Overview of the NIST Quality System for Measurement Services

Presented by: Sally Bruce, Quality Manager

September 15, 2016

NIST Quality Management System

NIST National Institute of Standards and Technology U.S. Department of Commerce

This presentation is designed to provide you with answers to these questions…

- What is the history of the NIST Quality Management System?
- What is the relationship of our quality system to the CIPM MRA? What is a CMC? What do those acronym mean?
- What does the quality system cover? What is its structure?
- How do organizational changes at NIST effect the quality system?
- How does the quality system relate to the NIST mission, vision, and values?
- Who is responsible for the quality system and who manages it?
- How is the health of the measurement services being reported and measured via the quality system?
- What are the processes used to verify that the system is working?
- How does the quality system earn its recognition and acceptance in the International metrology community?
- How does the quality system help us, help our customers?
- What are the benefits to having a NIST Quality Management System?
- What's on tap for its future?

NIST Quality Management System

Reconnaissance mutuelle
des étalons nationaux de mesure
et des certificats d'étalonnage et de mesurage
émis par les laboratoires nationaux de métrologie

Paris, le 14 octobre 1999

Mutual recognition
of national measurement standards
and of calibration and measurement certificates
issued by national metrology institutes

Paris, 14 October 1999

Comité international des poids et mesures

Bureau international des poids et mesures

Organisation intergouvernementale de la Convention du Mètre

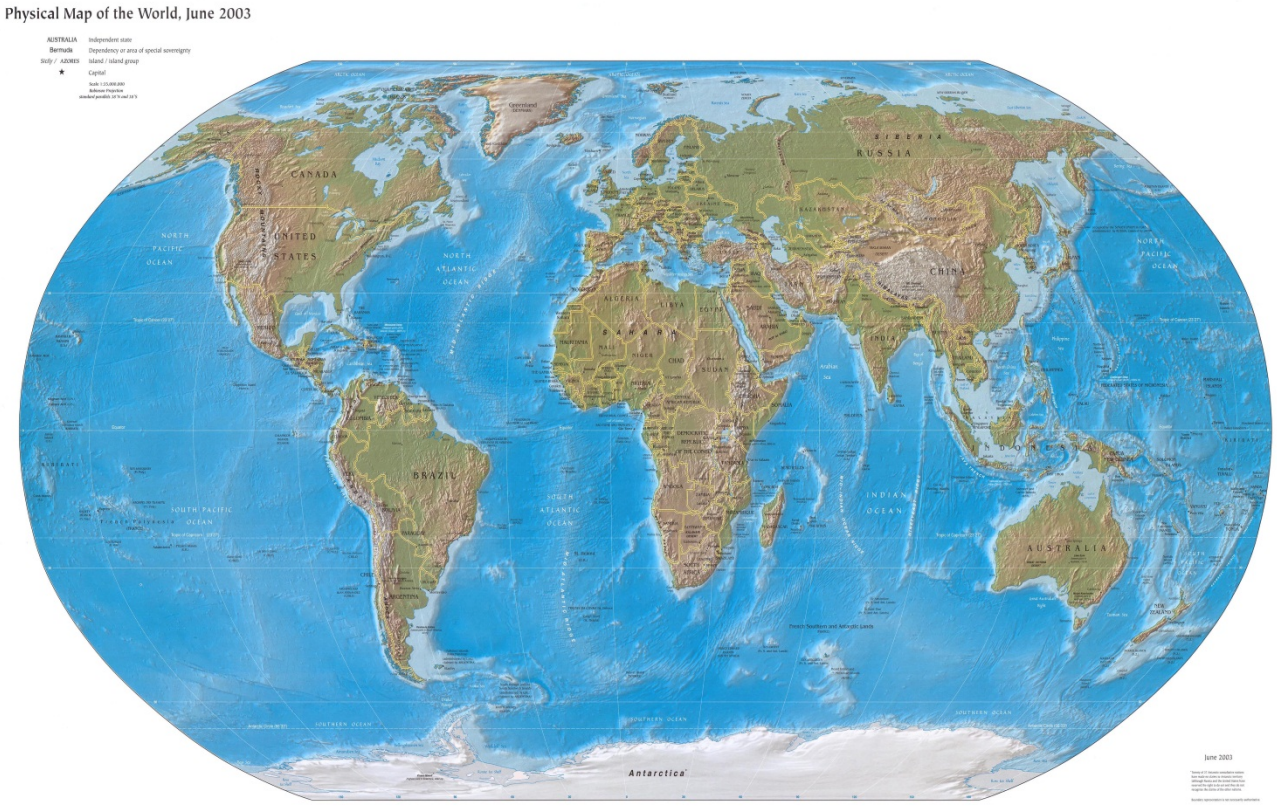
In October 1999, the directors of the national metrology institutes (NMIs) of thirty-eight Member States of the Metre Convention signed a Mutual Recognition Arrangement (MRA) for national measurement standards and for calibration and measurement certificates issued by national metrology institutes.

Mutual Recognition Arrangement

- **to establish the *degree of equivalence* of national measurement standards maintained by NMIs;**

- **to provide for the *mutual recognition* of calibration and measurement certificates issued by NMIs;**

- **thereby to provide governments and other parties with a *secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs*.**
  - **Ensure that measurements traceable to different NMIs can be accepted across borders**



Regional Metrology Organizations:

SIM, Euramet, APMP, COOMET, GULFMET, AFRIMET

The CIPM MRA has been signed by 102 institutes – 57 Member States, 41 Associates of the CGPM, and 4 international organizations – and covers a further 153 institutes designated by the signatory bodies.

Technical Basis for Comparability and Confidence in Measurements

International comparisons of measurements, known as key comparisons;
supplementary international comparisons of measurements;
quality systems;
and demonstrations of competence by NMIs.

Outcome

Statements of the calibration and measurement capabilities (CMCs) of each NMI in a database publicly available on the Web.

http://kcdb.bipm.org/

The objective of the CMCs is to document peer-reviewed and accepted statements of measurement capabilities that a NMI maintains to underpin the measurement services it provides to its customers.

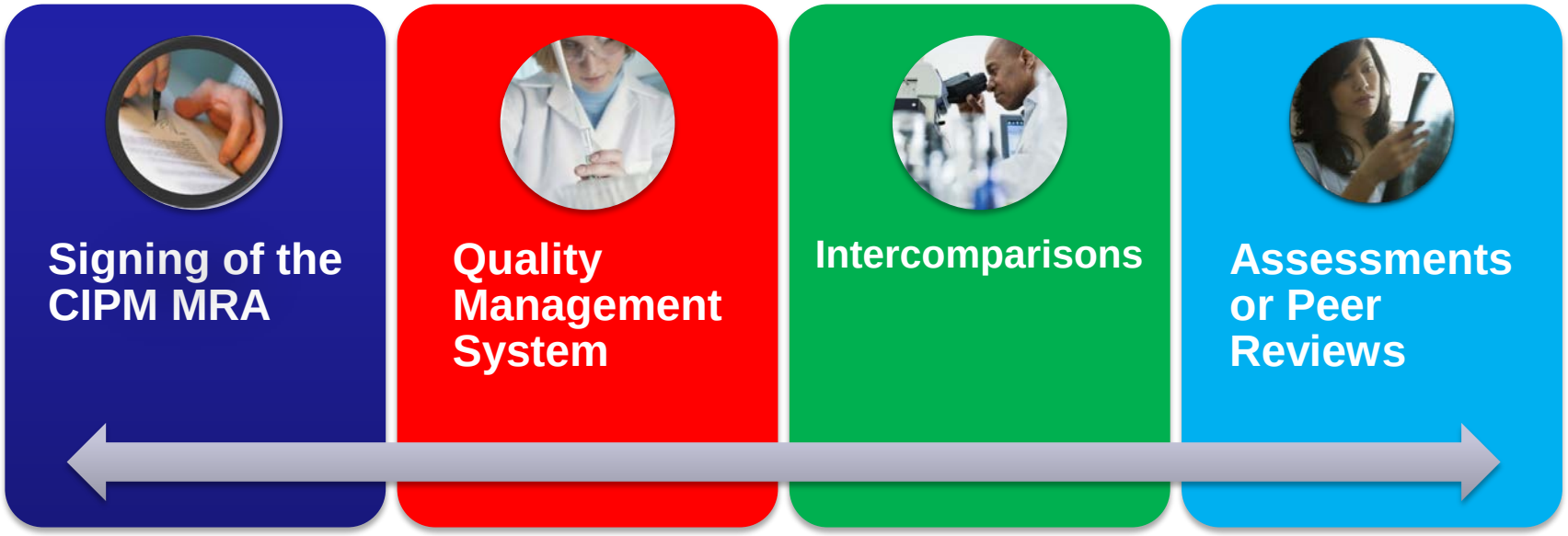
Three fundamental elements leading to the approval of an Institute's CMC's:

1) Successful participation by the institute in reviewed and approved scientific comparisons
2) Implementation by the institute of an appropriate and approved **quality management system**
3) Regional and Inter-regional review and approval of claimed calibration and measurement capabilities.

KCDB

(key comparison database)

Components for international recognition/approval of measurement capabilities



NIST has more than 2,000 capabilities listed in the KCDB and has participated in nearly 500 key comparisons.

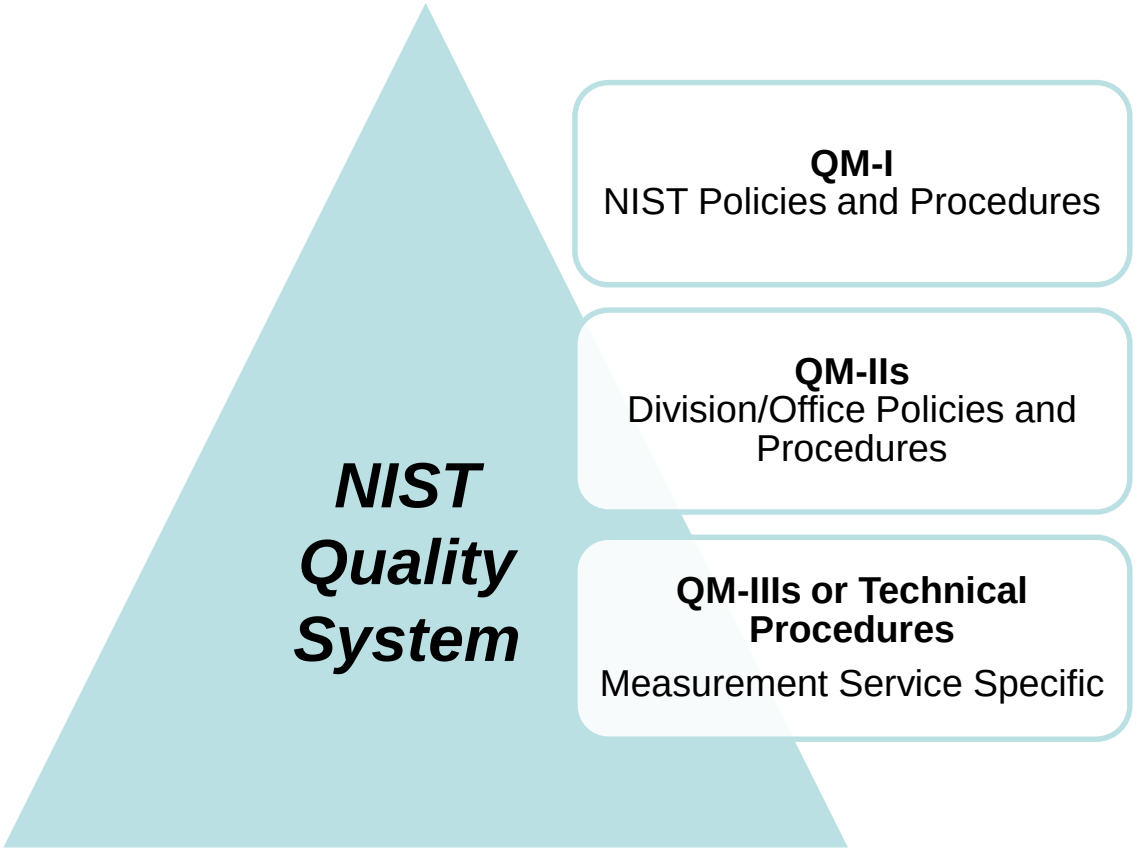
SIM
the Regional Metrology Organization for the Americas

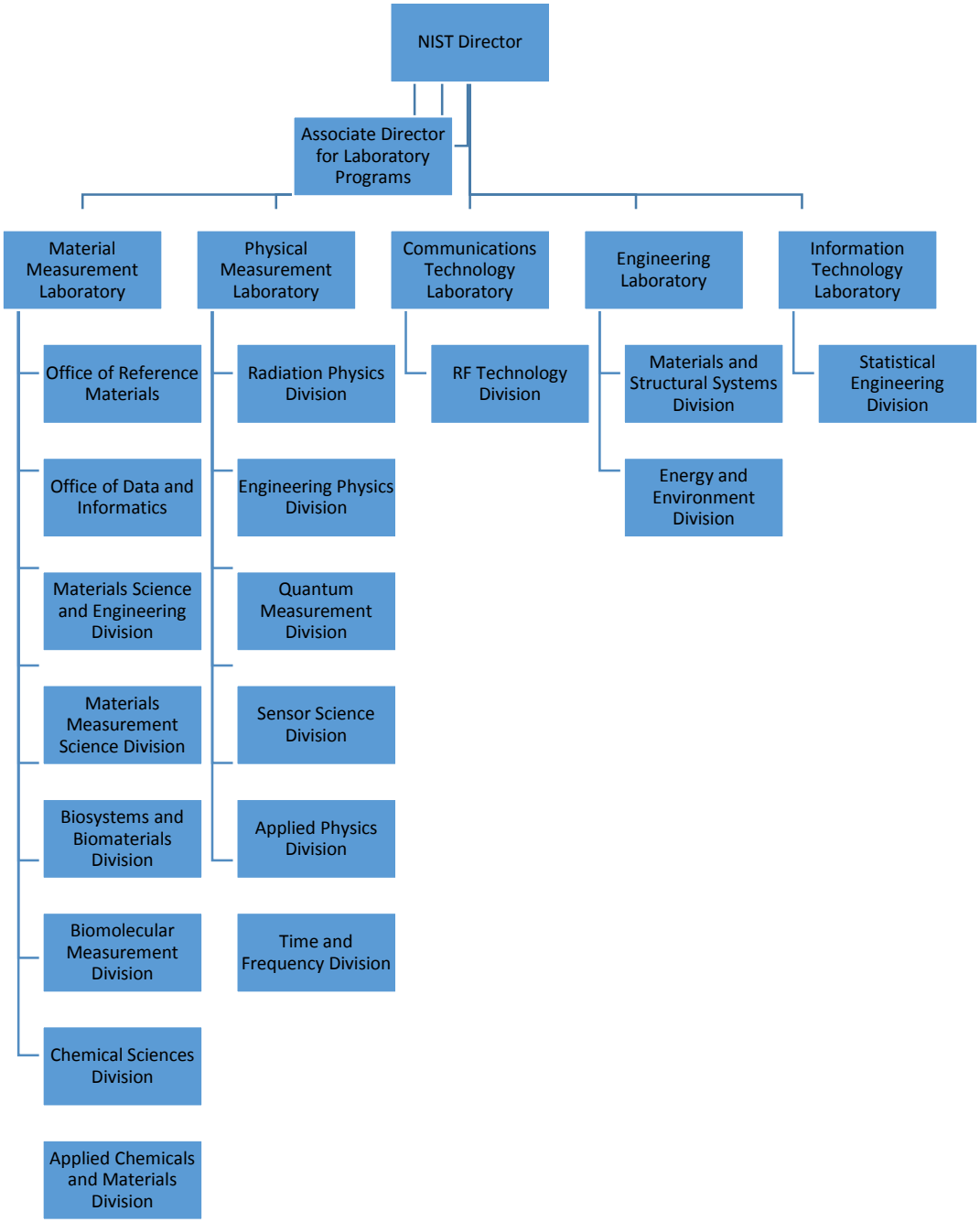
Flags of

The Organization of American States

Quality Management System

The documentation for the NIST Quality Management System has a tiered structure:




NIST Director
Associate Director for Laboratory Programs
Material Measurement Laboratory
Physical Measurement Laboratory
Communications Technology Laboratory
Engineering Laboratory
Information Technology Laboratory
Office of Reference Materials
Office of Data and Informatics
Materials Science and Engineering Division
Materials Measurement Science Division
Biosystems and Biomaterials Division
Biomolecular Measurement Division
Chemical Sciences Division
Applied Chemicals and Materials Division
Radiation Physics Division
Engineering Physics Division
Quantum Measurement Division
Sensor Science Division
Applied Physics Division
Time and Frequency Division
RF Technology Division
Materials and Structural Systems Division
Energy and Environment Division
Statistical Engineering Division

Management of QMS: Division Quality Managers

Division/Office	Quality Manager
Reference Materials	Maria Polakoski
Materials Science and Engineering	Carlos Beauchamp
Materials Measurement Science	Donald Windover
Biosystems and Biomaterials	Paul DeRose
Biomolecular Measurement	Ashley Beasley Green
Chemical Sciences	Mike Epstein
Applied Chemicals and Materials	Mike Lewis
Radiation Physics	Marc Desrosiers
Engineering Physics	Ted Doiron

Management of QMS: Division Quality Managers

Division/Office	Quality Manager
Quantum Measurement	Rick Seifarth
Sensor Science	Catherine Cooksey
Applied Physics	Igor Vayshenker
RF Technology	Tasshi Dennis
Time and Frequency	Mike Lombardi
Materials and Structure Systems	Paul Stutzman
Energy and Environment	Bob Zarr

NIST Measurement Products and Services

Measurement Research

~ 2,200 publications per year

Standard Reference Data

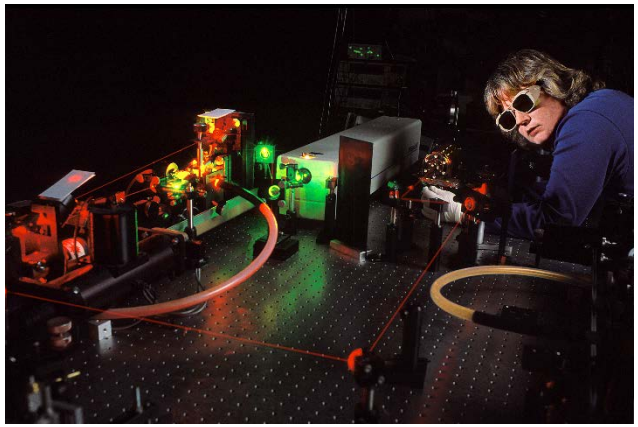
~ 100 different types

~ 6,000 units sold per year

~ 18 million data downloads per year

NVLAP: Laboratory Accreditation

~ 800 accreditations of testing and calibration laboratories



Copyright Robert Rathe

Standard Reference Materials

~ 30,000 units sold per year

Calibrations

~ 20,000 performed per year

>300 NIST staff members participate in more than 100 Standards Development Organizations

Photo credit: M. Baum/NIST

NIST Today: The Culture of Quality Aligned with our Mission, Vision, Competencies, and Values

Mission: 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.

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

Core competencies:

Measurement science
Rigorous traceability
Development and use of standards

NIST's core values

People: We value and support an inclusive, engaged, and diverse workforce capable of fulfilling the NIST mission.

Integrity: We are objective, ethical, and honest.

Customer focus: We anticipate the needs of our customers and are committed to meeting or exceeding their expectations.

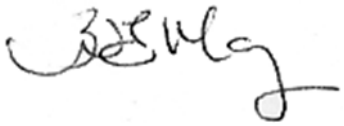
Excellence: We expect world-class performance and continuous improvement in all we do.

Institutional Commitment to Quality

The provision of measurement services, which include ***calibration*** and ***certified reference material*** related services, is an essential element of the work carried out by the National Institute of Standards and Technology (NIST) in fulfillment of its mission. In the conduct of this vital work, as in all its efforts, NIST is committed to performance excellence characteristic of a global leader in measurements and standards. Our goal is to provide measurement services that meet the needs of our customers and, through continuous improvement, to seek to anticipate their needs, exceed their expectations, and deliver outstanding value to the Nation.

Achievement of this goal has been a hallmark of NIST (known as the National Bureau of Standards prior to 1988) for over a century. It has always resulted from, and continues to rely on, the excellence and commitment of NIST staff at every level of the Institute. The NIST Quality Management System (NIST QMS) comprises policies and procedures that NIST follows in the pursuit of performance excellence. They are documented in this NIST Quality Manual (NIST QM). All staff members whose activities affect the quality of our ***measurement services*** are to be familiar with the NIST QMS described herein, and to implement it in their work. NIST commits that its QMS be, to the extent allowed by statute and regulation, in conformity with the international standard ISO/IEC 17025 and the relevant requirements of ISO Guide 34 and ISO/TS 8000 as they apply to the related measurement services that NIST delivers.

Signed:



Dr. Willie May, Director
National Institute of Standards and Technology

http://www.nist.gov/qualitysystem/

Leadership of the NIST Quality System

NIST Director, Willie May

Associate Director for Laboratory Programs, Principal Deputy Director Kent Rochford

Director of the Standards Coordination Office, Gordon Gillerman

NMSC Chartered in March 2016

Reports to the Associate Director for Laboratory Programs

- Identifies 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
- Identifies and addresses critical NIST-wide issues affecting measurement services and the national measurement standards underpinning them.

https://inet.nist.gov/nmsc

NIST Measurement Services Council (NMSC)








Kent Rochford, ADLP
Laurie Locascio, Director MML
Jim Olthoff, Director PML
Howard Harary, Director EL
Bob Hanisch, Director of Office of Data and Informatics, MML
Antonio Possolo, NIST Chief Statistician
Greg Strouse, Associate Director of Measurement Services, PML
Steve Choquette, Director of Office of Reference Materials, MML

NMSC

- To assist and advise the ALDP
  - Changes in modes or methods of delivery of measurement products/services
    - Licensing authorities
    - Standard Reference Instruments
    - Standard Reference Materials
    - Standard Reference Data
    - Calibration Services
    - CRADA’s that impact metrological traceability and those that are internationally partnered
    - Designated Institutes

NIST Quality Manager: Roles and Responsibilities

- Maintains document control for NIST-QM-I
  - Assures timely completion of any revisions
- Serves as Chair of the NIST Measurement Services Council
- Reports on the health of the NIST Quality System to the NIST Associate Director of Laboratory Programs
  - Conducts a NIST-wide evaluation of management reviews (quarterly reports)

NIST Quality Manager: Roles and Responsibilities

- Ensures that proper assessment tools are available to the assessors
- Trains the NIST assessors/peer reviewers
- Organizes, schedules, and oversees NIST-level quality management system assessments
- Serves as the NIST representative to the SIM Quality System Task Force
  - Presents NIST's quality systems
  - Reviews other NMI and DI quality systems

Management of QMS: Quarterly Reports from the Divisions

Management Review: Determining the health of the measurement services

- Quarterly schedule: Jan 15, April 15, July 15, and October 15

- Participants:
  - Division Quality Manager, Division Chiefs, NIST Quality Manager, NIST Measurement Services Council, and the Associate Director for Laboratory Programs at NIST (NIST Deputy Director)

Management of QMS:
Quarterly Reports from the Divisions

Management Review topics:

- Nonconforming work and corrective actions
- Improvements and preventive actions
- Customer feedback and complaints
- Internal audits
- Intercomparisons
- Changes in volume of work or type of work
- Termination or planned stoppage of services

Management of QMS:
Quarterly Reports from the Divisions

Management Review topics cont:

- Staffing changes
- Training given/received
- Visits/Visitors
- Publications- related to the services
- Peer evaluations or assessment activities
- Documentary Standards work

Management of QMS:
NIST-level Assessment Process

Overview of the process

- Define the Scope
- Identify the Team selection
- Gather and review the Quality manuals and associated documentation
- Schedule the assessment
- Gather at the Opening Meeting
- Conduct of the Assessment (with daily debrief meetings and briefing meetings)
- Present the report and the findings at the Closing meeting

Management of QMS:
NIST-level Assessment Process

Finding and Corrective actions (spreadsheet identifies the non-conformities and comments with objective evidence and correlation to the standard's requirement)

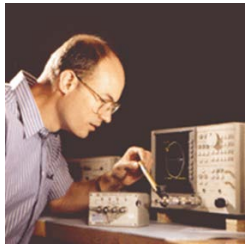
- Division remedies the findings by identifying root cause and determining, documenting and implementing actionable items

- Assessment team reviews the actions and verifies their closure

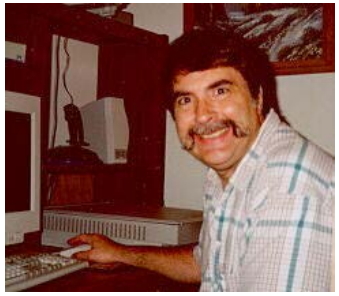
Management of QMS: Assessment Process

Assessment Review Board at NIST

Carlos Beauchamp, MML



Andrew Koffman, PML



Dr. Michael Epstein, MML

Greg Strouse, PML

Dr. Nathan Marsh, EL

SISTEMA INTERAMERICANO DE METROLOGIA

Inter-American Metrology System

SIM Quality System Task Force

Argentina, Bolivia, Brazil, Canada, Chile, Costa Rica, Ecuador, Jamaica, Panama, Paraguay, Peru, Mexico, Uruguay, USA

Materials for a QSTF Review

- Presentation and
- Written Report that includes
  - QMS Policies,
  - Org charts,
  - Customer Feedback Statistics,
  - Nonconforming Work Statistics,
  - Internal Audit reports,
  - Management Reviews,
  - Peer Review Reports,
  - Findings and Corrective Actions from Each of the above
  - Evidence of Vitality
    - Improvements
    - Staffing changes
    - Publications
    - Training given/received
    - Intercomparison performance

SIM
SISTEMA INTERAMERICANO DE METROLOGIA

Materials for a QSTF Review

- Copies of the following:
  - quality manuals
  - Internal Audits
  - Assessment Reports or Peer Review Reports
  - Bios of the Assessors
  - Listing of CMC's under review
  - Technical Procedures
  - Cross reference table between ISO/IEC 17025 and/or ISO Guide 34 and the documentation of the NMI or DI

Initial SIM QSTF Approvals for NIST

- 2004
  - Electrical Quantities
  - Photometry and Radiometry
  - Thermodynamics
  - Ionizing Radiation
  - Dimensional
  - Mass, Acoustics, Vibration
- 2005 and 2006
  - Time and Frequency
  - Ionizing Radiation (reference materials)
  - Chemistry (quality system that supported 1040 CMCs at the time)

SIM QSTF Re-approvals for NIST

- 2010-2012
  - Chemical (reference materials)
  - Rockwell Hardness
  - Photometry and Radiometry
  - Electromagnetics
    - Power, RF, Microwave
- 2014
  - Mass and Force
  - Thermodynamics
  - Length
  - Acoustics and Vibration
  - Optical Properties of Materials
  - Laser based Radiometry
  - Electromagnetics (low frequency)

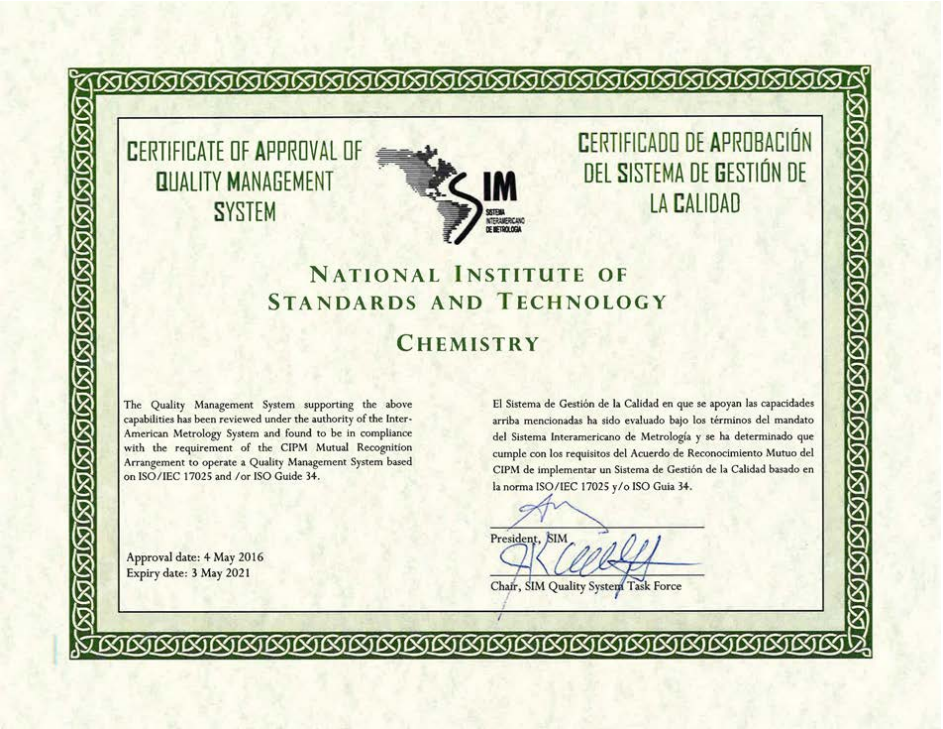
SIM QSTF Re-approvals for NIST

- 2015
  - Time and Frequency
  - Ionizing Radiation
  - Electromagnetics
    - Power, RF, Microwave
- 2016
  - Chemistry

Who needs these?

Recently requested this certificate:

- FDA
- Pharmaceutical Manufacturers
- Instrument makers
- Lead Forensic Scientist in a State Crime Lab
- IAEA



CERTIFICATE OF APPROVAL OF QUALITY MANAGEMENT SYSTEM

SIM SISTEMA INTERAMERICANO DE METROLOGIA

CERTIFICADO DE APROBACIÓN DEL SISTEMA DE GESTIÓN DE LA CALIDAD

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

CHEMISTRY

The Quality Management System supporting the above capabilities has been reviewed under the authority of the Inter-American Metrology System and found to be in compliance with the requirement of the CIPM Mutual Recognition Arrangement to operate a Quality Management System based on ISO/IEC 17025 and /or ISO Guide 34.

El Sistema de Gestión de la Calidad en que se apoyan las capacidades arriba mencionadas ha sido evaluado bajo los términos del mandato del Sistema Interamericano de Metrología y se ha determinado que cumple con los requisitos del Acuerdo de Reconocimiento Mutuo del CIPM de implementar un Sistema de Gestión de la Calidad basado en la norma ISO/IEC 17025 y/o ISO Guia 34.

Approval date: 4 May 2016
Expiry date: 3 May 2021

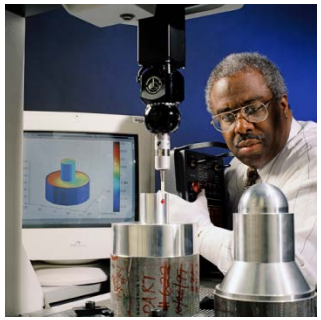
President, SIM

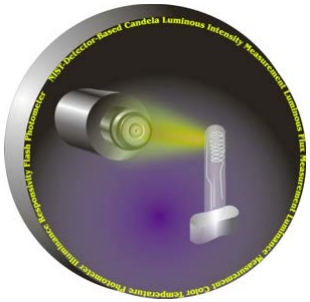
Chair, SIM Quality System Task Force

Certificates are on the quality system website

NIST Quality System

- Globally-accepted
- Enables the international acceptance of the portfolio of NIST measurement services, the national standards maintained by NIST, thereby facilitating the acceptance of our customers' measurements





Measurement Services External Review 2015
8 NMI Representatives from 5 Regions

- Comparing NIST to other NMIs
  - One of the most advanced NMIs
  - “Impressive”, “high quality”, and “world class”
  - Successful coverage of all major metrology areas
  - Impressive portfolio of underpinning research
  - Research drives new service upgrades and directions

- Areas to improve
  - Prioritize and harmonize international efforts
  - Training to develop metrology infrastructure

- NIST’s effectiveness at international engagement is an important element in world-wide acceptance of measurements.

OIG Audit of NIST Quality System, FY 2015

- Extensive review of documentation
- In depth review of four Divisions
- Staff interviews

- Outcome: Memo report, June 2015

  “. . . we did not identify significant risks to the QSMS.”

- Four recommendations:
  - Internal Audits
  - QMS training
  - Noting time spent on Quality system efforts
  - Back-up for NIST Quality Manager

- Overall, it was a Validation of the Excellent work of our Quality Managers

Viewpoints from our Quality Managers

- ✓ The NIST-wide Quality System has raised the “quality” profile in the NIST labs. We feel we can lead by example in an International metrology framework.
- ✓ Implementation of control charts has enabled the development of “realistic” uncertainty analyses, as continually we track the stability of our instrumentation.
- ✓ The focus on Customer satisfaction and customer feedback is valuable in our work.
- ✓ We see improvements in our record keeping and in documenting our analytical work.
- ✓ The tiered approach to the structure of the NIST Quality System enables us to custom-fit the implementation at the Division and Group levels.

NIST Quality Management System

Continual Improvement of QMS: Vitality and Looking Towards the Future

- Monitor Customer satisfaction
  - Exploring how the Customer Relationship Database solution for NIST can be leveraged to improve the quality reporting
- Improve the annual internal audit process
  - NIST-QM-I
  - Ensuring the Divisions meet their goal of every two years
    - NVLAP assistance is available
- ISO/IEC 17034 and ISO/IEC 17025 FDIS and DIS revisions, determining their effect on the NIST-QM-I

Thanks for your kind attention

To access the Quality System webpages and SharePoint from the NIST inet:

A-Z Index, Q for Quality System