The NIST Quality System for Measurement Services: A Look at its Past Decade and a Gaze towards its Future

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Abstract: As the National Metrology Institute (NMI) for the United States, the National Institute of Standards and Technology (NIST), formerly the National Bureau of Standards, has provided measurement services, both calibrations and reference materials, for more than 100 years. Through these services, our customers have benefitted from our measurement capabilities and expertise in many areas, including amount of substance; dimensional metrology; electricity and magnetism; ionizing radiation; mass and related quantities; photometry and radiometry; thermodynamics; and time and frequency. NIST's customers have also had access to some of the lowest measurement uncertainties available and a dependable way to establish traceability to the International System of Units (SI) [http://www.nist.gov/pml/wmd/metric/si-units.cfm].

In response to the signing of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA), NIST first established an institution-wide quality system for the measurement services 10 years ago [http://www.bipm.org/en/cipm-mra/objectives.html]. NIST's Quality System for Measurement Services has advanced the quality of service and measurements we provide our customers by fostering an environment in which NIST management and staff work towards continual improvement in the development and delivery of NIST measurement services.

This paper describes NIST's Quality System for the Measurement Services and its relevance to international standards of quality, such as the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17025 standard and ISO Guide 34 [http://www.nist.gov/nistqs/]. It also provides a history of this quality system and a glimpse of future goals for improving its implementation.

Learning Objectives: The reader or session attendee will know that NIST, the National Metrology Institute for the US, has a mature quality system based on ISO/IEC 17025 and ISO Guide 34. They will be able to recognize the scope of the quality system that covers NIST measurement services: calibrations, tests, and reference materials.

1. History of CIPM MRA: A driver for the NIST quality system

The emergence of a more globalized economy necessitated a comprehensive scheme to provide confidence for the equivalence of national measurement services, which ensure the technical basis for international trade, commerce and regulatory matters. The International Committee of Weight and Measures (CIPM) responded by implementing a "Mutual Recognition Arrangement of national measurement standards and of calibration and measurement certificates issued by national metrology institutes" (CIPM MRA). The CIPM MRA was first signed in October of 1999 by the directors of the national metrology institutes (NMIs) from 38 Member States of the Metre Convention (NIST being one of the 38) and representatives from 2 international organizations.[i]

The CIPM MRA calls for signatories/NMIs to participate in international comparisons of measurements (known as key comparisons) and supplementary international comparisons of measurements; implement quality systems; and demonstrate competence.[ii] Those original signatories had a 5-year deadline to implement their quality system and demonstrate its use in support of their measurement capabilities. Typically, in that five-year implementation period, the NMIs were also submitting their Calibration and Measurement Capabilities (CMCs), which are found in Appendix C of the CIPM MRA. The CMCs are the quantities for which calibration and measurement certificates are recognized by the institutes participating in the MRA.

Prior to the implementation of the formal NIST quality system, informal quality practices, policies, and procedures existed. In some parts of the organization, quality systems had been adopted that followed International Organization for Standardization (ISO) guide (25) and the American National Standards Institute (ANSI) standard (Z540-1) for calibration laboratories. Nevertheless, the NIST-wide quality system, initiated in 2003, represented a significant step towards providing our customers and international peers with overall confidence in the quality of NIST's measurements Institution-wide. Internally, it benefitted NIST by creating an environment for management and staff to work towards continual improvement in the development and delivery of NIST measurement services.

2. Scope of the NIST quality system: Measurement services, calibrations, and reference materials

The NIST quality system comprises its calibrations services, special tests, measurement assurance programs, and certified reference materials. In general, this includes all services listed in the NIST Special Publication (SP) 250, NIST Calibration Services Users Guide and the NIST Special Publication (SP) 260, Standard Reference Material Catalog. (The catalogs are available on-line at www.nist.gov/calibrations and www.nist.gov/srm, respectively.) By implication, the NIST quality system for measurement services also extends to include the Calibration and Measurement Capabilities (CMCs) http://kcdb.bipm.org/appendixC/default.asp listed in Appendix C of the CIPM MRA.

Last year NIST performed more than 17,000 calibrations and tests for its customers and provided more than 30,000 certified reference materials to its consumers.

3. Implementation of the quality management system at NIST

The format of the NIST quality system for measurement services was designed from its beginnings to be modular and tiered. NIST-QM-I is the first level and it contains NIST-wide policies and procedures stemming from the executive leadership at NIST. Most, if not all, govern all activities at NIST and are deemed controlling in-so-far as these activities are part of providing the measurement services. In November of 2012, the NIST policy for measurement quality was made a part of the NIST Directives Management System. This action caused an inherent elevation of the significance of the NIST quality systems for measurement services across the institute.

The NIST Director is ultimately responsible for the quality of the NIST measurement services. This responsibility is delegated by the NIST Director to the Associate Director for Laboratory Programs (Dr. Willie May), and, in turn, to the Directors of the Laboratories (Engineering

Laboratory, Material Measurement Laboratory, Information Technology Laboratory, and Physical Measurement Laboratory) who are directly involved in providing measurement services. The responsibility for the implementation and assessment of the NIST Quality Management Systems belongs to the NIST Quality Manager (Sally Bruce). 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. These responsibilities are delegated to and fulfilled by Dr. James Olthoff, Deputy Director of PML and Dr. Robert Watters, Associate Director for Measurement Services in MML and Chief of the Office of Reference Materials, respectively.

The technical effort required to deliver NIST measurement services is made by scientific and technical staff within the appropriate Divisions. The organization of these efforts varies among the various Divisions and is documented in the NIST sub-level quality documents. Staff in the NIST technical Divisions and in the Laboratories serve as liaisons with external customers. 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 Key Comparisons. The Material Measurement and the Physical Measurement Laboratories provide business, administrative, and documentary support for NIST measurement services.

The sub-level quality documentation (including the NIST-QM-xx series) contains policies and procedures established and maintained by each Division or Office to meet its technical needs. 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, and preparation. Characterization includes establishing homogeneity, stability, value assignment, and uncertainty of assigned values.

There are currently 16 Divisions or Offices that maintain sub-level quality documentation, and are in compliance with the NIST quality system. These are the Office of Reference Materials and the following Divisions: Applied Chemicals and Materials, Biomolecular Measurement, Biosystems and Biomaterials, Chemical Sciences, Electromagnetics, Engineering and Environment, Materials Measurement Science, Materials Science and Engineering, Materials and Structural Systems, Quantum Electronics and Photonics, Quantum Measurement, Radiation Physics, Semiconductor and Dimensional Metrology, Sensor Science, and Time and Frequency. Each Division or Office listed has a quality manager. Some of the larger divisions also have deputy quality managers.

4. Uniqueness of the NIST quality system: Additional requirements as a National Metrology Institute

Tens of thousands of calibration and testing laboratories around the world have adopted ISO/IEC 17025 as the basis for their quality systems. NIST, as the NMI of the US, is no exception. The NIST quality system for measurement services uses the requirements of both ISO/IEC 17025 and ISO Guide 34 as the heart of the quality management system (although the numbering of the standard and the NIST-QM-I vary slightly). In addition, there are unique requirements that NIST has adopted.

For example, beyond fulfilling the Personnel/Staffing requirements as stated in the standard (ISO/IEC 17025, Clause 5.2), NIST policy requires having on staff nationally or internationally recognized experts in the calibration, measurement, or reference material area or having regular advisory access to such experts.

The NIST approach to evaluating and expressing measurement uncertainty is currently articulated in the Appendix C of the NIST-QM-I. NIST has adopted in substance the approach recommended by CIPM. The NIST approach to evaluating and expressing measurement uncertainty will soon be incorporated into the NIST Directives Management System as a procedure, and it will be categorized as related to the Policy on Measurement Quality.

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

Due to the size and breadth of the NIST quality system, management reviews are conducted quarterly to ensure effective implementation. These reviews are based on the analysis of the quarterly reports that Divisions submit to their respective Laboratories, which in turn submit them to the NIST Quality Manager. 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 Guide 34, as appropriate;

•   reports to the NIST Associate Director for Laboratory Programs a summary of the findings, recommendations, and implementation plans, if required, including various quality control metrics;

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

The management reviews address the requirements as found in the standard (ISO/IEC 17025, Clause 4.15), but go beyond it by reporting on standards development activities, improvements to the services, publications related to the services, participation in tutorials and conferences where the measurement services are topics, experiences as peer reviewers or assessors, and certain metrics that feed into the Balanced Score Card for NIST.

5. Assessments of the NIST quality system

In addition to the requirement for internal audits performed at the Division and Office level of the organization, NIST performs assessments/peer reviews of the quality systems that support the CMCs. Appendix B of the NIST-QM-I describes this process. The purpose of the NIST-Level Assessment is to determine whether the quality systems are in compliance with the NIST Quality System. The scope of the assessment is the portfolio of services offered by the Divisions with particular attention to the declared CMCs with respect to the CIPM MRA. The assessment covers all requirements set forth in the NIST QM-I, and is facilitated by the use of the NIST QM-I checklist by the NIST assessors.

An assessment report template is used to record narrative summaries of the clauses of the NIST-QM-I. From the checklist all instances of "shalls" in the NIST-QM-I and its clauses and sub-clauses that defer to policies provided in the sub-level quality manuals are addressed. Findings are classified as nonconformities or comments. Nonconformities can be expressed as major or minor. A nonconformity is deemed major if the finding indicates that the CMC is in jeopardy or there is a potential inability to provide a given service.

Nonconformities are then put through the Division's non-conforming work and corrective action processes. Attempts to identify root cause are given, and preventive actions are enacted, if relevant. These incidents are potential drivers for improvements. It is common practice at NIST that the category of findings from the assessment known as comments are addressed as well as the non-conformities. Once the Division has deemed the actionable items from the assessment as closed, the assessor team reviews the corrective actions and evidence. The team has an opportunity to revisit the Division and its laboratories to ensure closure of any findings.

The Assessment Review Board (ARB) at NIST is an independent team of experienced assessors who, once the corrective actions are deemed by the assessor team as closed and appropriate for the findings, review the quality management system of the Division or Office that was assessed. This desktop review includes all the sub-level quality manuals. Additionally, they review the assessment records in their entirety: checklists, narratives, report, and files associated with the findings and corrective actions. Their review is twofold: to ensure that the assessment was fair and uniform and conforming to the NIST assessment process and that the findings and the corrective actions are appropriately closed. The ARB is comprised of two members from the Materials Measurement Laboratory, two members from the Physical Measurement Laboratory, and one from the Engineering Laboratory. The ARB members are contributors not only to the assessment process, but to the overall improvement of the NIST quality system. They have been instrumental in clarifying requirements of the quality system, specifically in NIST-QM-I, thereby eliminating any ambiguity of interpretation and ensuring uniform implementation across NIST.

6. International acceptance of the NIST quality system

In the fulfillment of the CIPM MRA, an NMI is required to have its quality management system reviewed and approved by its Regional Metrology Organization (RMO). The RMO of which NIST is a member is the Inter-American Metrology System (SIM). SIM representation includes the 34 member countries of the Organization of American States (OAS). 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 Joint Committee of the Regional Metrology Organizations and the BIPM (JCRB), which in turn uses this process to help build confidence among the NMIs by establishing a transparent QMS review process, which is mutually acceptable among all RMOs.

In 2002, the SIM Council approved the creation of a task force for reviewing the QMS of SIM CIPM MRA signatories. The task force is referred to as the SIM Quality System Task Force (SIM QSTF).

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

• Any SIM Member NMI can request the review of its quality management system, even if it is not yet a signatory of the MRA;

• A meeting to review the QMS of NMIs will be held at least once a year. The meeting will be open to all SIM members and observers from other RMOs, and will provide the opportunity for discussion and comments. SIM QSTF decisions will be made by the representatives of the SIM signatories to the CIPM MRA;

• The Task Force will assess whether or not the quality management system of each NMI complies with the requirements of the CIPM MRA. If it does not comply, the SIM QSTF will ask for additional information and/or corrective actions;

• NMIs may choose to present their quality management system in parts, covering different calibration and measurement services; and

• The quality management system review procedure will also apply to designated institutes (who must make the request for a review through their SIM Member NMI).

The SIM QSTF usually meets twice a year: once during the SIM General Assembly Week typically in October and again typically in March or April. The SIM Procedure for Review of the Quality Management System of National Metrology Institutes and Designated Institutes, known as SIM 09, describes the requirements for quality management system reviews, including the quality manual and description of the QMS for its calibration and measurement capabilities. The process of the CIPM MRA includes a five-year review cycle of the quality systems by the RMOs.

NIST has presented its quality management system to the SIM QSTF on a regular basis since 2003 when the NIST-QM-I was first presented to them. Since that time, NIST presents its quality system based on the categories of CMCs and typically by Division/Office. For some services, their quality systems have already been reviewed and approved three times. NIST has

presented quality systems for all of its CMCs and for services not yet covered by the CIPM MRA (such as Charpy, Thermal Insulation, and others). Some of NIST's services are unique to the world including flashing light photometry (aircraft safety lighting) and cryogenic flow measurements (for the transport of liquefied gases). Regardless, the NIST quality system supports not only the CMCs we have listed in the Appendix C, but also services that meet our customer's needs.

7. The future of the NIST quality system for measurement services
The Directives Management System (DMS) is the primary means to establish and communicate policies, requirements, responsibilities, guidance, and procedures and to ensure efficient operations for NIST. The Policy for Measurement Quality has been added to the DMS. A procedure for Evaluating and Expressing Measurement Uncertainty has been drafted and is under review. Once approved, it will become part of the DMS under the quality policy. Later this year, the procedure for NIST assessments will be pulled out of NIST-QM-I and added to the DMS. The goal will be to make the NIST-QM-I a leaner document with its components embedded into the NIST Directives Management System.

Addressed earlier in this paper, some metrics gleaned from the management review reports are included in the Balanced Score Card metrics. Currently, turnaround times for the provision of reference materials, customer satisfaction metrics for the measurement services, and the re-issuing of calibration and test reports are being recorded and reported. Preliminary tracking has been performed for turnaround times of calibration services; in the future, measures and metrics will be determined for this area. NIST provides a diverse offering of measurement services. While there is not a one size fits all for turnaround time, we are striving to identify and provide reliable completion dates to our customers.

An informal benchmarking effort began earlier this year with the NIST quality system for measurement services. The NIST quality manager is comparing the elements and implementation of the quality management systems of various other National Metrology Institutes. This comparison will include exploring various quality systems of NMIs within the SIM, Euramet, and Asia Pacific regions. It is anticipated that best practices will be identified and implemented within the NIST quality system.

There are also efforts underway to explore the expansion of the scope of the NIST quality system for measurement services. In 1969, Congress enacted and gave NIST (formerly NBS) the authority to provide Standard Reference Data. NIST now offers the NIST Data Gateway, easy access on the internet to over 80 NIST scientific and technical databases. The Gateway includes links to free online NIST data systems as well as to information on NIST PC databases available for purchase.[iv] We have recently offered customer feedback mechanisms online for these data services. Over time, it is possible that an ISO 9000 based quality system will be developed for the NIST data products. This possibility is in the exploration phase, and is driven by an internal quality commitment within NIST to its customers, not the CIPM MRA.

8. Conclusions
This year marks the 10th anniversary of the NIST-QM-I and the overall quality system for NIST measurement services. With the implementation of the quality system NIST strives to not only

meet requirements set forth by the CIPM MRA, but also to go beyond to provide our customers and stakeholders with a high level of satisfaction in our delivery of measurement services and in our provision of high quality reference materials and measurements.

9. Acknowledgements

Many people have been involved with championing, implementing, and managing the NIST quality system for measurement services throughout its ten-year history. In particular, the early leadership efforts and vision of the following contributors is greatly appreciated. The first author of the NIST-QM-I is Dr. Gregory Rosasco. Prior to the position of NIST quality manager, NIST had a committee of the Laboratory Directors who managed the measurement services activities in their labs and they served as corporate Quality Manager for NIST. This group, known as the Measurement Services Advisory Group, was chaired by Dr. Richard Kayser during the time when the quality system was initiated and then later by Dr. William Anderson.

The author is proud to work with the current leadership team of Dr. Willie May, Dr. Robert Watters, Dr. James Olthoff, Dr. Howard Harary, and Dr. Antonio Possolo. Their combined leadership efforts and commitment is unwavering and sets the overall direction for the future of the NIST quality system for measurement services.

In final, the author thanks the current quality managers throughout NIST: Carlos Beauchamp, Catherine Cooksey, Paul DeRose, Marc Desrosiers, Ted Doiron, Clarissa Ferraris, Ashley Beasley Green, Ron Ginley, Mike Lewis, Mike Lombardi, Maria Polakoski, Rick Seifarth, Kathy Sharpless, Donald Windover, Paul Williams, and Bob Zarr. Their dedication and efforts are paramount to the success of the NIST quality system for measurement services.

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[i] CIPM MRA-G-01, Guide to the implementation of the CIPMMRA,
http://www.bipm.org/utils/common/CIPM_MRA/CIPM_MRA-G-01.pdf

[ii] The essential points of the CIPM MRA, http://www.bipm.org/en/cipm-mra/objectives.html

[iii] NIST-QM-I, NIST Quality Manual for Measurement Services, http://www.nist.gov/qualitysystem/

[iv] NIST Standard Reference Data, The NIST Data Gateway, http://www.nist.gov/srd/index.cfm