collection, compilation, critical evaluation, publication and dissemination of standard reference data
The Secretary is authorized and directed to provide or arrange for the collection, compilation, critical evaluation, publication, and dissemination of standard reference data. In carrying out this program, the Secretary shall, to the maximum extent practicable, utilize the reference data services and facilities of other agencies and instrumentalities of the Federal Government and of State and local governments, persons, firms, institutions, and associations, with their consent and in such a manner as to avoid duplication of those services and facilities. All agencies and instrumentalities of the Federal Government are encouraged to exercise their duties and functions in such manner as will assist in carrying out the purpose of this chapter. This section shall be deemed complementary to existing authority, and nothing herein is intended to repeal, supersede, or diminish existing authority or responsibility of any agency or instrumentality of the Federal Government. (Pub. L. 90–396, §3, July 11, 1968, 82 Stat. 340.)

Digital data objects may include fingerprints, personal identity verification cards, videos, models, and software.

5.4 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 documents***.

5.5 Organizational structure for the provision of NIST *measurement services*

a) Organization and management structure

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 1 provides a schematic representation of this part of the NIST organization.

The technical effort required to deliver ***NIST measurement services*** is made by scientific and technical staff within the appropriate 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 Laboratory*** and the ***Physical Measurement Laboratory*** 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 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.

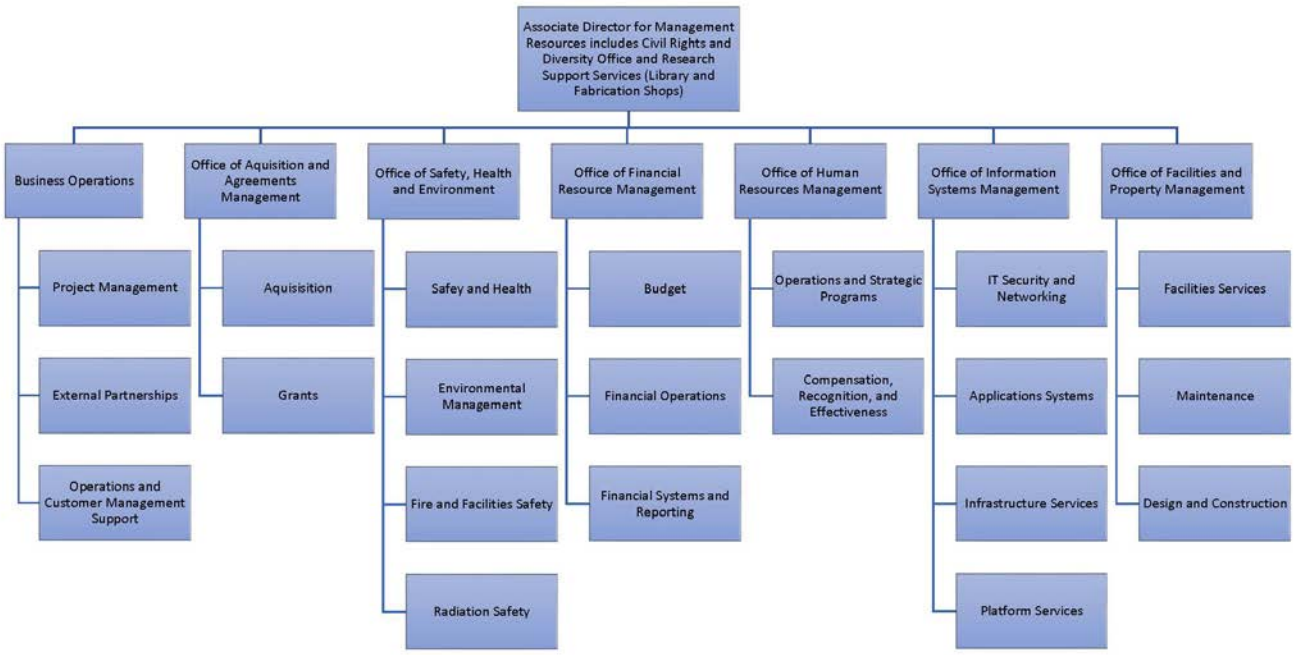

Figure 2 Organization chart for units that provide support services to the provision of ***NIST Measurement Services***

Neither the NIST QMS 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. An outline of the complete NIST organizational structure is available at [https://inet.nist.gov/org/full]. 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].

b) Laboratory staff responsibilities, authorities, and delegations

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. Division Chiefs are also responsible for ensuring the institutional competency needed to provide a ***calibration service***, ***reference material*** or ***standard reference data***. 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.

c) Documentation of *measurement services* procedures

Detailed descriptions of the NIST ***measurement services*** offered, and the associated procedures, methods of ***validation***, and ***measurement uncertainty***, are documented in the NIST ***sub-level quality documents*** (see **7.2.1.1**).

5.6 NIST Quality Management System personnel

The organizational hierarchy of the NIST QMS, Figure 3, is essentially identical to that shown in Figure 1 for the provision of NIST ***measurement services***.

The NIST Director is ultimately responsible for the quality of ***NIST measurement services***. This responsibility is delegated to the ADLP, 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 QMS 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 documents*** is delegated to the Chief of that Division or Director of that Office and the ***NIST Quality Manager***.

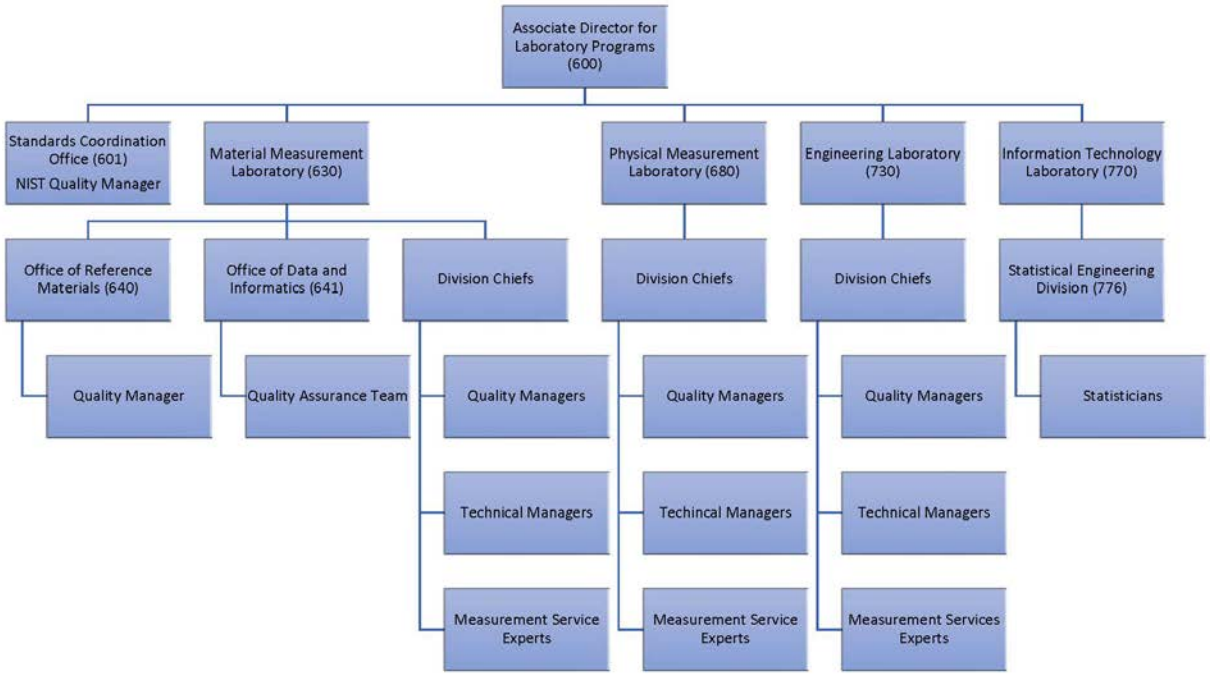

Figure 3 Organizational hierarchy for the implementation of the ***NIST QMS***

The ***NIST Quality Manager***

1) organizes and schedules NIST-level QMS 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*, *ISO 17034* and *ISO 17043*;
5) maintains document control for NIST-QM-I;
6) serves as the NIST representative to the ***SIM*** QSTF for the presentation of NIST quality systems and assessments and for the review of the quality systems of other ***NMIs*** in ***SIM***;
7) reviews the NIST quarterly quality reports and provides a cumulative summary quarterly report to the Associate Director for Laboratory Programs, the Laboratory 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 named member of the ***Assessment Review Board***. This person serves in this role if 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 QMS 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.

5.7 Measurement services communication

The ***NIST Quality Manager,*** the ADLP, the members of the ***NIST Measurement Services Council***, the Division Quality Managers and their respective Division Chiefs/Office Directors ensure that there is open communication within and between all levels of NIST ***measurement services*** concerning the effectiveness of the QMS, including maintaining the integrity of the QMS when changes are planned and implemented (see **5.6**).

Communication occurs through:

- NIST-Level assessments organized by the ***NIST Quality Manager*** and conducted at least once every five years;
- NIST-level management reviews conducted on a quarterly basis by ***Laboratory*** Directors or their delegates and the ***NIST Quality Manager***, reliant on quarterly quality reports that Divisions submit through their respective Laboratories to the ***NIST Quality Manager***;
- Division/Office-Level Audits (also known as internal audits) addressing all elements of the QMS and conducted at least every two years, but preferably each year; and
- ***NIST Measurement Services Council*** meetings occurring monthly.

6 Resource requirements

6.1 General

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

6.2 Personnel

6.2.1 Competence and impartiality

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 and impartial 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 and impartiality is the direct responsibility of the management chain for ***measurement services*** of the relevant technical Divisions, as described in Section **5.2**.

6.2.2 Job descriptions

Primary responsibilities, experience, and qualifications pertinent to ***calibrations***, ***reference materials***, and ***SRD*** are appropriately documented in ***sub-level quality documents*** for each person involved in managing or conducting such work (See Sections **5.2** and **5.5b)**).

6.2.3 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 **5.5**.

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

6.2.4 Delegation of duties, responsibilities and authorities

The duties, responsibilities and authorities of all 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.

6.2.5 Management of personnel

The NIST ***measurement service*** procedures for determining personnel competence requirements, selection of personnel, training of personnel, supervision of personnel, authorization of personnel, monitoring the competence of personnel, and retaining the records of these procedures are documented for each Division/Office in their respective NIST ***sub-level quality documents***.

6.2.6 Authorization of personnel

NIST ***measurement service*** personnel are authorized, usually by the Division Chiefs/Office Directors, to perform specific ***measurement service*** activities including, but not limited to: development, modification, verification and validation of methods; analysis of results, including statements of conformity or opinions and interpretations; and report, review and authorization of results as documented for each Division/Office in their respective NIST ***sub-level quality documents***.

For ***SRM*** or ***NIST RM*** services, the lead technical Division may interact in a collaborative or supportive role with 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 QMS. Should there not be an existing quality system, the supporting Division may document their role in the lead technical Division's quality management system.

6.2.6.1 Interaction with NIST Supporting Divisions

As discussed in section **5.5a)**, and indicated schematically in Figure 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.

6.2.6.2 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 **6.2.6.3** *Collaborators*)

6.2.6.3 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 QMS 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.

NIST ***measurement services*** do not use ***collaborators*** for the following processes related to the production and certification of ***reference materials***:
— the production planning;
— the selection of ***collaborators***;
— the assignment of property values and their uncertainties;
— the authorization of property values and their uncertainties;
— the authorization of ***reference material*** documents.

Note that the NIST definition and its use of ***collaborators*** is different from the definition as found in *ISO/IEC 17025* and *ISO/IEC 17034*, as they use the term "***subcontractor***" as a synonym for "***collaborator***."

6.3 Facilities and environmental conditions

6.3.1 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***.

6.3.2 Specific requirements for ***laboratory*** facilities and environmental conditions are documented in ***sub-level quality documents***.

6.3.3 Specific procedures and methods for achieving, monitoring, and controlling ***laboratory*** environmental conditions are detailed in ***sub-level quality documents***.

6.3.4 NIST ***measurement service*** procedures and methods for achieving, monitoring, and controlling ***laboratory*** environmental conditions take into account specific needs and conditions including access to, and use of, areas affecting ***laboratory*** activities; prevention of contamination, interference or adverse influences on ***laboratory*** activities; and effective separation between areas with incompatible ***laboratory*** activities, which are detailed in ***sub-level quality documents***.

6.3.5 When a NIST ***measurement service*** conducts activities at sites or facilities outside its permanent control, such as at special facilities away from the NIST campuses or when calibrating a ***Standard Reference Instrument (SRI)*** at the customer's laboratory, the NIST ***measurement service*** ensures that the facilities and environmental conditions are appropriate for the measurement.

6.4 Equipment

6.4.1 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 documents***.

6.4.2 When equipment outside of NIST's permanent control is used for conducting ***measurement service*** activities, the NIST ***measurement service*** ensures that the equipment meets the requirements of this QM-I document, as detailed in supporting ***sub-level quality documents***.

6.4.3 Procedures for the safe handling, transport, storage, use and planned maintenance of measuring instruments and equipment supporting NIST ***measurement service*** activities are documented in supporting ***sub-level quality documents***.

6.4.4 Equipment supporting NIST ***measurement service*** activities is verified to demonstrate that it conforms to specified requirements before being placed or returned into service. The ***verification*** procedures are detailed in supporting ***sub-level quality documents***.

6.4.5 Equipment supporting NIST ***measurement service*** activities can achieve the measurement accuracy and/or ***measurement uncertainty*** required to provide a valid result as discussed in supporting ***sub-level quality documents***.

6.4.6 Procedures for the ***calibration*** or checking of equipment supporting NIST ***measurement service*** activities to establish that it meets the laboratory's specification requirements for accuracy or ***measurement uncertainty***, and to establish the ***metrological traceability*** of the reported results are detailed in supporting ***sub-level quality documents***.

6.4.7 A program for the periodic ***calibration*** of the equipment supporting NIST ***measurement service*** activities is detailed in supporting ***sub-level quality documents***. The program is reviewed and adjusted as necessary to maintain confidence in the status of ***calibration***.

6.4.8 Equipment supporting NIST ***measurement service*** activities requiring periodic ***calibration***, or having a defined period of validity, are identified in a manner that readily indicates to ***measurement service*** staff the status of ***calibration*** or period of validity. These identification methods and policies are detailed in supporting ***sub-level quality documents***.

6.4.9 Equipment supporting NIST ***measurement service*** activities that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified requirements, is required to be taken out of service. The equipment is isolated, labeled or marked to indicate it being out of service until repair and ***calibration*** demonstrate that it can be returned to service. When equipment has been shown to be defective or outside specified requirements, the management procedure for nonconforming work is initiated as documented in supporting ***sub-level quality documents***.

6.4.10 Procedures for intermediate checks of the equipment supporting NIST ***measurement service*** activities (where appropriate) are documented in supporting ***sub-level quality documents***.

6.4.11 When ***calibrations*** and/or ***reference material*** data include reference values or correction factors, procedures are established to ensure that the values are correctly updated and implemented as discussed in supporting ***sub-level quality documents***.

6.4.12 In circumstances where equipment supporting NIST ***measurement service*** activities, including both hardware and software, requires special safeguards from unintended adjustments that would invalidate the test and/or ***calibration*** results, the NIST ***measurement service*** applies safeguards as discussed in supporting ***sub-level quality documents***.

6.4.13 Records for the equipment supporting NIST ***measurement service*** activities are documented in supporting ***sub-level quality documents***. These records include at least the following:

a) the identity of the item of equipment and its software;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) evidence of ***verification*** that equipment conforms with specified requirements;
d) the current location;
e) ***calibration*** dates, results of ***calibrations***, adjustments, acceptance criteria, and the due date of the next ***calibration*** or the ***calibration*** interval;

f) documentation of ***reference materials***, results, acceptance criteria, relevant dates and the period of validity;
g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological traceability

6.5.1 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 https://www.nist.gov/nist-policy-traceability).

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

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 [https://www.nist.gov/nist-policy-traceability].

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.

6.5.2 Consistent with the ***CIPM***, NIST ***measurements*** are directly traceable to the ***SI*** 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.

6.5.3 For some NIST chemical or materials metrology ***measurement service*** activities, ***metrological traceability*** to ***SI*** units is not technically possible. In these cases, traceability is achieved to other recognized standards or consensus values, for example as determined through ***key comparisons***, as described in supporting ***sub-level quality documents***.

6.6 Externally provided products and services

6.6.1 Federal Procurement Policy and Regulations govern procurement of products and services from sources external to NIST. Resource links to the policies, supporting guidance, and procedures applicable to all NIST procurements are detailed on the NIST Office of Acquisition & Agreements Management website [https://www.nist.gov/oaam/acquisition-management-division]. 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 usually by the Division Chief and are documented in the NIST ***sub-level quality documents***.

6.6.2 Procedures for procuring externally provided products and services supporting NIST ***measurement service*** activities and for the associated record keeping of the purchases are documented in supporting ***sub-level quality documents***, which include:
a) defining, reviewing and approving the NIST ***measurement service's*** requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c) ensuring that externally provided products and services conform to the NIST ***measurement service's*** established requirements before they are used or directly provided to the customer;
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

[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.

6.6.3 A ***NIST measurement service*** communicates its requirements for products and services to be procured from potential sources external to NIST through the various NIST procurement processes as documented in the NIST ***sub-level quality documents***. These requirements include:

a) the products and services to be provided;
b) the acceptance criteria;
c) competence, including any required qualification of personnel;
d) activities that the ***NIST measurement service***, or its customer, intends to perform at the external provider's premises.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 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, the Standard Reference Material (SRM) Catalog Ordering website, and the Standard Reference Data (SRD) ordering website. These policies apply NIST-wide and are approved by the Associate Director for Laboratory Programs and the Directors of ***PML*** and ***MML***. Additional procedures and descriptions of the ***NIST measurement services*** are documented in the NIST ***sub-level quality documents***.

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 ***SRIs*** 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 ***SRIs*** 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 ***Standard Reference Data*** ordering website. 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 a 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 documents***. Non-controlled copies of these are found on the Quality SharePoint site https://share.nist.gov/sites/qs/division_docs/default.aspx.

7.1.2 The NIST ***measurement service*** informs the customer when the test or ***calibration method*** requested by the customer is outside the scope of the ***measurement service***, inappropriate or out of date.

7.1.3 NIST does not routinely issue statements of conformity to a specification or standard nor does NIST state pass/fail or in tolerance/out of tolerance conditions. An exception to this statement exists with the American Petroleum Institute for thread gages, for which NIST provides conformance decisions against the NIST held Grand Master Gages. This is addressed in the sub-level quality documents for NIST's Dimensional Metrology services.

7.1.4 A procurement contract for a NIST ***measurement service*** must be acceptable to both NIST and the customer, with

any differences resolved before ***measurement service*** activities commence. NIST ***measurement services*** do not accept customer requested deviations that could impact the integrity of the ***measurement service*** or the validity of the results.

7.1.5 If there is a deviation from a NIST ***measurement service*** procurement contract, the customer is informed as described in supporting ***sub-level quality documents***.

7.1.6 If a NIST ***measurement service*** procurement contract is amended after work has commenced, the contract review is repeated, and any amendments are communicated to all affected personnel as described in supporting ***sub-level quality documents***.

7.1.7 The NIST ***measurement service*** cooperates with customers or their representatives in clarifying the customer's request and in monitoring the performance of the NIST ***measurement service*** in relation to the work performed, which under special circumstances may include: providing reasonable access to relevant areas of the ***laboratory*** to witness customer-specific tests or ***calibrations***; or the preparation, packaging, and dispatch of items. The extent of customer cooperation is documented in supporting ***sub-level quality documents***.

7.1.8 The NIST ***measurement service*** retains records of procurement contracts, changes to the contracts, and pertinent discussions with a customer relating to the customer's requirements or the results of the ***laboratory*** activities, as documented in supporting ***sub-level quality documents***.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 Methods and procedures

Calibration services **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 documents***.

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 sub-level quality documentation by the appropriate technical Division. (Also see Appendix E)

Standard reference data: Unlike NIST ***calibration measurement services*** and NIST ***reference material measurement services***, the NIST ***Standard Reference Data (SRD) measurement service*** does not normally conduct measurements for customers. ***SRD*** providers acquire, assess and evaluate data from a variety of sources, and compile the data into databases for customers. The critical evaluation techniques, methods, and procedures employed by the NIST technical divisions to produce ***SRD*** databases are documented in **Selection, verification and validation of methods** of Appendix G and the Division's ***sub-level quality documents***.

7.2.1.2 The test or ***calibration methods***, procedures and supporting documentation pertinent to a NIST ***measurement service***, such as instructions, standards, manuals and reference data relevant to the ***laboratory*** activities, are kept up to date and readily available to ***measurement service*** personnel.

7.2.1.3 In cases where a NIST ***measurement service*** conducts its measurements in accordance with international, regional or national standards, the latest valid version of a method is used unless it is not appropriate or possible to do so, as documented in the NIST ***sub-level quality documents***.

7.2.1.4 In most cases, the NIST ***measurement service*** chooses the test or ***calibration method*** to be used. If the customer requests deviations from the NIST ***measurement service*** method, the technical Divisions may agree to perform a ***Special Test*** (see **7.2.1.1**) as documented in the NIST ***sub-level quality documents***.

7.2.1.5 In cases where the NIST ***measurement service*** decides to conduct a ***Special Test*** or to conduct measurements in accordance with international, regional or national standards, the NIST ***measurement service*** verifies that it is capable of properly performing the method and achieving the required results. The ***verification*** procedures are documented in the NIST ***sub-level quality documents***. Records of the ***verification*** are retained as documented in the NIST ***sub-level quality documents***.

7.2.1.6 When a NIST Division decides to develop a new test or ***calibration method*** as part of an existing ***measurement service*** or a new ***measurement service***, for example, in response to customer requests or in addressing industry needs, the development is a planned activity approved by the Division Chief or designee and assigned to competent personnel equipped with adequate resources as discussed in the NIST ***sub-level quality documents***. Throughout the development of the new test or ***calibration method***, the NIST ***measurement service*** confirms that the customer's or industrial needs are being met. Modifications to the development plan are approved and authorized by the Division Chief or designee as detailed in the NIST ***sub-level quality documents***.

7.2.1.7 NIST ***measurement services*** do not deviate from approved and documented test or ***calibration methods***. If the customer requests deviations from the NIST ***measurement service*** method, the technical Divisions may agree to perform a ***Special Test*** (see **7.2.1.1**) as documented in the NIST ***sub-level quality documents*** (see **7.2.1.6**).

7.2.2 Validation of methods

7.2.2.1 The NIST ***measurement service*** validates its approved and documented test and ***calibration methods***, as well as ***Special Tests*** (see **7.2.1.1**) as extensively as is necessary to meet the needs of the given application or field of application. As applicable, ***validation*** may include procedures for sampling, handling and transportation of test or ***calibration*** items. The ***validation*** techniques used for the specific ***measurement service*** are documented in the NIST ***sub-level quality documents***. The techniques used may include one or a combination of the following:

a) ***calibration*** or evaluation of bias and precision using reference standards or ***reference materials***;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of ***measurement uncertainty*** of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

7.2.2.2 When the NIST ***measurement service*** decides to modify a validated test or ***calibration method***, the influences of such changes are determined and if found to affect the original ***validation***, a new method ***validation*** is performed. The techniques (see **7.2.2.1**) used to validate the modified test or ***calibration method*** are documented in the NIST ***sub-level quality documents***.

7.2.2.3 The validated test and ***calibration methods*** used by NIST ***measurement services*** are developed or chosen to be relevant to the customers' needs and consistent with specified requirements. NIST is dedicated to understanding and determining the appropriateness of NIST measurement methods and results in support of their customers. The measurement procedures and performance characteristics of the validated methods used by NIST ***measurement services*** are stated in detail on the ***NIST Calibrations website***, ***NIST Standard Reference Materials website***, and the ***NIST Standard Reference Data website***.

7.2.2.4 The NIST ***measurement service*** retains records of method ***validations*** that include:

a) the ***validation*** procedure used;
b) specification of the requirements;
c) determination of the performance characteristics of the method;
d) results obtained;
e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 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. The sampling plan is based on appropriate statistical methods. Details of this process can be found in the respective NIST ***sub-level quality documents***.

7.3.1.1 Calibration of Individual Instruments: NIST normally calibrates individual instruments and explicitly states that the measurement results apply only to that specific instrument. Generally, NIST ***calibrations*** and ***special tests*** do not rely on sampling.

7.3.1.2 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.

7.3.1.3 ***Standard Reference Data***: When NIST providers of ***Standard Reference Data (SRD)*** carry out sampling of data in the evaluation of an ***SRD*** database, the requirements of this Section **7.3***Sampling* do not apply. See Section **G7.3***Sampling* of Appendix G.

7.3.2 Sampling method: When sampling is conducted, NIST ***sub-level quality documents*** includes:

a) the selection of samples or sites;
b) the sampling plan;
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or ***calibration***.

7.3.3 Sampling records: When sampling is conducted, NIST ***measurement service*** activities retain records of the sampling data that forms part of the testing or ***calibration*** that was undertaken, and includes:
a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name);
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of test or calibration items

Standard Reference Data: For NIST providers of ***Standard Reference Data (SRD)***, the requirements of this Section **7.4***Handling of test or calibration items* do not apply. See an analogous Section **G7.4** in Appendix G for the handling of SRD data.

7.4.1 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 documents*** and/or the ***reference material*** project completion memo.

7.4.2 Identification of test or calibration item: NIST ***measurement service*** activities utilize systems for the unambiguous identification of test or ***calibration*** items to ensure that items will not be confused physically or when referred to in records or other documents. The identification system is documented in the ***sub-level quality documents*** and/or the ***reference material*** project completion memo.

7.4.3 Deviations from specified conditions: When a test or ***calibration*** item deviates from specified conditions, the NIST ***measurement service*** determines the suitability of the item for measurement usually in consultation with the customer. In cases where the item is tested or calibrated, the deviations from the specified conditions are recorded and the report includes a disclaimer indicating that the results may be affected by the deviation. These procedures are documented in the ***sub-level quality documents*** and/or the ***reference material*** project completion memo.

7.4.4 Environmental conditions: NIST ***measurement service*** activities provide appropriate storage conditions and, where necessary, conditioning environments for test or ***calibration*** items. Environmental requirements for the storage or conditioning of test or ***calibration*** items are documented in the NIST ***sub-level quality documents***.

7.5 Technical records

7.5.1 It is NIST policy that technical records for ***measurement service*** activities contain the results, report, identification of factors affecting the measurement result and its associated ***measurement uncertainty***, and sufficient information to enable the repetition of the ***measurement service*** activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

Technical records for ***SRD*** programs include the identity of personnel responsible for the critical evaluation of the data, and documents the data evaluation techniques, methods, and procedures employed by the NIST technical division.

Data plans and other technical records that are aimed towards the ability to reproduce NIST measurements, the production of ***reference materials*** or the critical evaluation of ***SRD*** are designed to address ***discoverability*** and ***preservation***. The data plans are documented in the NIST ***sub-level quality documents*** of the technical Divisions.

Additional procedures and requirements for the technical records of the NIST ***measurement services*** are documented in the NIST ***sub-level quality documents***.

7.5.2 When there are amendments to technical records of NIST ***measurement services***, the amended records can be tracked to previous versions or to original observations, retaining both the original and amended data and files. The records include the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations, as discussed in the NIST ***sub-level quality documents***.

7.6 Evaluation of measurement uncertainty

7.6.1 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. NIST ***SRD*** programs critically evaluate the reported uncertainties associated with ***SRD*** databases. 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. Detailed evaluations of uncertainty for each NIST ***measurement service*** is documented in the NIST ***sub-level quality documents***.

7.6.2 NIST ***measurement services*** performing ***calibrations***, including ***calibrations*** of its own equipment, evaluates the ***measurement uncertainty***, as documented in the NIST ***sub-level quality documents***.

7.6.3 A NIST ***measurement service*** that performs testing, as a function of the ***measurement service*** activities, evaluates the ***measurement uncertainty*** of the test results, as documented in the NIST ***sub-level quality documents***.

7.7 Ensuring the validity of results

7.7.1 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, which includes the recording of resulting data in such a way that trends are detectable. Statistical techniques are usually applied to the data to assure the validity of the results. The monitoring practices are planned and reviewed, and documented in the NIST ***sub-level quality documents***. Monitoring procedures include the following practices, where appropriate:

- 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.

7.7.2 NIST ***measurement services*** monitor their performance by comparison with results of other laboratories, through participation in ***key comparisons*** and interlaboratory comparisons. 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***. In some cases, a NIST ***measurement service*** participates in proficiency testing programs managed by proficiency testing providers that meet the requirements of *ISO/IEC 17043*. The comparison monitoring procedures are planned, reviewed and documented in the NIST ***sub-level quality documents***.

7.7.3 NIST ***measurement services*** analyze the data produced from monitoring activities (see **7.7.1** and **7.7.2**), and utilize the analyses to control the ***measurement service*** process and, if applicable, to improve the ***measurement service*** activities. If the analyses of data from monitoring activities find the results to be outside pre-defined criteria, an investigation and appropriate action is taken to prevent the occurrence of non-conforming work (see **7.10**), as described in the NIST ***sub-level quality documents***.

7.8 Reporting of results

7.8.1 General

7.8.1.1 Signatory Authority: Reports of NIST ***measurement service*** tests or ***calibrations*** are reviewed by specific personnel as documented in the NIST ***sub-level quality documents***. All Reports of Calibration and Reports of Special Test are 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. The list of authorized NIST official signatories for the reports is documented in the NIST ***sub-level quality documents***.

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.

7.8.1.2 Reports of NIST ***measurement services*** are written, issued and retained as technical records as documented in the NIST ***sub-level quality documents***. The types of reports include:

NIST Calibration Services

- ***NIST Report of Calibration and Report of Test***
  the visible output of NIST ***calibration measurement services*** that is prepared to ensure that it accurately conveys all information pertaining to a calibration so that data may be used with maximum benefit by all concerned.

Report requirements for NIST ***Calibration Services*** are given in:
Section **7.8.2**: Common requirements for reports (test, calibration or sampling)
Section **7.8.3**: Specific requirements for test reports
Section **7.8.4**: Specific requirements for calibration certificates

Report requirements for NIST ***Measurement Assurance Programs (MAP)*** are given in:
Section **F4.8** *Reports* of Appendix F.

- ***Standard Reference Instruments (SRI)***
  NIST ***Calibration Services*** provides measurement traceability as a ***Special Test*** for each ***SRI*** purchased by a customer. 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, as documented in the NIST ***sub-level quality documents***.

NIST Reference Materials

- ***NIST SRM® Certificate or Certificate of Analysis***
  in accordance with latest published version of *ISO Guides 30 and 31*, a NIST ***SRM certificate*** is a ***Reference Material Certificate*** containing the name, description, and intended purpose of the material, the logo of the U.S. Department of Commerce, the name of NIST as the certifying body, instructions for proper use and storage of the material, certified property value(s) with associated uncertainty(ies), method(s) used to obtain property values, the period of validity, if appropriate, and any other technical information deemed necessary for its proper use. A ***Certificate*** is issued for an ***SRM*** certified for one or more specific physical or engineering performance properties and may contain NIST reference, information, or both values in addition to certified values. A ***Certificate of Analysis*** is issued for an ***SRM*** certified for one or more specific chemical properties. Note: *ISO Guide 31* is updated periodically; check with ISO for the latest version. (NIST directive Order O5601.00)

- ***NIST RM Report of Investigation***
  document issued with a NIST RM that contains all the technical information necessary for proper use of the material, the logo of the U.S. Department of Commerce, and the name and title of the NIST officer authorized to issue it. ***Reports of Investigation*** may contain reference values, information values or statements related to the homogeneity and stability of studied parameters, but they do not contain certified values. (NIST directive Order O5601.00)

- ***NIST Certificate of Traceability***
  document stating the purpose, protocols, and measurement pathways that support claims by an ***NIST Traceable Reference Material (NTRM)*** to specific NIST standards or stated references. No NIST certified values are provided, but rather the document references a specific NIST report of analysis, bears the logo of the U.S. Department of Commerce, the name of NIST as a certifying body, and the name and title of the NIST officer authorized to accept responsibility for its contents. (NIST directive Order O5601.00)

Report requirements for NIST ***Reference Materials*** are given in:
Section **E7.14** *RM documents and labels* of Appendix E.

Distribution of Standard Reference Data

Documentation requirements for NIST ***Standard Reference Data*** are given in:
Section **G7.8** *Reporting of results* of Appendix G.

7.8.1.3 Reports of NIST ***measurement service*** tests or ***calibrations*** are composed and issued in a specific format as documented in the NIST ***sub-level quality documents*** and are not reported in a simplified way.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 NIST ***measurement services*** reports requirements:

Reports of Calibrations and Special Test

NIST Reports of Test or Calibration are designed by each ***measurement service*** to provide accurate, clear, unambiguous

and objective information necessary for the interpretation of the results and all information required by the method used. In addition to the report requirements of *ISO 17025:2017*, NIST Reports of Test or Calibration include the following information:

- the NIST ***Calibration Services*** test or ***calibration*** number, and service ID number
- the Order Number, previously, the ***Test Folder number***,
- 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).

Reports of Test or Calibration conform to *ISO/IEC 17025:2017* and at a minimum, contain or address the following, unless there are valid reasons for not doing so, as documented in the NIST ***sub-level quality documents***:

a) a title (e.g. "Report of Test", "Calibration Report" or "Report of Special Test");
b) the first page shall be on NIST letterhead or be equivalently identified as originating from NIST;
c) the name and address of the laboratory;
d) the NIST Calibration Services test or calibration number, and service ID number;
e) page numbers, with the last page designated as the end of the report;
f) the name and address of the customer (refer to USPS Publication 28, Postal Addressing Standards);
g) identification of the method used;
h) a description, unambiguous identification, and, when necessary, the condition of the item(s) tested or calibrated;
i) the date of receipt of the test or calibration item(s), where this is critical to the validity and application of the results;
j) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
k) the date(s) of performance of the laboratory activity;
l) the date of issue of the report;
m) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
evidence or a statement that the measurement results are traceable;
n) the results with, where appropriate, the units of measurement;
an evaluation of the measurement uncertainty associated with each measured value
o) a description of the calibration method; additions to, deviations, or exclusions from the method;
p) the name of the person(s) performing the measurements and analyses;
the name, function, and signature of the person(s) authorizing the report;
q) an explanation of the proper use and interpretation of the reported results; as necessary (this can be in the form of an addendum).

7.8.2.2 NIST ***measurement services*** are responsible for all information provided in the report, except when information is provided by the customer. Data provided by a customer is identified. In addition, a disclaimer is put on the report when information is supplied by the customer that can affect the validity of results.

7.8.3 Specific requirements for test reports

Attributes and contents of test reports issued by NIST are addressed in 7.8.2.1.

7.8.3.1 NIST does not perform sampling as a separate or distinct measurement service.

7.8.4 Specific requirements for calibration certificates

NIST does not issue calibration certificates.

7.8.4.1 NIST does not perform sampling as a part of its calibration services.

7.8.4.2 NIST ***measurement service*** Reports of Calibration do not contain any recommendation on the ***calibration*** interval; however, ***Certificates*** for ***Standard Reference Materials (SRMs)*** and Reports of Investigation for ***NIST Reference Materials (RMs)*** may include a period of validity, as documented in the NIST ***sub-level quality documents***.

7.8.5 Reporting sampling

NIST does not offer sampling as a measurement service.

7.8.6 Reporting statements of conformity

NIST only issues statements of conformity for the American Petroleum Institute for thread gages. This is addressed in the sub-level quality documents for Dimensional Metrology.

7.8.7 Reporting opinions and interpretations

7.8.7.1 NIST Measurement Services do not issue opinions or interpretations.

7.8.8 Amendments to reports

7.8.8.1 When a NIST ***measurement service*** issued report needs to be changed, amended or re-issued, the change of information is clearly identified and, where appropriate, the reason for the change included in the report, as documented in the NIST ***sub-level quality documents***.

7.8.8.2 Amendments to a NIST ***measurement service*** issued report are made in the form of a further document, or data transfer, that meets all the requirements of the original report, and includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording, as documented in the NIST ***sub-level quality documents***.

7.8.8.3 When it is necessary to issue a complete new NIST ***measurement service*** report, the new report is uniquely identified and contains a reference to the original that it replaces, as documented in the NIST sub ***sub-level quality documents***.

7.9 Complaints

7.9.1 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. The process for handling complaints is documented in the following clauses of section **7.9** and Appendix A. Additional ***measurement service*** specific procedures for addressing complaints are documented in the NIST ***sub-level quality documents***.

7.9.2 All NIST ***measurement service*** staff have access to the applicable complaint handling process and are instructed on its use, as documented in the NIST ***sub-level quality documents***.

7.9.3 In the case of complaints regarding any aspect of a ***measurement service***, the actions are taken in accord with the provisions of Section **7.10.1** and Appendix A. In addition, the actions taken include recording:

1) the nature of the complaint, date received, name of person registering the complaint, NIST recipient assigned to address complaint, the Order number, previously, the ***Test Folder Number*** (if relevant), and initial response to the complainant;
2) the final resolution of the complaint to include applicable elements of Section **7.10.1**;
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 documents***.

7.9.4 Upon receipt of a complaint, the ***measurement service*** confirms whether the complaint relates to ***measurement service*** activities that it is responsible for and, if so, deal with it. Complaints related to ***measurement services*** of other Divisions should be forwarded to the relevant Divisions through Division quality managers. The ***measurement service*** is responsible for all decisions at all levels of the handling process for complaints.

7.9.5 Whenever possible, the ***measurement service*** acknowledges receipt of the complaint, and provides the complainant with progress reports and the outcome, as documented in the NIST ***sub-level quality documents***.

7.9.6 The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original ***measurement service*** activities in question, as documented in the NIST ***sub-level quality***

documents.

7.9.7 Whenever possible, the ***measurement service*** gives formal notice of the end of the complaint handling to the complainant, as documented in the NIST ***sub-level quality documents***.

7.10 Nonconforming work

7.10.1 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.

7.10.2 All incidents of nonconforming work are documented in the Division's/Office's quarterly quality report, and as documented in the NIST ***sub-level quality documents***.

7.10.3 When the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the ***measurement service*** operations with its own management system, the ***measurement service*** implements corrective action as documented in the NIST ***sub-level quality documents*** (see **8.7**).

7.11 Control of data and information management

7.11.1 The ***measurement service*** staff are ensured access to the data and information needed to perform ***measurement service*** activities, as documented in the NIST ***sub-level quality documents***.

7.11.2 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 documents***. The ***laboratory*** information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces within the ***laboratory*** information management system(s), by the ***measurement service*** before introduction. Whenever there are any changes, including ***laboratory*** software configuration or modifications to commercial off-the-shelf software, they are authorized, documented and validated before implementation, as documented in the NIST ***sub-level quality documents***. Commercial off-the-shelf software in general use within its designed application range is considered sufficiently validated.

7.11.3 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.

7.11.4 NIST ***measurement services*** information management systems are managed and maintained on-site, as documented in the NIST ***sub-level quality documents***.

7.11.5 The NIST ***measurement service*** ensures that instructions, manuals and reference data relevant to the ***measurement service*** information management system(s) are made readily available to personnel, as documented in the NIST ***sub-level quality documents***.

7.11.6 The NIST ***measurement service*** ensures that data calculations and data transfers are systematically checked, as documented in the NIST ***sub-level quality documents***.

8 Management system requirements

8.1 NIST quality management system

8.1.1 General

The NIST Quality Management System (QMS) for ***measurement services*** as described in this manual and as documented in the NIST ***sub-level quality documents*** (see **8.2.4**). The organizational hierarchy of the NIST QMS, Figure 3, is essentially identical to that shown in Figure 1 for the provision of NIST ***measurement services***.

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 QMS 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 documents*** is delegated to the Chief of that Division or Director of that Office and the NIST Quality Manager.

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 QMS 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.

8.1.2 In addition to meeting the requirements of Clauses 4 to 7 of *ISO 17025:2017*, the NIST QMS for ***measurement services*** is implemented as defined by Option A in Clause 8 of *ISO 17025:2017*, and addresses the following:

- management system documentation (see **8.2**);
- control of management system documents (see **8.3**);
- control of records (see **8.4**);
- actions to address risks and opportunities (see **8.5**);
- improvement (see **8.6**);
- corrective actions (see **8.7**);
- internal audits (see **8.8**);
- management reviews (see **8.9**).

8.1.3 The NIST QMS for ***measurement services*** was not established and is not maintained in accordance with the requirements of ISO 9001, as defined by Option B in Section 8 of *ISO 17025:2017*. NIST does not seek registration to ISO 9001.

8.2 Management system documentation

8.2.1 NIST is committed to the formal QMS outlined in this manual, which conforms to international standard *ISO/IEC 17025* and to the relevant requirements of *ISO/IEC 17034* and *ISO 17043* 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 **6.2.6.2**)

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.

8.2.2 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.

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*** that are assessed by NIST experts and are trustworthy such that people can use the data with confidence and base significant decisions on the data. At a minimum, the following quality objectives must be met:

- Compliance with ***SRD*** critical evaluation criteria (see section **G7.2** Selection, verification and validation of methods)
- Greatest degree of accuracy (closeness to true value) as deemed possible by NIST experts
- Provenance, i.e., sources of information are sufficiently documented

NIST expects risks to impartiality be eliminated or minimized as an essential obligation to its customers. Evidence of addressing the risks to impartiality is documented in the NIST ***sub-level quality documents***.

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

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

Other specific client service measures may be found in the NIST ***sub-level quality documents***.

8.2.3 NIST is committed to performance excellence as is characteristic of a global leader in ***measurements*** and standards. The 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. The NIST QMS) comprises policies and procedures that NIST follows in the pursuit of performance excellence. They are documented in the NIST Quality Manual (NIST QM), as approved and signed by the NIST Director in the Introduction to this document.

8.2.4 The NIST Quality Manual (QM) for Measurement Services documents the NIST QMS for ***measurement services***, and 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 documents*** (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.

8.2.5 All staff members whose activities affect the quality of NIST ***measurement services*** are to be familiar with the NIST QMS described in this document (QM-I) and in the QMS ***sub-level quality documents***, and to implement it in their work. Training materials and records are available from the NIST Quality Manager. Additional training materials and requirements may be found in the NIST sub-level quality documents and from the Division Quality Managers.

8.3 Control of management system documents

8.3.1 In general, NIST QMS documents are managed following Administrative Manual Subchapter 2.06 on Records Management. The policies and procedures governing control of documents, records, and data obtained as part of a ***calibration*** procedure, ***SRD*** evaluation, or ***reference material*** characterization are documented in this document (NIST QM-I) and the ***sub-level quality documents***. 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].

8.3.2 The NIST QMS ensures that the NIST QM documents, including the NISTQM-I, NIST-QM-xx series and supporting documents, are controlled as follows:

a) documents are approved for adequacy prior to issue by authorized personnel;
b) documents are periodically reviewed, and updated as necessary;
c) changes and the current revision status of documents are identified;
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
e) documents are uniquely identified;
f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

NIST-QM-I (this document):

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.

A (read/print-only) copy of NIST-QM-I is also 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 residing 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 documents*** 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.

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 indicates 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.

Sub-level quality documents:

The procedures for the approval, review, revision, availability, identification, and handling of obsolete ***sub-level quality documents*** (NIST-QM-xx series and supporting documents) differ between NIST ***measurement services*** and are documented in the NIST ***sub-level quality documents***. Supporting documents include documents relevant to the NIST ***measurement service*** activities, such as test and ***calibration*** procedures, instructions, standards, manuals and reference data. Applicable documents are uniquely identified and are available at points of use.

8.4 Control of records

8.4.1 ***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].

8.4.2 NIST ***measurement services*** implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The NIST ***measurement service*** retains ***measurement service*** records for a period consistent with NIST and Division policies. Access to these records is consistent with applicable confidentiality commitments, and records are readily available when authorized. Detailed descriptions of the NIST ***Measurement Services*** record control policies and procedures are documented in the associated NIST ***sub-level quality documents***.

8.5 Actions to address risks and opportunities

8.5.1 NIST ***measurement services*** address the risks and opportunities associated with NIST ***measurement services*** activities in order to:

a) give assurance that the QMS achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the NIST ***measurement service***;
c) prevent, or reduce, undesired impacts and potential failures in the NIST ***measurement service*** activities;
d) achieve improvement.

8.5.2 NIST ***measurement services*** formulate action plans to address risks and opportunities, including how to integrate and implement the actions into the management system and how to evaluate of the effectiveness of the actions. The plans are documented in the NIST ***sub-level quality documents***.

8.5.3 Actions taken to address risks and opportunities are commensurate and proportional to the potential impact on the validity of ***measurement service*** results. The actions taken to address risks and opportunities are documented in the NIST ***sub-level quality documents***.

8.6 Improvement

8.6.1 NIST expects continuous improvement in the provision of ***measurement services*** and encourages identification of opportunities for improvement from all staff. 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 actions that would foster continued and improved quality. Actions and opportunities for improvement are acted upon, monitored and recorded within the Division/Office quality management systems.

8.6.2 NIST pro-actively seeks ***customer feedback*** from its ***measurement service*** customers. Customer satisfaction surveys for ***Calibrations*** and ***Reference Materials*** are available online. The E-Commerce System, previously, 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.

8.7 Corrective actions

8.7.1 The Corrective Action Procedure is found in Appendix A. The procedure specifies how NIST identifies and manages nonconformities found in its provision of ***measurement services***, its QMS, 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).

8.7.2 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 Appendix A); others may have simpler remedies.

8.7.3 The completed Corrective Action Request (CAR) form (see Appendix A) 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.

8.8 Internal audits

8.8.1 NIST conducts two levels of internal audits at planned intervals to provide information on whether the NIST QMS and NIST ***measurement service*** activities conform to *ISO 17025:2017* and *ISO/IEC 17034:2016* to the extent allowed by statute and regulation:

1) NIST-Level Assessments (also known as NIST-Level Peer reviews)
2) Division/Office-Level Audits (also known as internal audits) and NIST-QM-I internal audits.

8.8.2 The frequency, methods, responsibilities, planning requirements, implementation and reporting of NIST QMS audits/assessments are as follows and as documented in the NIST ***sub-level quality documents***.

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.

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 QMS. 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 QMS, 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 documents***. In conducting these technical reviews, a Division may involve internal and/or external technical experts. For additional information on quality assurance practices, see Section **7.7.1**.

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

8.9 Management reviews

8.9.1 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 through their respective Laboratories to the ***NIST Quality Manager***. ***Laboratory*** Directors or their delegates 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 are communicated to the ***NIST Quality Manager***. The ***NIST Quality Manager***:

- reviews all Office, Division, and ***Laboratory*** reports, assessing the implementation of the NIST QMS and conformity to *ISO/IEC 17025* and *ISO/IEC 17034*, as appropriate;
- reports to the NIST Associate Director for Laboratory Programs (ADLP) a summary of the findings, recommendations, and implementation plans, if required;
- provides the report electronically via email to the ADLP prior to meeting with them to discuss the quarterly report findings and recommendations;
- communicates this information to Offices, Divisions, and Laboratories as appropriate;
- records this report and a report of any actions taken subsequent to the presentation to the ADLP as part of the documentation of the NIST QMS;
- makes the report and the Division Quarterly Quality reports available on the SharePoint site;
- provides a copy of the report to the NMSC after meeting with the ADLP; and
- makes recommendations, if any, as to the fitness of any specific ***measurement service*** in the NIST portfolio to the ADLP.

8.9.2 The QMS quarterly reports that Divisions submit through their respective Laboratories to the ***NIST Quality Manager,*** include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;
b) fulfilment of objectives, including quality objectives;
c) suitability of policies and procedures;
d) status of actions from previous management reviews;
e) outcome of recent internal audits;
f) corrective actions;
g) assessments by external bodies;
h) changes in the volume and type of the work or in the range of ***laboratory*** activities;
i) customer and personnel feedback;
j) complaints;
k) effectiveness of any implemented improvements;
l) adequacy of resources;
m) results of risk identification;
n) outcomes of the assurance of the validity of results; and
o) other relevant factors, such as monitoring activities and training.

8.9.3 Management review reports

Typically, the management reviews at NIST rely on the Quarterly Quality Reports prepared by the Division/Office Quality Manager and submitted by their Division Chief/Office Director through their respective ***Laboratories*** 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 17025:2017* Clause 8.9 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***.

Appendix A Corrective Action Procedure

A1 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 QMS, 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 to prevent their recurrence (corrective actions).

A2 References

A2.1 NIST-QM-I, the NIST quality manual for measurement services

A2.2 NIST Policy for Measurement Quality

A3 Definitions

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

A4 Responsibilities

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

a) ***Assessment Review Board (ARB)***;
b) Quality Manager;
c) ADLP;
d) all NIST staff who provide ***measurement services*** in an administrative or technical capacity.

A5 Procedure

A5.1 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.

A5.2 Determining the causes of and correcting nonconformities

A5.2.1 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 A5.3); others may have simpler remedies.

A5.2.2 The ***NIST Quality Manager*** reviews the inputs from the activities listed in **A5.1**. If a nonconformity is identified, the corrective action process is initiated.

A5.2.3 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.

A5.3 Formal corrective action process

A5.3.1 The ***ARB*** is responsible for reviewing requests for corrective actions.

A5.3.2 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").

A5.3.3 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.

A5.3.4 The Quality Manager forwards a copy of the form to CAR owner and creates a case file for the quality records.

A5.3.5 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.

A5.3.6 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.

A5.3.7 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.

A5.3.8 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.

A5.3.9 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.

A5.3.10 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.

A5.3.11 The Quality Manager enters the date the CAR was closed after all affected procedures, instructions, and forms are revised and reissued, as needed.

A5.4 Corrective action follow-up

A5.4.1 The status and results of open CARs and CARs recently closed are considered as inputs to management reviews for the ADLP.

A5.4.2 Closed CARs will be reviewed and verified for effectiveness at the internal audit following their closure.

A5.5 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

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 QMS of ***NMIs***
   - knowledge and experience assessing the management requirements of *ISO/IEC 17025* and/or *ISO/IEC 17034* 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/IEC 17034* 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/IEC 17034* where applicable. While most or all of the assessors will be NIST staff members, NIST retirees may be 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***, 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 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, beginning with receipt of the assessment findings report 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 ***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 or CTL (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 QMS.

d) The ***ARB*** will also ensure that the assessment process is consistent across the NIST Laboratories and to identify possible improvements in the assessment process.

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 QNS

In the fulfillment of the ***CIPM MRA***, an ***NMI*** is required to have its QMS 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 ***CIPM MRA*** signatories in ***SIM***. The ***SIM*** associate representative to the ***JCRB*** coordinates the task force work. The task force is referred to as the SIM QSTF. The ***SIM*** Council also agreed in 2005 to the following general guidelines:

- any ***SIM*** Member ***NMI*** can request the review of its QMS, 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 the QMS 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 QMS in parts, covering different ***calibration*** and ***measurement services***; and
- the QMS 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 QMS of ***National Metrology Institutes*** and Designated Institutes, is documented in SIM 09 and QSTF-00. These documents describe the requirements and procedures for QMS reviews including the quality manual and description of the QMS for its ***calibration*** and measurement capabilities.

The following website contains the ***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 Measurement Uncertainty

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].

The computation of consensus values for key comparisons and other interlaboratory studies, or to blend measurement results obtained by different methods, may be done by using the NIST Consensus Builder, available at https://consensus.nist.gov [8], which also produces unilateral and bilateral degrees of equivalence for key comparisons.

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 any case, 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.

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[8] A. Koepke, T. Lafarge, A. Possolo, B. Toman (2017) Consensus building for interlaboratory studies, key comparisons, and meta-analysis, Metrologia 54(3), S34-S62, DOI 10.1088/1681-7575/aa6c0e.

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

D1 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.

D2 References

NIST-QM-I Sections: **2**; 5.5 **(3)**, 5.5 **(4)**; and **8.3.2**

D3 Definitions

D4 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.

D5 Procedure

D5.1 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.

D5.2 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 ADLP, 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. The routing of the CD 15 includes: the NIST Director and Chief of Staff, the ADLP and SCO Director.

D5.3 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 at http://www.nist.gov/qualitysystem/. The NMSC, ***ARB***, NIST QMS sub-level 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.

D5.4 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 1. NIST-QM-I Document Tracking Version History

Effective Date	Version	Date Obsolete
4-Mar-2003	**NIST-QM-I Version 1**	**4-Mar-2004**
4-Mar-2004	**NIST-QM-I Version 2**	**20-Mar-2006**
20-Mar-2006	**NIST-QM-I Version 3**	**19-Aug-2008**
19-Aug-2008	**NIST-QM-I Version 4**	**3-Sep-2009**
3-Sep-2009	**NIST-QM-I Version 5**	**1-Aug-2010**
1-Aug-2010	**NIST-QM-I Version 6**	**9-Aug-2011**
9-Aug-2011	**NIST-QM-I Version 7**	**7-May-2013**
7-May-2013	**NIST-QM-I Version 8**	**13-Nov-2015**
13-Nov-2015	**NIST-QM-I Version 9**	**27-Dec-2016**
27-Dec-2016	**NIST-QM-I Version 10**	**29-Mar-2019**
29-Mar-2019	**NIST-QM-I Version 11**	

Appendix E Requirements for ISO 17034:2016
General requirements for the competence of reference material producers

E1 Scope

The NIST ***measurement services*** that produce ***reference materials*** comply with NIST QMS Sections 2 to 8 and Appendixes A to D, where applicable, that address the requirements of *ISO/IEC 17025:2017*. This Appendix E addresses the additional requirements of *ISO 17034:2016* that NIST ***reference material*** producers comply with including the entire category of NIST artifact-based services such as ***Standard Reference Materials® (SRMs®)***, NIST ***Reference Materials (RMs)***, and ***NIST Traceable Reference Materials (NTRMs℠)***.

E2 References

The References given in Section **2** *References* apply to this Appendix.

Office of Reference Materials Procedures and Instructions Manual
(https://share.nist.gov/sites/orm/msdqs/MSDPI/default.aspx)

E3 Definitions

The definitions given in Section **3** *Definitions* apply to this Appendix.

NIST Certified Value
value reported on an ***SRM certificate*** or ***certificate of analysis*** for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been fully investigated or accounted for by NIST. (NIST directive Order O5601.00)

NIST Information Value
value that is considered to be of interest and use to the ***SRM*** user, but insufficient information is available to assess adequately the uncertainty associated with the value or only a limited number of analyses were performed. Information values cannot be used to establish metrological traceability (NIST directive Order O5601.00).

NIST Reference Value
noncertified values that represent the best estimate of the true values based on available data; however, the values do not meet the NIST criteria for certification and are provided with associated uncertainties that may reflect only measurement reproducibility, may not include all sources of uncertainty, or may reflect a lack of sufficient statistical agreement among multiple analytical methods (NIST directive Order O5601.00)

E4 General requirements

It is NIST policy for producers of ***reference materials*** to be in compliance with the relevant requirements of ISO 17034:2016 for the production of ***reference material*** to the extent allowed by statute and regulation. A NIST ***measurement service*** that assigns a value to a ***reference material*** is considered a producer of ***reference material*** whether the material is produced entirely in-house at NIST or is procured from an outside source in partial form or in finished form.

By complying with the NIST QMS Sections 2 to 8 and Appendixes A to D above, NIST ***measurement services*** that produce ***reference material*** also comply with most of the contractual, impartiality, confidentiality, resource, measurement, traceability, control of records, and management system requirements of ISO 17034 as indicated

in the following sections with references to the applicable sections. Additional NIST policy requirements related to the production and handling of ***reference materials*** that are not fully addressed by the requirements of ISO 17025 are specifically stated in this Appendix E, primarily, but not solely, in Sections:
E7.2 *Production planning*;
E7.3 *Production control*;
E7.4 *Material handling and storage*;
E7.5 *Material processing*;
E7.10 *Assessment of homogeneity*;
E7.11 *Assessment and monitoring of stability*;
E7.12 *Characterization*;
E7.13 *Assignment of property values and their uncertainties*;
E7.14 *RM documents and labels*; and
E7.15 *Distribution service*.

E4.1 Contractual matters

The NIST QMS policies for contractual matters as they apply to NIST ***measurement services*** including the production and certification of ***reference materials*** are documented in Section **5.6** *NIST Quality Management* System personnel and Section **7.1** *Review of requests, tenders and contracts*. See also the Office of Reference Materials Procedures and Instructions Manual.

E4.2 Impartiality

The NIST QMS policies for impartiality, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **4.1**.

E4.3 Confidentiality

The NIST QMS policies for confidentiality, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **4.2**.

E5 Structural requirements

NIST structural requirements, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **5** *Structural requirements*.

Responsibilities: As set forth in NIST directive Order O5601.00 (7/20/2015), the responsibilities for the production of NIST ***reference materials***, including ***Standard Reference Materials® (SRMs®)***, ***Reference Materials (RMs)***, and ***NIST Traceable Reference Materials (NTRMs℠)***, as applicable, are the following:

NIST Laboratory

- Plans, sets priorities, funds, and implements the development, production, delivery, and quality of ***reference materials***;
- Establishes technical criteria for the development and certification of ***reference materials***;
- Determines specifications for and acquires material;
- Provides ORM with specifications for material preparation, if appropriate, and storage of units;
- Ensures that all NIST Working Capital Fund (WCF) resources loaned to it are used appropriately and properly accounted for;
- Determines the number of units to be produced and the appropriate time period for cost recovery with a maximum of five years to calculate the unit sales prices, as well as provides the basis for the annual unit sales estimate;
- Develops and carries out a material stability monitoring plan and perpetuation plan for each new ***reference material***;
- Performs continuous assessment of customer needs and requirements for ***reference materials***;
- Prepares and packages material, or requests ORM to do so;
- Provides customer technical support as needed;
- Establishes and maintains a quality system that assures quality in the results of its ***measurement services***; and

- Provides representation on relevant national and international committees for the technical aspects of ***reference materials***.

Office of Reference Materials (ORM)

- Provides guidance to the NIST Laboratories, upon request, for the development, production, and certification of ***reference materials***;
- Evaluates the business case of projects that have been submitted by the NIST Laboratories for WCF and Service Development (SD) funding and communicates the results of that evaluation back to the Laboratories;
- Reviews ***Laboratory*** Operations estimates and determines fees and impact on prices. Communicates finding to the Laboratories;
- Performs activities related to preparing, packaging, labeling (includes implementing the Globally Harmonized System (GHS) for classification and labeling), pricing, marketing, warehousing, selling, and distributing ***reference materials***;
- Assists the OUs in determining GHS requirements for non SRM related products for materials used for interlab exercises;
- Coordinates the GHS related determinations with OSHE;
- Reviews ***certificates*** for NIST-wide uniformity and ISO Guide compliance and prepares and maintains other documentation (i.e. safety data sheets) related to ***reference materials***;
- Prepares and updates the ***Special Publication (SP) 260 SRM catalog*** and price list;
- Prepares and issues other documents such as journal articles, brochures, and newsletters that provide current information about ***reference materials***;
- Exhibits ***reference materials*** and related publications and documentation at technical meetings, conferences, and trade shows;
- Provides the necessary information, reports, and administrative support to NIST customers and NIST Laboratories;
- Provides an archive of the documentation related to the certification, production and analysis of the ***reference materials,*** including where possible the data submitted to SED for certification;
- Responsible for shipping of all ***reference materials*** in accordance with all applicable DOT and international transport requirement; and
- Provides national and international representation for business and policy aspects of ***reference materials***.

Statistical Engineering Division (SED)

- Assists in the design of sampling and measurement strategies for certification of ***reference materials***;
- Provides technical guidance on the implementation of NIST uncertainty policy;
- Develops standardized statistical design and analysis templates that can be used by NIST ***Laboratory*** personnel to carry out statistical analyses for classes of ***reference materials*** that follow fixed approaches;
- Provides training on the proper use, interpretation, and limitations of these templates;
- Provides data analysis and uncertainty assessment for ***reference materials*** for which appropriate standardized analysis templates are not available; and
- Certifies the computation for unit values and stated uncertainties, as appropriate.

Office of Financial Resource Management - Budget Division

- Reviews and approves the annual ***reference materials*** Operations budget as proposed by ORM;
- Reviews and approves annual ***reference material*** surcharge levels;
- Determines the annual Service Development (SD) and WCF Production funding levels, including carryover, and communicates to ORM the allocation levels by NIST Laboratory;
- Reviews and approves WCF Stock Transfer Notices (STNs) that transfer units to stock and establish unit sales prices;
- Reviews and approves the annual inflationary factor for materials and labor as proposed by ORM for calculation of the replacement surcharge; and
- Monitors expense and income, work-in-process, and sales activities for the ***reference materials*** Programs.

Office of Financial Resource Management – Finance Division

- Performs all NIST billings and collections for ***reference materials*** sold;

- Performs all debt management activities and reporting for outstanding ***reference material*** invoices;
- Performs the deferral of Service Development income in excess of expenses at yearend; and
- Serves as liaison for all financial audit activities regarding the ***reference materials*** Programs.

The importance of communicating with customers and meeting the requirements of customers of NIST ***measurement services***, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Sections **8.2.2** and **8.2.3**.

E6 Resource requirements

In general, NIST QMS resource requirements, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **6** *Resource requirements*. See also the Office of Reference Materials Procedures and Instructions Manual.

E6.1 Personnel

The NIST QMS policies and procedures for NIST personnel involved in the delivery of NIST ***measurement services***, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **6.2** *Personnel*.

E6.2 Use of collaborators and subcontracting

The NIST QMS policies on the use of ***collaborators*** and ***subcontractors***, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **6.2.6.2** *Subcontracting of Tests, Calibrations, and Reference Material Certifications* and Section **6.2.6.3** *Collaborators*.

E6.3 Provision of equipment, services and supplies

The NIST QMS requirements for material processing equipment, measuring equipment, services and supplies, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **6.4** *Equipment* and Section **6.6** *Externally provided products and services*.

E6.4 Facilities and environmental conditions

The NIST QMS requirements for facilities and environmental conditions, as they apply to NIST ***measurement services*** including the production, certification, and storage of ***reference materials***, are documented in Section **6.3** *Facilities and environmental conditions* and Section **7.4** *Handling of test or calibration items*.

E7 Technical and production requirements

E7.1 General requirements

All NIST producers of ***reference materials***, including ***Standard Reference Materials® (SRMs®)***, ***Reference Materials (RMs)***, and ***NIST Traceable Reference Materials (NTRMs^{CM})***, address all requirements in Section **E7** for the production of ***reference materials*** and for certified values and other property values where necessary.

E7.2 Production planning

E7.2.1 NIST ***reference material*** producers identify and plan those processes that directly affect the quality of ***reference material*** production. The production plan and any approval process are documented in the NIST ***sub-level quality documents***.

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. See also the Office of Reference Materials Procedures and Instructions Manual.

E7.2.2 NIST ***reference material*** producers specify all technical input to be obtained from ***collaborators*** (see Section **6.2.6.3**). The required information is recorded and regularly reviewed, as documented in the NIST ***sub-level quality documents***.

E7.2.3 During the planning stage, NIST ***reference material*** producers address the following, as documented

in NIST ***sub-level quality documents***:

a) material selection (including, where appropriate, sampling);
b) ***verification*** of the identity of the material;
c) maintaining suitable environments for all aspects of production (see **E6.4**);
d) material processing (see **E7.5**);
e) choice of measurement procedures (see **E7.6**,);
f) ***validation*** of measurement procedures (see **E7.6**);
g) ***verification*** and ***calibration*** of measuring equipment (see **E7.7**);
h) specification of acceptance criteria for, and assessment of, homogeneity, including sampling (see **E7.10**);
i) specification of acceptance criteria for, and assessment and monitoring of, stability, including sampling (see **E7.11**);
j) designing and organizing appropriate characterization, including sampling (see **E7.12**);
k) assessing commutability (where appropriate);
l) assigning property values (see **E7.13**);
m) establishing uncertainty budgets and estimating uncertainties of certified value(s) (see **E7.13**);
n) defining acceptance criteria for measurand levels and their uncertainties;
o) establishing ***metrological traceability*** of measurement result(s) and certified value(s) (see **E7.9**);
p) issuing RM documents (see **E7.14**);
q) ensuring adequate storage facilities and conditions (see **E7.4**);
r) ensuring appropriate labelling and packaging of the RMs (see **E7.14**);
s) ensuring appropriate transport arrangements (see **E7.15**);
t) ensuring post-production stability monitoring, if applicable (see **E7.11)**;
u) ensuring an adequate post-distribution service for RM users (see **E7.15**).

E7.2.4 When multiple batches of the same material are produced at the same time, or are produced in successive batches at substantially different times using similar starting materials and by applying the same procedures, the NIST ***reference material*** producer verifies consistency between batches as documented in the NIST ***sub-level quality documents***.

E7.3 Production control

The NIST ***reference material*** producer verifies that the production plan is implemented as specified. Deviations from the plan are documented and approved as documented in the NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual. Also see NIST Policy P 5600.00 and Order O5601.00 Standard Reference Materials Program for additional production and control processes.

E7.4 Material handling and storage

E7.4.1 The material handling and storage requirements, documented in Section **7.4** *Handling of test or calibration items*, apply to ***reference materials***. In addition, the NIST ***reference material*** producer makes arrangements to ensure the integrity of ***reference materials***, such as adverse environmental influences or possible contamination, from the candidate material stage throughout the production process, as documented in the NIST ***sub-level quality documents***. Once the NIST ***reference material*** producer delivers prepared ***reference materials*** to the ***NIST Office of Reference Materials (ORM)***, the integrity of the ***reference materials*** is maintained by procedures documented in the Office of Reference Materials Procedures and Instructions Manual.

E7.4.2 The NIST ***reference material*** producer and ***ORM*** have procedures for identifying, preserving and separating ***reference materials*** from chemicals and other samples, from the time of processing through to their distribution to users, as documented in the NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual.

E7.4.3 The NIST ***reference material*** producer works with ***ORM*** to develop and ensure adequate packaging of the ***reference materials***, as documented in the NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual.

E7.4.4 As needed, the NIST ***reference material*** producer and ***ORM*** develop procedures for assessing the ***reference material*** for possible deterioration at appropriate intervals throughout the storage period, as documented in the NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and

Instructions Manual.

E7.4.5 The NIST ***reference material*** producer works with ***ORM*** to develop and control the ***reference material*** packaging and labeling processes to ensure conformity with safety and transport requirements, as documented in the NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual.

E7.4.6 ***ORM***, with input from the NIST ***reference material*** producer, choose appropriate shipping containers and shipping methods to ensure that the integrity of the ***reference material*** is maintained up to the point of first use by the customer, as documented in NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual.

E7.5 Material processing

E7.5.1 The NIST ***reference material*** producer works with ***ORM*** to establish procedures to ensure that the ***reference material*** undergoes adequate processing for its intended use, as documented in NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual.

Procedures for the processing of NIST ***reference material*** address at least the following:

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

E7.5.2 The NIST ***reference material*** producer operates material processing equipment in accordance with documented procedures, such as manufacturer's instructions, as documented in NIST ***sub-level quality documents***.

E7.6 Measurement procedures

The NIST QMS requirements for measurement procedures, as they apply to NIST ***measurement services*** including the certification of ***reference materials***, are documented in Section **7.2** *Selection, verification and validation of methods.*

E7.7 Measuring equipment

The NIST QMS requirements for measuring equipment, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **6.4** *Equipment*.

E7.8 Data integrity and evaluation

The NIST QMS requirements for data integrity and evaluation, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **7.7** *Ensuring the validity of results* and Section **7.11** *Control of data and information management*.

E7.9 Metrological traceability of certified values

The NIST QMS requirements for ***metrological traceability*** of NIST certified values, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **6.5** *Metrological traceability*.

E7.10 Assessment of homogeneity

E7.10.1 The NIST ***reference material*** producer assesses the homogeneity of a candidate ***reference material*** in its final form to ensure its fitness for purpose. The procedures for homogeneity assessment are specific to each ***reference material*** characterized. The details of the Division procedures for assessing homogeneity are documented in the NIST ***sub-level quality documents***.

E7.10.2 When the ***reference material*** is produced in multiple batches, either the equivalence of the batches is demonstrated, or the homogeneity of each batch is evaluated separately, as documented in NIST ***sub-level quality documents***.

E7.10.3 The NIST ***reference material*** producer selects and validates procedures to measure homogeneity so that the precision and selectivity are fit for the purpose required, as documented in NIST ***sub-level quality documents***.

E7.10.4 Where homogeneity needs to be determined experimentally, the NIST ***reference material*** producer determines the homogeneity for every property of interest unless it can be shown, using scientific evidence or previous experience, that particular groups of properties are sufficiently closely associated that measurement of one property in such a group furnishes evidence of homogeneity for other properties in the same group. The procedures and processes used are documented in NIST ***sub-level quality documents***.

E7.10.5 For certified values, such as reported for NIST ***Standard Reference Materials® (SRMs®)***, the ***reference material*** homogeneity is quantified as an uncertainty contribution to the certified value unless homogeneity can be shown to be a negligible contribution to the uncertainty, as documented in NIST ***sub-level quality documents***.

E7.11 Assessment and monitoring of stability

E7.11.1 The NIST ***reference material*** producer develops procedures for the assessment and monitoring of the ***reference material*** stability, which include the following, as documented in NIST ***sub-level quality documents***:

a) assess, by experimentation if necessary, the stability of all relevant properties of a ***reference material*** under proposed storage conditions and choose pre-treatment, packaging and storage conditions in accordance with the results of the assessment;
b) assess, by experimentation if necessary, the stability of all relevant properties of a ***reference material*** under proposed conditions of transport, and choose transport conditions to maintain stability during transport;
c) establish any necessary advice on storage and use of the material to maintain stability at the customer's premises;
d) select a scheme for monitoring the stability of materials held in long term storage that permits prompt detection of change, taking into account the possible rate of change;
e) where the stability of a certified value cannot be ensured, make due allowance in the stated uncertainty for possible change in the value prior to use or, where the change with time can be predicted, provide a means of correcting the certified value and its uncertainty for the expected change over time;
f) where repeated sampling from a ***reference material*** unit or repeated use of an entire ***reference material*** unit is permitted by the instructions for use, assess the possible effects on the stability of the material and take appropriate action.

E7.11.2 The NIST ***reference material*** producer experimentally assesses the stability of the ***reference material*** before release unless the ***reference material*** producer has evidence of stability or prior experience of stability from closely similar materials held for an extended period under the same planned storage conditions, as documented in NIST ***sub-level quality documents***.

E7.11.3 When the ***reference material*** is produced in multiple batches and the stability of each batch is not evaluated separately, the NIST ***reference material*** producer evaluates the stability of a statistically-determined sampling of different batches, as documented in NIST ***sub-level quality documents***.

E7.12 Characterization

E7.12.1 The NIST ***reference material*** producer characterizes the ***reference material*** in order to assign property values, as documented in NIST ***sub-level quality documents***.

E7.12.2 The NIST ***reference material*** producer defines whether a quantitative or a qualitative property will be characterized and, if quantitative, whether the measurand is operationally defined or is defined independently of any specific procedure, as documented in NIST ***sub-level quality documents***.

E7.12.3 The NIST ***reference material*** producer develops a characterization strategy appropriate for the intended use of the ***reference material***, as documented in NIST ***sub-level quality documents***.

E7.12.4 The NIST ***reference material*** producer specifies the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability whether or not traceability

and ***measurement uncertainty*** are reported on the RM documentation, as documented in NIST ***sub-level quality documents***. To this end, the NIST ***reference material*** producer:

a) documents a measurement plan that clearly describes the tasks to be performed and communicates this to all personnel responsible for measurements used in characterization;
b) for certified values, demonstrates the competence of any ***collaborator*** involved in the characterization.

E7.12.5 The NIST ***reference material*** producer performs a technical evaluation of the data and the documents involved in characterization to confirm adherence to the measurement plan, and, in the case of deviations from the plan, assesses whether the deviation necessitates exclusion of the data from characterization, as documented in NIST ***sub-level quality documents***.

E7.13 Assignment of property values and their uncertainties

E7.13.1 The NIST ***reference material*** producer develops and uses documented procedures for assigning property values to ***reference materials***, as documented in NIST ***sub-level quality documents***.

E7.13.2 The documented procedures used by the NIST ***reference material*** producer for assigning property values include the following, as appropriate:

a) details of the experimental designs and statistical techniques used;
b) policies on treatment and investigation of anomalous results, including outliers;
c) whether weighting techniques are used for contributions to assigned property values derived from different procedures or laboratories with different measurement uncertainties;
d) the approach used to assign uncertainties to the property values;
e) any other significant factors that may affect the assignment of property values.

E7.13.3 When assigning property values, NIST ***reference material*** producers consider all pertinent technical information on test methods and equipment, including reported uncertainty information, and evidence of ***laboratory*** performance, as documented in NIST ***sub-level quality documents***.

E7.13.4 NIST ***reference material*** producers conduct thorough investigations of outliers before excluding them solely on statistical evidence, to determine the reasons for the discrepancies, as documented in NIST ***sub-level quality documents***.

E7.13.5 The NIST QMS requirements for evaluating uncertainty of NIST certified values, as they apply to ***reference materials***, are documented in Section **7.6** *Evaluation of measurement uncertainty*.

E7.13.6 When certified values are being reported, the NIST ***reference material*** producer may consult with ***ORM***, and the NIST Statistical Engineering Division, to address uncertainty contributions of each of the following, as documented in NIST ***sub-level quality documents***:

a) changes of property values during transport;
b) changes of property values during storage;
c) between-unit and within-unit inhomogeneity;
d) characterization, including any difference between multiple procedures used for characterization.

E7.14 RM documents and labels

NIST ***reference material*** producers work with ***ORM*** to prepare and issue documentation with the NIST ***reference material*** including: NIST ***SRM®*** ***Certificate*** or ***Certificate of Analysis***, NIST ***RM*** Report of Investigation, NIST Certificate of Traceability and other documentation, as documented in NIST ***sub-level quality documents***, and in accordance with the Office of Reference Materials Procedures and Instructions Manual. See Formatting Manual - Cert, COA, ROI: https://share.nist.gov/sites/orm/msdqs/MSDPI/MSD%20Procedures%20and%20Instructions%20Manual/FormattingManual_CertCOAROI%20MNL.pdf.

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

E7.14.1 In addition to the report requirements of *ISO 17034:2016*, NIST ***SRM®*** ***Certificate*** or ***Certificate of Analysis*** and NIST ***RM*** Report of Investigation include the following information:

- reference material number and batch number

At a minimum, the documentation issued with the NIST ***reference material*** conforms to *ISO 17034:2016* and includes at least the following, as documented in NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual:

a) title of the document;
b) unique identifier of the ***reference material***;
c) the name of the ***reference material***;
d) name and contact details of the NIST ***reference material*** producer;
e) intended use;
f) minimum sample size (whenever applicable);
g) period of validity;
h) storage information;
i) instructions for handling and use that are sufficient to ensure the integrity of the material;
j) page number and the total number of pages;
k) document version;
l) information on commutability of the material (where appropriate).

E7.14.2 In addition to the minimum requirements given in **E7.14.1**, the documentation issued with the ***NIST SRM®*** also contains at least the following additional information, as documented in NIST ***sub-level quality documents*** and the Office of Reference Materials Procedures and Instructions Manual:

a) description of the ***SRM***;
b) property of interest, property value and associated uncertainty;
c) measurement procedure for operationally defined measurands;
d) ***metrological traceability*** of the certified values;
e) name and function of ***reference material*** producer's approving officer.

E7.14.3 NIST is required to comply with the Occupational Safety and Health Administration's Hazard Communication Standard 2012 for labeling of NIST reference material. ORM takes full responsibility to ensure that the labels comply with Global Health Standards to enable transportation and shipment of the materials. This is documented in the Office of Reference Materials Procedures and Instructions Manual.

E7.15 Distribution service

E7.15.1 NIST ***reference material*** producers work with ***ORM*** to develop and document ***reference material*** shipping conditions (including shipping temperature, packaging, duration of transport and other precautions necessary for integrity of the material) and procedures including customs documentation, as documented in NIST ***sub-level quality documents***, and in accordance with the Office of Reference Materials Procedures and Instructions Manual.

E7.15.2 ***ORM*** maintains records of NIST ***reference material*** sales and distribution in accordance with the Office of Reference Materials Procedures and Instructions Manual

E7.15.3 NIST ***reference material*** producers work with ***ORM*** to develop and document ***reference material*** user guidance and technical support, typically included in the ***reference material certificate***, as documented in NIST ***sub-level quality documents***, and the Office of Reference Materials Procedures and Instructions Manual.

E7.15.4 NIST ***measurement services*** and ***ORM*** make their best efforts to notify customers of any change to the property value or uncertainty for any ***reference material*** within the validity period of the ***reference material certificate*** or product information sheet, as documented in NIST ***sub-level quality documents***, and the Office of Reference Materials Procedures and Instructions Manual.

E7.15.5 ***ORM*** maintains nonexclusive agreements with licensed distributors of NIST ***reference material***, which are limited to 3rd party validated reference material producers (see https://www.nist.gov/srm/ordering-policies-and-pricing/licensed-distributors). ***ORM*** ensures that an effective post-distribution service is maintained and makes arrangements with the distributors to ensure that its activities are executed in accordance with the relevant clauses of *ISO 17034*, as documented in ***ORM sub-level quality documents***, and in accordance with the Office of Reference Materials Procedures and Instructions Manual.

E7.16 Control of quality and technical records

The NIST QMS procedures for the control of quality and technical records, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, regarding confidentiality, identification, collection, required information content, reporting, indexing, access, storage, retention time, maintenance and disposal of quality and technical records, are documented in Section **4.2** *Confidentiality*, Section **7.5** *Technical records*, Section **7.8** *Reporting of results*, Section **8.3** *Control of management system documents* and Section **8.4** *Control of records*. See also the Office of Reference Materials Procedures and Instructions Manual.

Correcting mistakes: When mistakes occur in records related to the production and certification of ***reference materials***, the method for correction include the preservation of the original data, the date and person making the alteration, along with the corrective data. The applicable method employed is documented in NIST sub-level quality documents. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

E7.17 Management of non-conforming work

The NIST QMS requirements for the management of non-conforming work, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, is documented in Section **7.10** *Nonconforming work*.

E7.18 Complaints

The NIST QMS requirements for handling of complaints, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, is documented in Section **7.9** *Complaints*.

E8 Management system requirements

E8.1 NIST quality management system

E8.1.1 General

The NIST management system is a QMS for ***measurement services*** as described in this manual and as documented in the NIST ***sub-level quality documents*** (see **8.2.4**).

E8.1.2 In addition to meeting the requirements of Clauses 4 to 7 of ISO *17034:2016*, the NIST QMS for NIST ***measurement services*** that produce and certify NIST ***reference materials***, is implemented as defined by Option A in Clause 8 of ISO *17025:2017*.

E8.1.2.1 The NIST QMS is documented in Section **8.2.4** and applies to NIST ***measurement services*** for the production and certification of NIST ***reference materials***.

E8.1.2.2 The scope of NIST ***measurement service*** activities, including those activities related to the production and certification of ***reference materials***, are documented in Section **1***Scope*. Specific ***measurement service*** activities are documented in the NIST ***sub-level quality documents***.

E8.1.2.3 The NIST QMS for ***measurement services*** related to the production and certification of ***reference materials*** addresses the following:

— quality policy (see **E8.2**);
— general management system documentation (see **E8.3**);
— control of management system documents (see **E8.4**);
— control of records (see **E8.5**);
— management review (see **E8.6**);
— internal audit (see **E8.7**);
— actions to address risks and opportunities (see **E8.8**);
— corrective actions (see **E8.9**);
— improvement (see **E8.10**);
— feedback from customers (see **E8.11**).

E8.1.3 Although the NIST management system, as it applies to NIST ***measurement services*** that produce and certify ***reference materials***, is based on the requirements of *ISO 9001*, NIST does not seek registration to *ISO 9001*, and is implemented as defined by Option A in Clause 8 of *ISO 17025:2017* (see **8.1.2**).

E8.2 Quality policy

The NIST quality policy, as it applies to NIST ***measurement services*** including the production and certification of ***reference materials***, is documented in Section **8.2** *Management system documentation* and Section **8.2.3**. The overall objectives of the NIST quality policy and the NIST QMS for ***measurement services*** are reviewed as part of the management review as documented in Section **8.9** *Management reviews*.

E8.3 General management system documentation

The NIST Quality Manual (QM) for Measurement Services (this document) documents the NIST QMS for NIST ***measurement services*** including the production and certification of ***reference materials***. The NIST Quality Manual (QM) is organized in multiple levels as described in Section **8.2.4**, and is communicated to, understood by, available to and implemented by all staff members whose activities affect the quality of NIST ***measurement services*** as documented in Section **8.2.5**.

E8.4 Control of management system documents

The NIST QMS requirements for the control of management system documents, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.3** *Control of management system documents*.

E8.5 Control of records

The NIST QMS requirements for the control of records, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.4** *Control of records*.

E8.6 Management review

The NIST QMS requirements for management reviews, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.9** *Management reviews*.

E8.7 Internal audit

The NIST QMS requirements for internal audits, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.8** *Internal audits*.

E8.8 Actions to address risks and opportunities

The NIST QMS required actions to address risks and opportunities, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.5** *Actions to address risks and opportunities*.

E8.9 Corrective actions

The NIST QMS policies, procedures and appropriate authorities for implementing corrective actions, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.7** *Corrective actions* and Appendix A.

E8.10 Improvement

The NIST QMS policies and procedures to improve the effectiveness of the NIST Quality Management System, as they apply NIST ***measurement services*** including to the production and certification of ***reference materials***, are documented in Section **8.6** *Improvement*.

E8.11 Feedback from customers

The NIST QMS policies and procedures for seeking feedback from customers to improve the NIST Quality Management System and ***measurement service*** activities, as they apply to NIST ***measurement services*** including the production and certification of ***reference materials***, are documented in Section **8.6.2**.

Appendix F Requirements for ISO 17043:2010
Conformity assessment – General requirements for proficiency testing

F1 Scope

NIST ***proficiency testing*** programs are directly associated with existing NIST ***measurement services*** and comply with NIST QMS Sections 2 to 8 and Appendixes A to D, where applicable, that address the requirements of *ISO/IEC 17025:2017*. The NIST ***proficiency testing*** programs that use ***reference materials*** as the testing artifacts also comply with NIST QMS Appendix E that addresses the requirements of *ISO/IEC 17034:2016*. This Appendix F addresses the additional requirements of *ISO 17043:2010* that NIST ***measurement services*** conducting ***proficiency testing*** programs comply with**,** including the NIST ***Measurement Assurance Programs***

(MAP).

F2 References

The References given in Section **2** *References* apply to this Appendix.

ISO/IEC 17000:2004, Conformity assessment — Vocabulary and general principles

F3 Terms and definitions

The definitions given in Section **3** *Definitions* apply to this Appendix.

For the purposes of this Appendix F, the following terms and definitions from *ISO 17043:2010* apply.

assigned value
value attributed to a particular property of a proficiency test item

coordinator
one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme

customer
organization or individual for which a proficiency testing scheme is provided through a contractual arrangement

interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

outlier
observation in a set of data that appears to be inconsistent with the remainder of that set

NOTE An outlier can originate from a different population or be the result of an incorrect recording or other gross error.

participant
laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency testing provider

NOTE In some cases, the participant can be an inspection body.

proficiency testing
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

proficiency test item
sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

proficiency testing provider
organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme

proficiency testing round
single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants

proficiency testing scheme
proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, ***calibration*** or inspection

robust statistical method
statistical method insensitive to small departures from underlying assumptions surrounding an underlying probabilistic model

standard deviation for proficiency assessment

measure of dispersion used in the evaluation of results of proficiency testing, based on the available information

NOTE 1 The standard deviation applies only to ratio and differential scale results.

NOTE 2 Not all proficiency testing schemes evaluate proficiency based on the dispersion of results.

F4 Technical Requirements

F4.1 General

By complying with the NIST QMS Sections 2 to 8 and Appendixes A to D above, NIST ***measurement services*** that conduct ***proficiency testing*** programs also comply with most of the personnel, equipment, accommodation, environmental, confidentiality, and management requirements of *ISO 17043* as indicated in the following sections with references to the applicable sections. Additional NIST policy requirements related to conducting NIST ***proficiency testing*** programs that are not fully addressed by the requirements of *ISO 17025* are specifically stated in this Appendix F, primarily, but not solely, in Sections:
F4.4 *Design of proficiency testing schemes*
F4.5 Choice *of method or procedure*
F4.6 Operation *of proficiency testing schemes*
F4.7 *Data analysis and evaluation of proficiency testing scheme results*
F4.8 Reports; and
F4.9 *Communication with participants*.

F4.2 Personnel

The NIST QMS policies and procedures for NIST personnel, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **6.2** *Personnel*.

F4.3 Equipment, accommodation and environment

The NIST QMS requirements for equipment, facilities and environmental conditions, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **6.4** *Equipment*, Section **6.3** *Facilities and environmental conditions* and Section **7.4** *Handling of test or calibration items*.

F4.4 Design of proficiency testing schemes

F4.4.1 Planning

F4.4.1.1 NIST ***proficiency testing*** programs identify and plan all processes that directly affect the quality of the proficiency testing scheme and ensure that the plans are carried out in accordance with prescribed procedures, as documented in NIST ***sub-level quality documents***.

NOTE The informative Appendixes A, B and C of *ISO/IEC 17043* may provide helpful information to developing and planning a NIST ***proficiency testing*** program.

F4.4.1.2 The planning of the ***proficiency testing*** scheme is planned by NIST staff and not by outside ***collaborators***, advisors or experts, and is not subcontracted. It is acceptable for NIST staff to utilize advice or assistance from outside advisors or experts when planning ***proficiency testing*** scheme.

F4.4.1.3 Before commencement, the NIST ***proficiency testing*** program fully documents the ***proficiency testing*** plan that addresses the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion:

a) the name and location of the NIST ***measurement service***;
b) identification of the ***proficiency testing*** program manager and other personnel involved in the design and operation of the ***proficiency testing*** scheme;
c) the activities to be conducted by NIST ***collaborators*** and the names and addresses of NIST ***collaborators*** involved in the operation of the ***proficiency testing*** scheme;
d) criteria to be met for participation;
e) the number and type of expected ***participants*** in the ***proficiency testing*** scheme;

f) selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific ***proficiency testing round***;
g) a description of the range of values or characteristics, or both, to be expected for the ***proficiency test items***;
h) the potential major sources of errors involved in the area of ***proficiency testing*** offered;
i) requirements for the production, quality control, storage and distribution of ***proficiency test items***;
j) reasonable precautions to prevent collusion between ***participants*** or falsification of results, and procedures to be employed if collusion or falsification of results is suspected;
k) a description of the information which is to be supplied to ***participants*** and the time schedule for the various phases of the ***proficiency testing*** scheme;
l) for continuous ***proficiency testing*** schemes, the frequency or dates upon which proficiency test items are to be distributed to ***participants***, the deadlines for the return of results by ***participants*** and, where appropriate, the dates on which testing or measurement is to be carried out by ***participants***;
m) any information on methods or procedures which ***participants*** need to use to prepare the test material and perform the tests or measurements;
n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability;
o) preparation of any standardized reporting formats to be used by ***participants***;
p) a detailed description of the statistical analysis to be used;
q) the origin, ***metrological traceability*** and ***measurement uncertainty*** of any ***assigned values***;
r) criteria for the evaluation of performance of ***participants***;
s) a description of the data, interim reports or information to be returned to ***participants***;
t) a description of the extent to which ***participant*** results, and the conclusions that will be based on the outcome of the ***proficiency testing*** scheme, are to be made public; and
u) actions to be taken in the case of lost or damaged ***proficiency test items***.

The ***proficiency testing*** plan is documented in NIST ***sub-level quality documents***.

F4.4.1.4 NIST ***proficiency testing*** programs are required to have access to the necessary technical expertise and experience in the relevant field of testing, ***calibration***, sampling or inspection, as well as statistics, including a nationally or internationally recognized expert in the ***calibration***, measurement, ***reference material***, or ***standard reference data*** area (see **6.2.1** *Competence and impartiality*), as documented in NIST ***sub-level quality documents***.

F4.4.1.5 The technical expertise of NIST ***proficiency testing*** programs, as appropriate, determine matters such as the following:

a) planning requirements as listed in **F4.4.1.3**;
b) identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous ***proficiency test items***, or in the provision of a stable ***assigned value*** for a ***proficiency test item***;
c) preparation of detailed instructions for ***participants***;
d) comments on any technical difficulties or other remarks raised by ***participants*** in previous ***proficiency testing rounds***;
e) provision of advice in evaluating the performance of ***participants***;
f) comments on the results and performance of ***participants*** as a whole and, where appropriate, groups of ***participants*** or individual ***participants***;
g) provision of advice for ***participants*** (within limits of confidentiality), either individually or within the report;
h) responding to feedback from ***participants***; and
i) planning or participating in technical meetings with ***participants***.

F4.4.2 Preparation of proficiency test items

F4.4.2.1 The NIST ***proficiency testing*** program establishes and implements procedures to ensure that ***proficiency test items*** are prepared in accordance with the plan described in the ***proficiency testing*** plan, as

documented in NIST ***sub-level quality documents***.

F4.4.2.2 The NIST ***proficiency testing*** program establishes and implements procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all ***proficiency test items***, as documented in NIST ***sub-level quality documents***. The procedures ensure that materials used to manufacture ***proficiency test items*** are obtained in accordance with relevant regulatory and ethical requirements.

F4.4.2.3 The NIST ***proficiency testing*** program should match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or ***calibration***.

F4.4.2.4 For NIST ***proficiency testing*** schemes that require ***participants*** to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the NIST ***proficiency testing*** program, the NIST ***proficiency testing*** program issues instructions for preparation, packaging and transport of the proficiency test item, as documented in NIST ***sub-level quality documents***.

F4.4.3 Homogeneity and stability

F4.4.3.1 NIST ***proficiency testing*** programs plan the ***proficiency testing scheme*** and choose ***proficiency test items*** to minimize any adverse effect on the evaluation of the participant's performance. NIST recognizes the importance that homogeneity and stability of the test items have on the test results. The NIST ***proficiency testing*** program often utilizes NIST ***reference material*** as the ***proficiency test items*** or materials that are evaluated for homogeneity and stability using the same criteria as would be used to develop a NIST ***reference material*** (see Section **E7.10** *Assessment of homogeneity* and Section **E7.11** *Assessment and monitoring of stability*). In cases where the test items used for NIST ***proficiency testing*** programs are instruments or devices rather than material, stability of these ***proficiency test items*** is also evaluated. Acceptable levels of homogeneity and stability are established as documented in NIST ***sub-level quality documents***.

F4.4.3.2 Where appropriate, NIST ***proficiency testing*** programs conduct the assessment of homogeneity and stability of the test items in accordance with appropriate statistical designs. The statistical analysis is often developed in collaboration with the NIST Statistical Engineering Division, and, where possible, includes a statistically appropriate selection (random or otherwise) of test items from the whole batch for evaluation. The procedures for the assessment of homogeneity and stability of the test items are documented in NIST ***sub-level quality documents***.

F4.4.3.3 For ***proficiency test items*** that are materials, the assessment of homogeneity is usually performed after the ***proficiency test items*** have been packaged in the final form and before distribution to ***participants*** unless stability studies indicate that they should be stored in bulk form, or where no influence of packaging is reasonably expected, or when homogeneity testing cannot be carried out prior to distribution for practical, technical or logistical reasons. The schedule for evaluating ***proficiency test items*** is documented in NIST ***sub-level quality documents***.

F4.4.3.4 NIST ***proficiency testing*** programs make every effort to ensure that ***proficiency test items*** are sufficiently stable and do not undergo any significant change throughout the conduct of the ***proficiency testing round***, including storage and transport conditions. When the level of instability or inhomogeneity of test samples is such that there could be an effect on the participants results, the stability is quantified and considered as an additional component of the ***measurement uncertainty*** associated with the assigned value of the proficiency test item, and/or taken into account in the evaluation criteria. The process of evaluating ***proficiency testing*** results when instability must be considered is documented in NIST ***sub-level quality documents***.

F4.4.3.5 When ***proficiency test items*** from previous ***rounds*** are retained for future use, the NIST ***proficiency testing*** program re-evaluates and confirms the property values to be determined in the ***proficiency testing scheme*** prior to distribution. The procedures for the re-assessment of property values of the test items are documented in NIST ***sub-level quality documents***.

F4.4.3.6 In circumstances where homogeneity and stability testing is not feasible, the NIST ***proficiency testing*** program documents in ***sub-level quality documents*** that the procedures used to collect, produce, package and

distribute the ***proficiency test items*** are sufficient for the purpose of the proficiency testing.

F4.4.4 Statistical design

F4.4.4.1 NIST ***proficiency testing*** programs, working with the NIST Statistical Engineering Division, develop statistical designs to meet the ***proficiency testing scheme*** and purpose(s) covering the processes of planning, collection, analysis and reporting of the ***proficiency testing*** data. In cases where the ***proficiency testing*** design is mandated by a specification given by a regulatory authority or accreditation body, the statistical design and data analysis methods may be taken directly from the specification.

F4.4.4.2 NIST ***proficiency testing*** programs document, in NIST ***sub-level quality documents***, the statistical design and data analysis methods used to identify the assigned value and evaluate ***participant*** results, with a description of the reasons for their selection and assumptions upon which they are based. The statistical design and data analysis methods used are developed in collaboration with the NIST Statistical Engineering Division.

F4.4.4.3 NIST ***proficiency testing*** programs consider the following when designing a statistical analysis:

a) the accuracy (trueness and precision) as well as the ***measurement uncertainty*** required or expected for each measurand or characteristic in the ***proficiency testing***;
b) the minimum number of ***participants*** in the ***proficiency testing*** scheme needed to meet the objectives of the statistical design; in cases where there is an insufficient number of ***participants*** to meet these objectives or to produce statistically meaningful analysis of results, the NIST ***proficiency testing*** program shall document, and provide to ***participants***, details of the alternative approaches used to assess ***participant*** performance;
c) the relevance of significant figures to the reported result, including the number of decimal places;
d) the number of ***proficiency test items*** to be tested or measured and the number of repeat tests, ***calibrations*** or measurements to be conducted on each ***proficiency test item*** or for each determination;
e) the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria;
f) procedures to be used to identify or handle outliers, or both;
g) where relevant, the procedures for the evaluation of values excluded from statistical analysis; and
h) where appropriate, the objectives to be met for the design and the frequency of proficiency testing rounds.

F4.4.5 Assigned values

F4.4.5.1 NIST ***proficiency testing*** programs develop and document, in NIST ***sub-level quality documents***, the procedure for determining the assigned values for the measurands or characteristics in a ***proficiency testing*** scheme, taking into account the ***metrological traceability*** and ***measurement uncertainty*** required to demonstrate that the ***proficiency testing scheme*** is fit for its purpose

F4.4.5.2 NIST ***proficiency testing*** programs in the area of ***calibration*** assign values to the ***proficiency test items*** with ***metrological traceability*** and ***measurement uncertainty***, as documented in NIST ***sub-level quality documents***.

F4.4.5.3 NIST ***proficiency testing*** programs, in areas other than ***calibration***, determine the relevance, needs and feasibility for ***metrological traceability*** and associated ***measurement uncertainty*** of the assigned value by considering requirements of ***participants*** or other interested parties, or by the design of the ***proficiency testing scheme***, as documented in NIST ***sub-level quality documents***.

F4.4.5.4 In all cases, NIST ***proficiency testing*** programs determine the assigned value(s) of ***proficiency test items***, and do not use a consensus value for the assigned value.

F4.4.5.5 NIST ***proficiency testing*** programs have policies regarding the disclosure of assigned values that ensures ***participants*** cannot gain advantage from early disclosure, as documented in NIST ***sub-level quality documents***.

F4.5 Choice of method or procedure

F4.5.1 The NIST ***proficiency testing*** program may instruct ***participants*** to use a specific measurement method

or allow the ***participant*** to use the test method, ***calibration*** or measurement procedure of their choice, as documented in NIST ***sub-level quality documents***.

F4.5.2 Where ***participants*** are permitted to use a method of their choice, the NIST ***proficiency testing*** program develops a policy and follows a procedure regarding comparison of results obtained by different test or measurement methods and assesses the ***participant's*** results based on the equivalency of the measurement methods, as documented in NIST ***sub-level quality documents***.

F4.6 Operation of proficiency testing schemes

F4.6.1 Instructions for participants

F4.6.1.1 The NIST ***proficiency testing*** program gives ***participants*** sufficient prior notice before sending ***proficiency test items***, and provides the date on which the ***proficiency test items*** are likely to arrive or to be dispatched, unless the design of the ***proficiency testing scheme*** makes it inappropriate to do so, as documented in NIST ***sub-level quality documents***.

F4.6.1.2 The NIST ***proficiency testing*** program provides detailed documented instructions to all participants, as documented in NIST ***sub-level quality documents***, which includes the following:

a) the necessity to treat ***proficiency test items*** in the same manner as the majority of routinely tested samples (unless there are particular requirements of the ***proficiency testing scheme*** which require departure from this principle);
b) details of factors which could influence the testing or ***calibration*** of the ***proficiency test items***, e.g. the nature of the ***proficiency test items***, conditions of storage, whether the ***proficiency testing scheme*** is limited to selected test methods, and the timing of the testing or measurement;
c) detailed procedure for preparing or conditioning, or both preparing and conditioning, of the ***proficiency test items*** before conducting the tests or ***calibrations***;
d) any appropriate instructions on handling the ***proficiency test items***, including any safety requirements;
e) any specific environmental conditions for the ***participant*** to conduct tests or ***calibrations***, or both, and, if relevant, any requirement for the ***participants*** to report relevant environmental conditions during the time of the measurement;
f) specific and detailed instructions on the manner of recording and reporting test or measurement results and associated uncertainties. If the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability;
   NOTE This instruction usually includes parameters such as the units of measurement, the number of significant figures or decimal places and reporting basis (e.g. on dry weight, or "as received").
g) the latest date for the provider to receive the proficiency testing or measurement results for analysis;
h) information on the contact details of the NIST proficiency testing program for enquiries; and
i) instructions on return of the proficiency test items, when applicable.

F4.6.2 Proficiency test items handling and storage

F4.6.2.1 The applicable material handling and storage requirements, documented in Section **7.4** *Handling of test or calibration items* and in Section **E7.4** *Material handling and storage* apply to ***proficiency test items***, as documented in the NIST ***sub-level quality documents***.

F4.6.2.2 The NIST ***proficiency testing*** program provides a secure storage area for the ***proficiency test items*** preventing damage or deterioration between preparation and distribution of the ***proficiency test items***. Appropriate procedures for authorizing access to such areas are defined in NIST ***sub-level quality documents***.

F4.6.2.3 When appropriate, the condition of stored chemical or material ***proficiency test items*** are assessed at specified intervals during their storage life to detect possible deterioration, as documented in NIST ***sub-level quality documents*** (also see **E7.11** *Assessment and monitoring of stability*).

F4.6.2.4 Where potentially hazardous ***proficiency test items***, chemicals and materials are used, the NIST ***proficiency testing*** program ensures their safe handling, decontamination and disposal, as documented in NIST

sub-level quality documents.

F4.6.3 Packaging, labelling and distribution of proficiency test items

F4.6.3.1 NIST ***proficiency testing*** programs have procedures for the packaging, labelling and distribution of ***proficiency test items*** to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements, as documented in NIST ***sub-level quality documents***.

F4.6.3.2 The NIST ***proficiency testing*** program specifies relevant environmental conditions for the transport of ***proficiency test items***. Where relevant, the NIST ***proficiency testing*** program monitors the pertinent environmental conditions of the ***proficiency test item*** during transport and assesses the impact of environmental influences on the ***proficiency test item***, as documented in NIST ***sub-level quality documents***.

F4.6.3.3 In ***proficiency testing schemes*** where ***participants*** are required to transport the ***proficiency test items*** to other ***participants***, the NIST ***proficiency testing*** program supplies instructions for this transport to the ***participants***, as documented in NIST ***sub-level quality documents***.

F4.6.3.4 The NIST ***proficiency testing*** program ensures that individual ***proficiency test items*** are clearly labeled, and the labels are designed to remain legible and intact throughout the ***proficiency testing round***, as documented in NIST ***sub-level quality documents***.

F4.6.3.5 The NIST ***proficiency testing*** program develops a procedure to enable the confirmation of delivery of the ***proficiency test items***, as documented in NIST ***sub-level quality documents***.

F4.7 Data analysis and evaluation of proficiency testing scheme results

F4.7.1 Data analysis and records

F4.7.1.1 The requirements for validating data processing equipment and software, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **7.11.2**.

F4.7.1.2 NIST ***proficiency testing*** programs establish and implement appropriate methods and procedures to check the validity of data entry, data transfer, statistical analysis, and reporting of ***participants*** results, as documented in NIST ***sub-level quality documents***.

F4.7.1.3 The NIST ***proficiency testing*** program is required to analyze data such that the generation of summary statistics, performance statistics, and associated information is consistent with the statistical design of the ***proficiency testing scheme***.

F4.7.1.4 NIST ***proficiency testing*** programs use ***robust statistical methods*** or appropriate tests to detect statistical outliers to minimize the influence of outliers on summary statistics, as documented in NIST ***sub-level quality documents***.

F4.7.1.5 NIST ***proficiency testing*** programs develop criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors, as documented in NIST ***sub-level quality documents***.

F4.7.1.6 NIST ***proficiency testing*** programs develop criteria and procedures to identify and manage ***proficiency test items*** that have been distributed and are subsequently found to be unsuitable for performance evaluation, e.g. because of inhomogeneity, instability, damage or contamination, as documented in NIST ***sub-level quality documents***.

F4.7.2 Evaluation of performance

F4.7.2.1 NIST ***proficiency testing*** programs use valid methods of performance evaluation that meet the purpose of the ***proficiency testing scheme***. The methods of evaluation, including a description of the basis for the evaluation, are documented in NIST ***sub-level quality documents***. The evaluation of performance is conducted by NIST staff and not by ***collaborators***, and is not subcontracted (see **F5.5**).

F4.7.2.2 NIST ***proficiency testing*** programs provide expert commentary on the performance of ***participants***

regarding the following, as appropriate:

a) overall performance against prior expectations, taking measurement uncertainties into account;
b) variation within and between ***participants***, and comparisons with any previous ***proficiency testing rounds***, similar ***proficiency testing schemes***, or published precision data;
c) variation between methods or procedures;
d) possible sources of error (with reference to outliers) and suggestions for improving performance;
e) advice and educational feedback to participants as part of the continual improvement procedures of ***participants***;
f) situations where unusual factors make evaluation of results and commentary on performance impossible;
g) any other suggestions, recommendations or general comments; and
h) conclusions.

F4.8 Reports

F4.8.1 NIST ***proficiency testing*** programs produce test reports that are clear and comprehensive and include data covering the results of all ***participants***, together with an indication of the performance of individual ***participants***, as appropriate. The authorization of the final report is conducted by NIST staff and not by ***collaborators***, and is not subcontracted (see **F5.5**), as documented in NIST ***sub-level quality documents***.

F4.8.2 NIST ***proficiency testing*** reports include the following, unless it is not applicable or the NIST ***proficiency testing*** program has valid reasons for not doing so:

a) the name and contact details for the NIST ***proficiency testing*** program;
b) the name and contact details for the coordinator;
c) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
d) an indication of which activities are performed by ***collaborators***;
e) the date of issue and status (e.g. preliminary, interim, or final) of the report;
f) page numbers and a clear indication of the end of the report;
g) a statement of the extent to which results are confidential;
h) the report number and clear identification of the proficiency testing scheme;
i) a clear description of the ***proficiency test items*** used, including necessary details of the ***proficiency test item's*** preparation and homogeneity and stability assessment;
j) the ***participants'*** results;
k) statistical data and summaries, including ***assigned values*** and range of acceptable results and graphical displays;
l) procedures used to establish any assigned value;
m) details of the ***metrological traceability*** and ***measurement uncertainty*** of any assigned value;
n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;
o) ***assigned values*** and summary statistics for test methods/procedures used by each group of ***participants*** (if different methods are used by different groups of ***participants***);
p) comments on ***participants'*** performance by the NIST ***proficiency testing*** program and technical advisers;
q) information about the design and implementation of the ***proficiency testing scheme***;
r) procedures used to statistically analyze the data;
s) advice on the interpretation of the statistical analysis; and
t) comments or recommendations, based on the outcomes of the ***proficiency testing round***.

F4.8.3 NIST ***proficiency testing*** programs produce test reports and make them available to participants within planned timescales, as documented in NIST ***sub-level quality documents***.

F4.8.4 NIST ***proficiency testing*** programs develop a policy for the use of reports by individuals and organizations, as documented in NIST ***sub-level quality documents***.

F4.8.5 When it is necessary to issue a new or amended report for a ***proficiency testing scheme***, the report

includes the following:

a) a unique identification;
b) a reference to the original report that it replaces or amends; and
c) a statement concerning the reason for the amendment or re-issue.

F4.9 Communication with participants

F4.9.1 A NIST ***proficiency testing*** program makes available detailed information about the proficiency testing scheme, as documented in NIST ***sub-level quality documents***, including:

a) relevant details of the scope of the ***proficiency testing scheme***;
b) any fees for participation;
c) documented eligibility criteria for participation;
d) confidentiality arrangements; and
e) details of how to apply.

F4.9.2 A NIST ***proficiency testing*** program promptly informs participants of any changes in the ***proficiency testing scheme*** design or operation, as documented in NIST ***sub-level quality documents***.

F4.9.3 A NIST ***proficiency testing*** program documents procedures for enabling ***participants*** to appeal against the evaluation of their performance in a ***proficiency testing scheme***. The availability of this process is communicated to ***proficiency testing scheme participants***, as documented in NIST ***sub-level quality documents***.

F4.9.4 The NIST ***proficiency testing*** program maintains and retains records of communications with ***participants***, as appropriate, as documented in NIST ***sub-level quality documents***.

F4.9.5 If statements of participation or performance are issued by a NIST ***proficiency testing*** program, the statements contain sufficient information as to not be misleading. Applicable statements are documented in NIST ***sub-level quality documents***

F4.10 Confidentiality

The NIST QMS policies for confidentiality, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **4.2**.

F5 Management requirements

F5.1 Organization

The NIST organizational requirements, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **5** *Structural requirements*.

F5.2 Management system

The NIST management system is a Quality Management System for ***measurement services*** as described in Section **8.1** *NIST quality management system* and Section **8.2** *Management system documentation*.

F5.3 Document control

The NIST QMS procedures and requirements for the control of management system documents, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.3** *Control of management system documents*.

F5.4 Review of requests, tenders and contracts

The NIST QMS policies for the review of requests, tenders and contracts, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **7.1** *Review of requests, tenders and contracts*.

F5.5 Subcontracting services

The NIST QMS policies on the use of ***collaborators*** and ***subcontractors***, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **6.2.6.2** *Subcontracting of Tests, Calibrations, and Reference Material Certifications* and Section **6.2.6.3** *Collaborators*.

F5.6 Purchasing services and supplies

The NIST QMS procedures and requirements for purchasing services and supplies, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **6.6** *Externally provided products and services.*

F5.7 Service to the customer

The NIST QMS policies for willing and open communication and cooperation with customers (participants), as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.2.2**.

The NIST QMS policies and procedures for seeking feedback from customers to improve the NIST Quality Management System and ***measurement service*** activities, including ***proficiency testing*** programs, are documented in Section **8.6.2**.

F5.8 Complaints and appeals

The NIST QMS requirements for the handling of complaints, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, is documented in Section **7.9** *Complaints*.

F5.9 Control of nonconforming work

The NIST QMS requirements for the control of non-conforming work, as they applies to NIST ***measurement services*** including ***proficiency testing*** programs, is documented in Section **7.10** *Nonconforming work.*

F5.10 Improvement

The NIST QMS policies and procedures to improve the effectiveness of the NIST Quality Management System, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.6** *Improvement*.

F5.11 Corrective actions

The NIST QMS policies, procedures and appropriate authorities for implementing corrective actions, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.7** *Corrective actions* and Appendix A.

F5.12 Preventive actions

The NIST QMS policies and procedures to improve the effectiveness of the NIST Quality Management System and subsequent preventive actions to be taken, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.6** *Improvement*.

F5.13 Control of records

The NIST QMS requirements for the control of records, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.4** *Control of records*.

F5.14 Internal audits

The NIST QMS requirements for internal audits, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.8** *Internal audits*.

F5.15 Management reviews

The NIST QMS requirements for management reviews, as they apply to NIST ***measurement services*** including ***proficiency testing*** programs, are documented in Section **8.9** *Management reviews*.

Appendix G Requirements for providers of NIST Standard Reference Data

G1 Scope

This Appendix G addresses the parts of the NIST QMS Sections 2 to 8 and Appendixes A to D that are applicable to NIST ***Standard Reference Data***, and addresses differing or additional requirements unique to NIST ***Standard Reference Data*** as a NIST ***measurement service***.

G2 References

The References given in Section **2** *References* apply to this Appendix.

G3 Terms and definitions

The definitions given in Section **3** *Definitions* apply to this Appendix.

G4 General requirements

G4.1 Impartiality

The NIST QMS policies for impartiality, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **4.1** *Impartiality*.

G4.2 Confidentiality

The NIST QMS policies for confidentiality, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **4.2** *Confidentiality*.

G5 Structural requirements

The NIST QMS structural requirements, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **5** *Structural requirements*.

G6 Resource requirements

NIST providers of ***Standard Reference Data (SRD)*** are directly associated with and rely on the expertise of NIST technical divisions. The ***SRD*** are usually maintained by current technical personnel, but, in some cases, the databases were developed in the past and the expertise no longer resides at NIST. The NIST QMS resource requirements, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **6** *Resource requirements*.

G7 Process requirements

G7.1 Review of requests, tenders and contracts

The ***Office of Data and Informatics (ODI)*** within the ***Material Measurement Laboratory*** is the entity that provides business, administrative, and documentary support for NIST ***Standard Reference Data***. The NIST policies for the review of requests, tenders and contracts, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **7.1** *Review of requests, tenders and contracts*.

G7.2 Selection, verification and validation of methods

G7.2.1 Selection and verification of methods

Standard Reference Data (SRD) must be compliant with rigorous critical evaluation criteria. The techniques, methods, and procedures employed by the NIST technical divisions to meet the critical evaluation criteria are documented in the ***sub-level quality documents***.

The definition of "Critically evaluated data" is not addressed in the Standard Reference Data Act: Public Law 90-396, July 11, 1968, the American Innovation and Competitiveness Act, Section 108, Standard Reference Data Act Update: Public Law 114-329, January 6, 2017, S. 3084, nor in numerous NBS Bulletins on this topic. The SRD Update Act of 2017, 15 U.S.C. Chapter 7A, stipulates that ***SRD*** may be quantitative (i.e., numerical), or digital data objects, such as fingerprints, PIV cards, and software. Based on NIST publications and discussions with ***SRD*** researchers, the NIST ***Office of Data and Informatics*** developed the following criteria for critical evaluation of numerical data (see SRD definition (**5.3.3**), bullets i to iii) and digital data objects (see SRD definition (**5.3.3**), bullet iv).

For numerical data, the critical evaluation criteria are:

a) Assurance of the *integrity* of the data, such as provision of uncertainty determinations and use of standards;
b) Demonstration of the *reasonableness* of the data, such as consistency with physical principles and comparison with data obtained by independent methods; and
c) Assessment of the *usability* of the data, such as inclusion of metadata and well-documented measurement procedures.

For digital data objects, the critical evaluation criteria are:

a) Assurance that the object is *based on* physical principles, fundamental science, and/or widely accepted standard operating procedures for data collection; and
b) Demonstration of *evidence* that
   i) The object has been *tested*, and/or
   ii) Calculated and experimental data have been *quantitatively compared*

G7.2.2 Validation of methods

The Division Chiefs have the responsibility to ensure that ***Standard Reference Data*** products are validated and documented in sufficient detail with regard to the three ***SRD*** quality objectives in Section **8.2.2**. 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 Policy and Order 1801.

G7.3 Sampling of candidate SRD data

When NIST providers of ***Standard Reference Data (SRD)*** carry out sampling of data in the evaluation of an ***SRD*** database, a sampling plan is used that is based on appropriate statistical methods to ensure the validity of the database in whole. The Division chiefs have the responsibility to ensure that the sampling of NIST data products are documented in sufficient detail and that the documentation addresses the three ***SRD*** quality objectives in Section **8.2.2**.

G7.4 Handling of SRD data

G7.4.1 Chiefs of the technical and support Divisions assure that staff members understand the importance of properly identifying and securing ***SRD*** data, are properly trained, and consistently handle ***SRD*** data appropriately. The specific procedures for the identification, storage, security and transferring of candidate and validated ***SRD*** data are documented in the ***sub-level quality documents***.

G7.4.2 NIST providers of ***Standard Reference Data (SRD)*** utilize systems for the unambiguous identification of ***SRD*** data to ensure there will not be confusion with other data or when ***SRD*** data is referred to in records or other documents. The identification system is documented in the ***sub-level quality documents***.

G7.5 Technical records

The NIST QMS requirements for technical records, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **7.5** *Technical records*.

G7.6 Evaluation of measurement uncertainty

The NIST QMS requirements for the evaluation of measurement uncertainty, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **7.6** *Evaluation of measurement uncertainty*.

G7.7 Ensuring the validity of results

The NIST QMS requirements for ensuring the validity of results, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **7.7** *Ensuring the validity of results*.

G7.8 Reporting of results

The documentation distributed with an *SRD* database includes or addresses the following:

a) ***SRD*** identifier
b) name of ***database***
c) description of ***database***
d) instructions for use
e) NIST name and/or logo
f) NIST technical contact name and their contact information (example; email address and phone number)
g) version and version history, if available
h) 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.

G7.9 Complaints

The NIST QMS policies for complaints, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **7.9** *Complaints*.

G7.10 Nonconforming work

The NIST QMS policies for nonconforming work, as they apply to NIST ***measurement services*** including

Standard Reference Data programs, are documented in Section **7.10** *Nonconforming work*.

G7.11 Control of data and information management

The NIST QMS policies for the control of data and information management, as they apply to NIST ***measurement services*** including ***Standard Reference Data*** programs, are documented in Section **7.11** *Control of data and information management*.

G8 Management system requirements

The NIST QMS requirements for the management system, as they apply to NIST measurement services including Standard Reference Data programs, are documented in Section **8** *Management system requirements*.

ISO/TS 8000-150: NIST complies with the following two implementation requirements of *ISO Technical Specification ISO/TS 8000-150:2011* Data quality — Part 150: Master data: Quality management framework (Clause 5.1) as they are relevant to NIST ***Standard Reference Data*** programs.

1) *assign roles for data quality management within their organization;*

   The Associate Director for Laboratory Programs has ultimate line management responsibility for the provision of ***measurement services*** including ***Standard Reference Data*** programs (see **5.2**). Within the Office of the Associate Director, the ***NIST Quality Manager*** has responsibility for the quality of the ***Standard Reference Data*** programs by overseeing the implementation and assessment of the NIST QMS. The ***Material Measurement Laboratory (MML)*** Director, acting through Division Chiefs, is responsible for the creation and implementation of policy affecting the provision of ***Standard Reference Data***. The ***Office of Data and Informatics (ODI)*** within the ***Material Measurement Laboratory*** is responsible for providing business, administrative, and documentary support for NIST ***Standard Reference Data***.

2) *embed processes for data quality management within the organizations business processes.*

   For over 50 years, NIST has developed and distributed ***Standard Reference Data*** in Chemistry, Engineering, Fluids and Condensed Phases, Material Sciences, Mathematical and Computer Sciences and Physics. The NIST QMS for ***measurement services*** encompasses the NIST ***Standard Reference Data*** services as described in this Appendix.