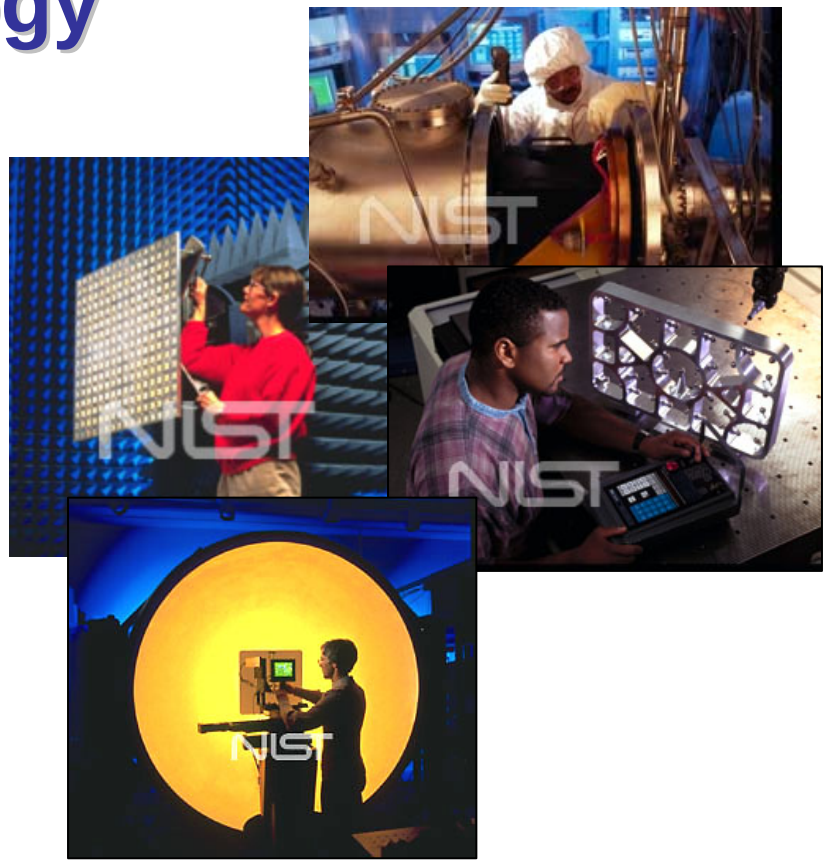
The Role of NIST in Support of US Industry and Global Comparability

Willie E. May
Director
Chemical Science and Technology Laboratory,

National Institute of Standards and Technology

NIST is a
non-regulatory agency
in the
Technology Administration
of the
US Department of Commerce.



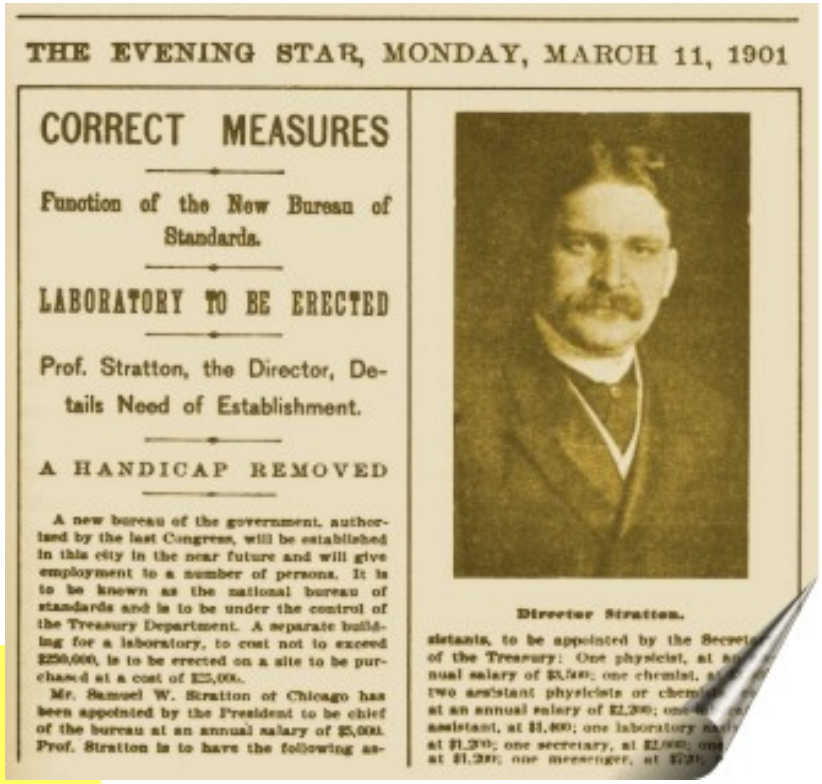
Mission **... to develop and promote measurement, standards, and technology to enhance productivity, facilitate trade, and improve the quality of life.**

NIST (NBS) established in 1901

"It is therefore the unanimous opinion of your committee that no more essential aid could be given to

- **manufacturing**
- **commerce**
- **the makers of scientific apparatus**
- **the scientific work of Government**
- **schools, colleges, and universities**

than by the establishment of the institution proposed in this bill."



THE EVENING STAR, MONDAY, MARCH 11, 1901

CORRECT MEASURES

Function of the New Bureau of Standards.

LABORATORY TO BE ERECTED

Prof. Stratton, the Director, Details Need of Establishment.

A HANDICAP REMOVED

A new bureau of the government, authorized by the last Congress, will be established in this city in the near future and will give employment to a number of persons. It is to be known as the national bureau of standards and is to be under the control of the Treasury Department. A separate building for a laboratory, to cost not to exceed $250,000, is to be erected on a site to be purchased at a cost of $25,000.

Mr. Samuel W. Stratton of Chicago has been appointed by the President to be chief of the bureau at an annual salary of $5,000. Prof. Stratton is to have the following as-

Director Stratton.

sistants, to be appointed by the Secretary of the Treasury: One physicist, at an annual salary of $3,500; one chemist, at [illegible] two assistant physicists or chemists at an annual salary of $1,200; one [illegible] assistant, at $1,000; one laboratory [illegible] at $1,200; one secretary, at $2,000; one [illegible] at $1,200; one messenger, at $720;

House Committee on Coinage, Weights and Measures ...
May 3, 1900
on the establishment of the National Bureau of Standards (now NIST)

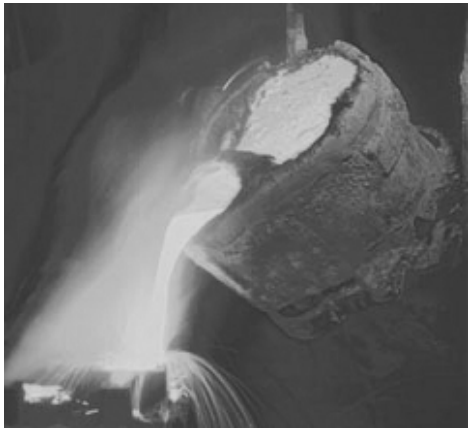
Early Drivers for NIST (NBS) Activities

1904

Out-of-town fire companies arriving at a Baltimore fire cannot couple their hoses to the hydrants. 1526 buildings razed. In 1905 NFPA adopted NBS-developed national hose coupling standard

1905

Standard samples program begins with "standardized irons" in collaboration with the American Foundrymans Association



1912

41,578 train derailments in the previous decade led to NBS measurement and test program

The articulation and focus of NIST's Mission continually changes to meet current National needs...

- **Mission:** *To promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology – in ways that enhance economic security and improve the quality of life for all Americans*
  - *NIST is well positioned – at the nexus of science and industry – to advance this mission in support of industry and national needs*
- **Implementation Strategies:**
  1) Help the U.S. to drive and take advantage of the increased pace or technological change
  2) Foster more efficient transactions in the domestic and global marketplace by promoting more effective development and use of standards by manufacturers and the service sector
  3) Address selected critical national needs *assigned* to NIST

NIST Assets Today

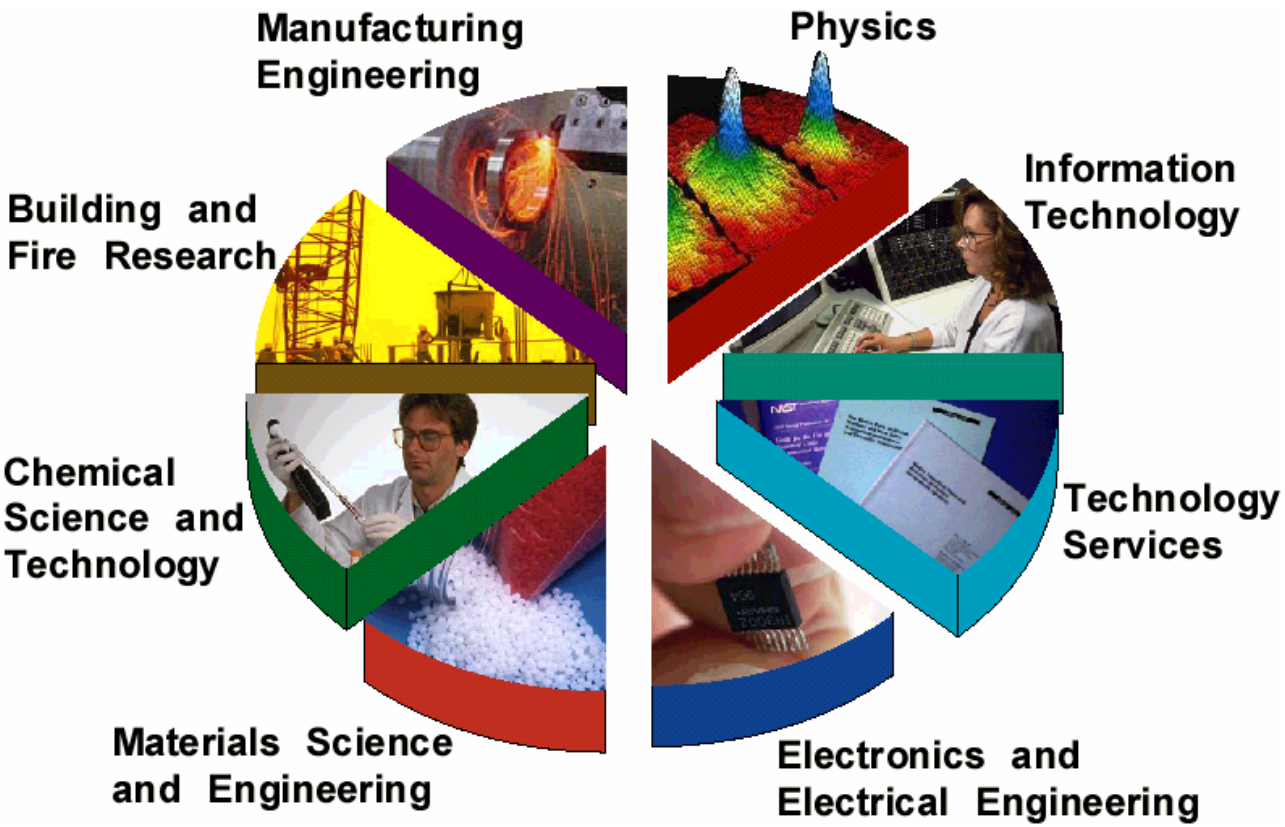
Assets:

- **NIST Laboratories**
- **Advanced Technology Program**
- **Manufacturing Extension Partnership**
- **Baldrige National Quality Award**

- **3,000 employees**
- **1,600 guest researchers**
- **$858 million (FY05 est. budget)**

Partnerships with industry, academia, and other government agencies have been an integral part of NIST culture since 1901.

NIST's Laboratories



... the Nation's ultimate reference point for measurements, standards, and technology research to support industry, science, health, safety, and defense.

Laboratory-based research on two campuses…

Gaithersburg, MD

Boulder, CO

..and in three joint Institutes

CARB
University of Maryland

JILA
University of Colorado

HML
Charleston, SC

NIST Has Unique Research Facilities

NIST Advanced Measurement Laboratory

… one of the most technologically advanced facilities in the world with state-of-the-art environmental controls:

- **Vibration**
- **Temperature**
- **Humidity**
- **Air cleanliness**

NIST Center for Neutron Research

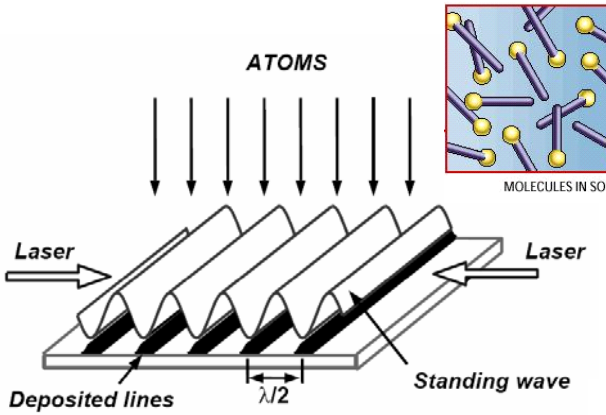
… a national center for research using thermal and cold neutrons

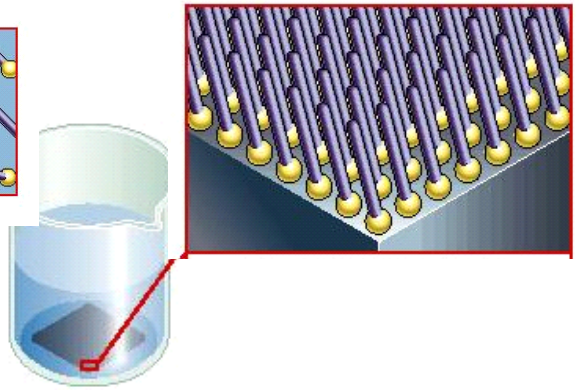
Nanomanufacturing User Facility

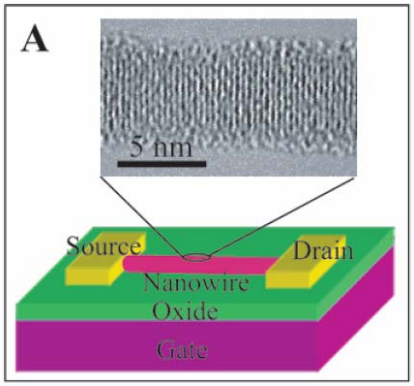
VISION

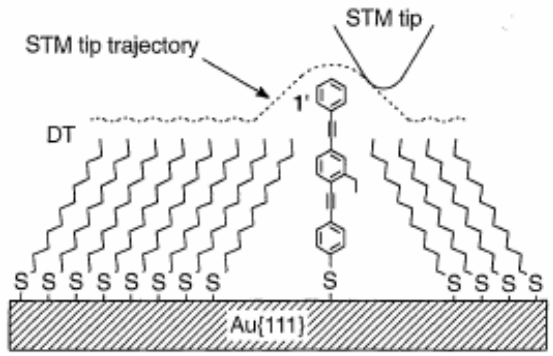
National User Facility which couples NIST's unique combination of expertise and facilities in measurement science to facilitate innovation in nanotechnology and related frontier areas of science and technology.

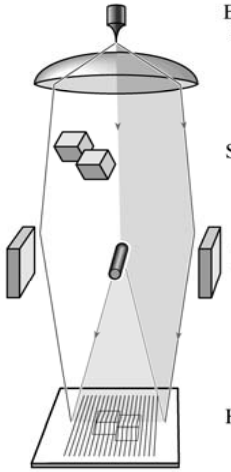
NIST will help solve industry's nano measurement problems.

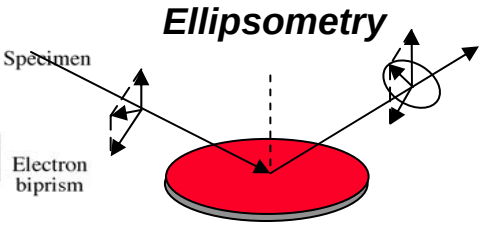










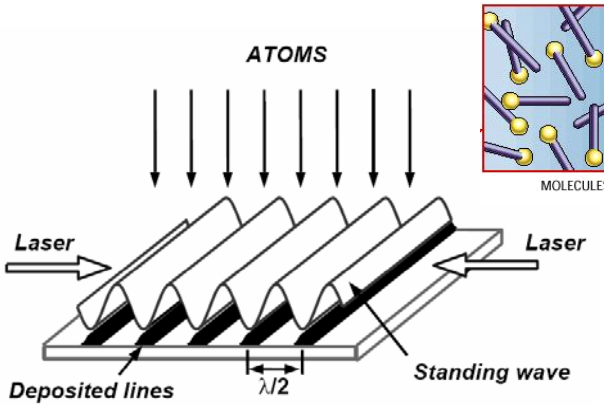


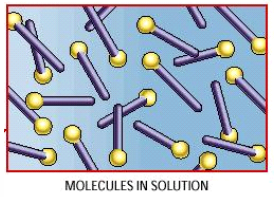
MISSION

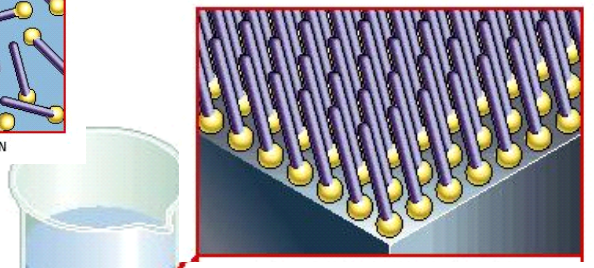
To develop state-of-the-art infrastructure at NIST necessary to vigorously pursue nanometrology, nanostandards, and nanomanufacturing research.

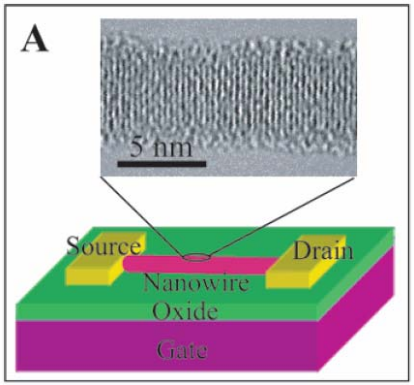
The focus of research in the NUF will be:

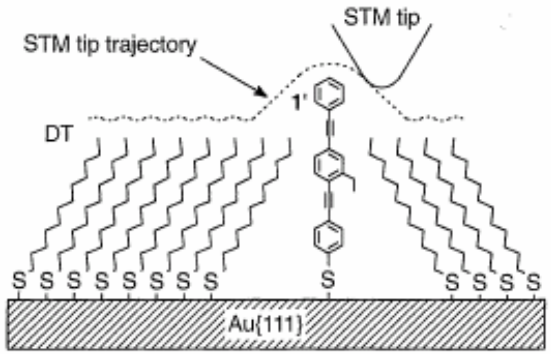
- removing barriers to innovation in nanomanufacturing,
- educating the next generation of nanotechnologist.

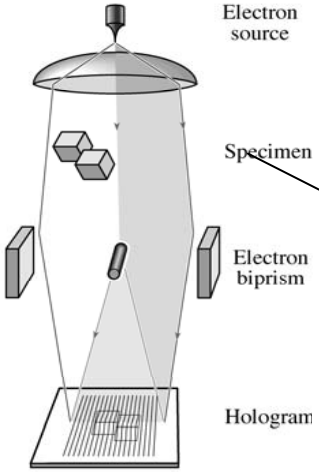


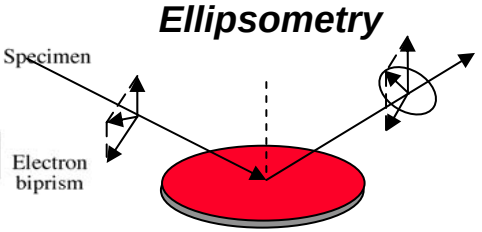




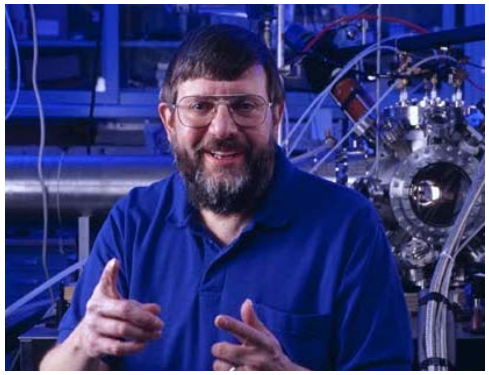




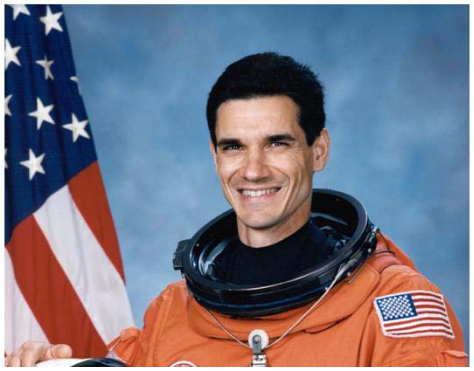




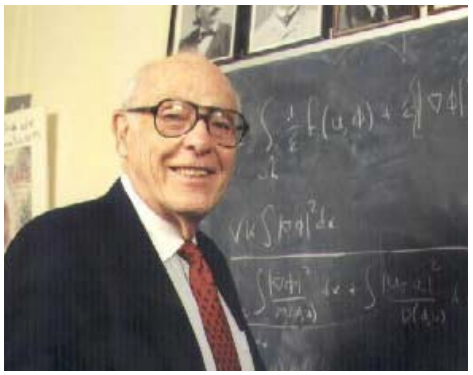
NIST has... ...world-class staff



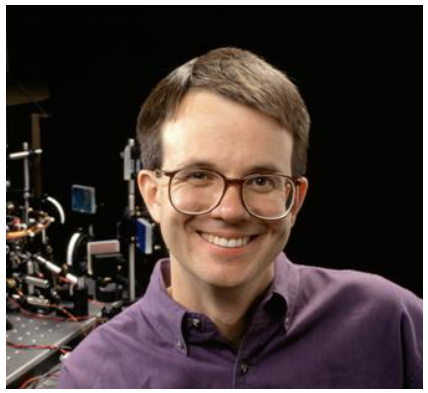
Bill Phillips
1997 Nobel Prize in Physics



Greg Linteris
2 Space Shuttle missions



John Cahn
1998 National Medal of Science



Eric Cornell
2001 Nobel Prize in Physics

Anneke Sengers
2003 L'Oréal-UNESCO Women in Science Award

Debbie Jin
2003 MacArthur Fellowship

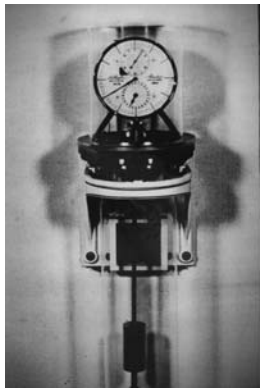
John Hall
2005 Nobel Prize in Physics

Seven SI base units:

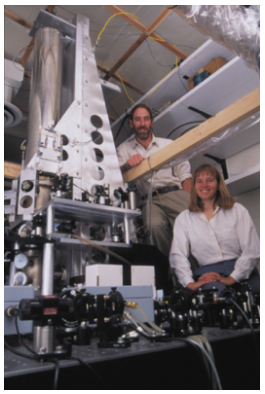
Quantity	*SI Base Unit*	*Definition*
length	meter (m)	distance traveled by light in a vacuum in 1/299792458 of a second
mass	kilogram (kg)	mass of a platinum/iridium cylinder kept in Paris
time	second (s)	time required for 9,192,631,770 cycles of the 3.26 cm microwave line of cesium-133.
temperature	kelvin (K)	273.16 degree K is assigned to the triple point of water (where vapor, liquid, and ice are at equilibrium)
electric current	ampere (A)	amount of current flowing through each of two long parallel wires separated by 1 m that results in a force of 0.2 micronewtons per meter along the wires
luminous intensity	candela (cd)	luminous intensity of 1/600000 m2 of a radiating cavity at the melting point of platinum (2042 K)
amount of substance	mole (mol)	amount of substance that contains the same number of particles as the number of atoms in a sample of pure carbon-12 weighing exactly 12 g

NIST leads the development of primary standards

pendulum clock
1 s in 3 years
(1904)

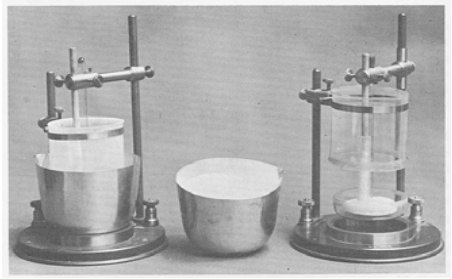


second



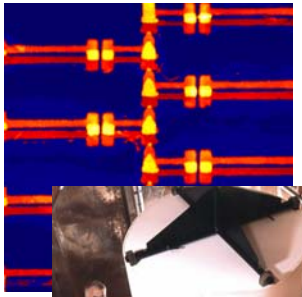
NIST F1
atomic clock
1 s in 30 million
years
(1999)

silver voltameter
current standard
(1910)

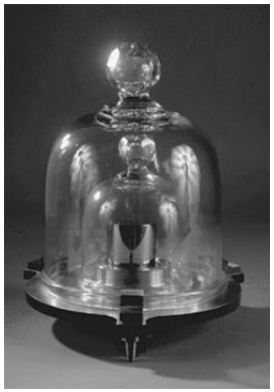


ampere

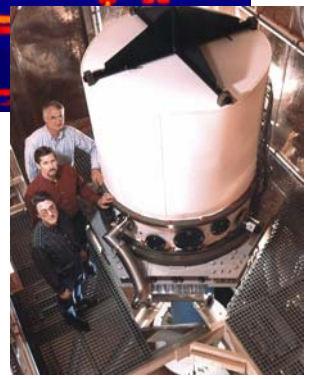
single
electron
counter
(20xx)



physical artifact
(1889)



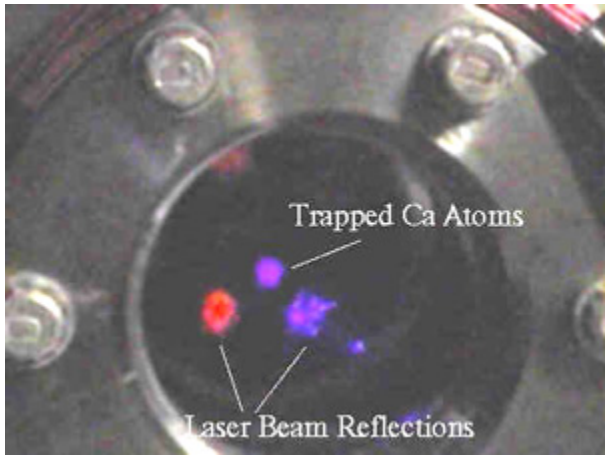
kilogram



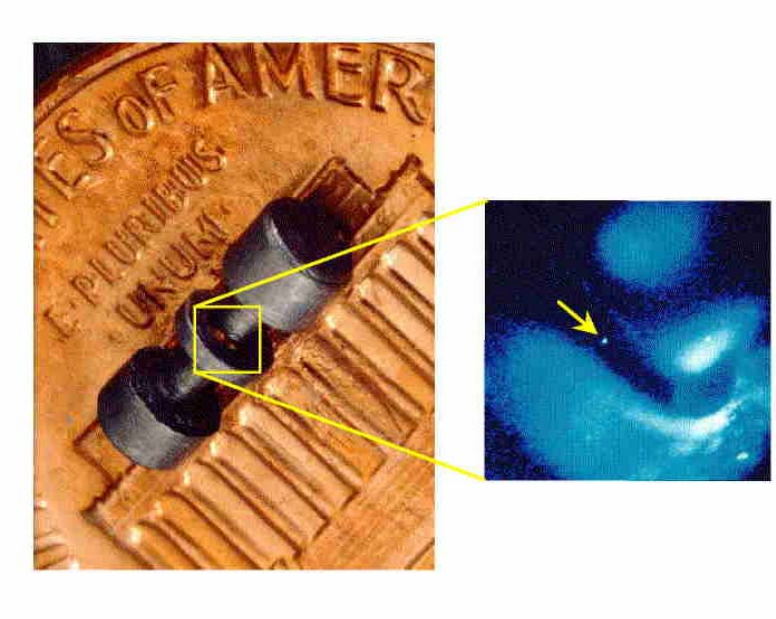
electronic
kilogram
(20xx)

NIST Research to Develop Future Clocks

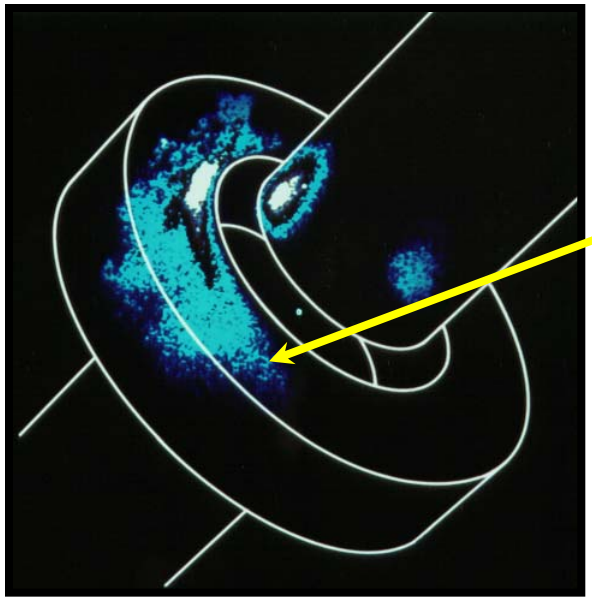
Optical clocks have the potential for accuracy about 1,000 times better than NIST F-1
(10^{-18}, 1 second in 30 billion years).



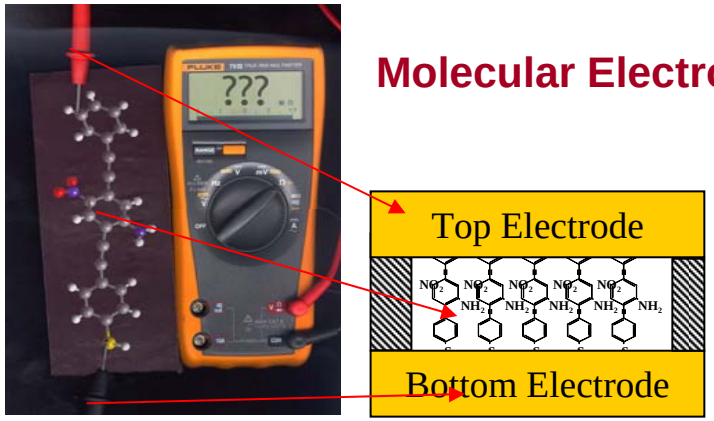
Laser-cooled calcium trap.



Single mercury ion trap.

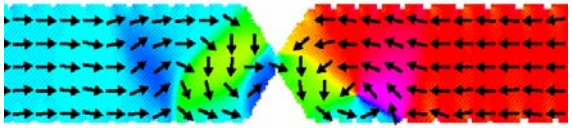


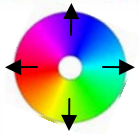
Measurements, Standards, & Data for the Nanoscale



Molecular Electronics

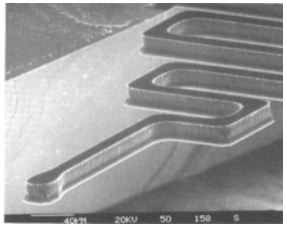
Imaging Magnetic Nanostructures

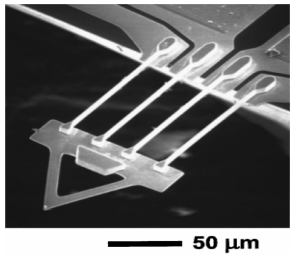


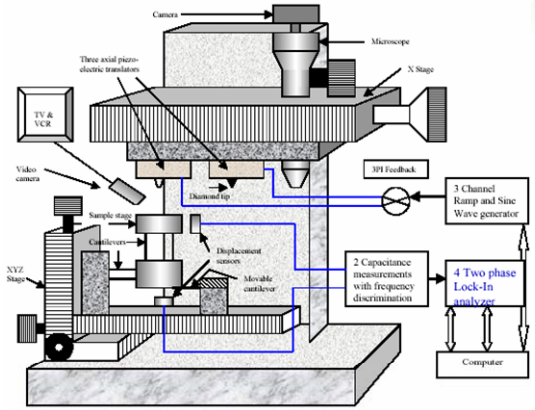


Nanoconstriction domain wall

Cantilever Fabrication for Lateral Force Measurement

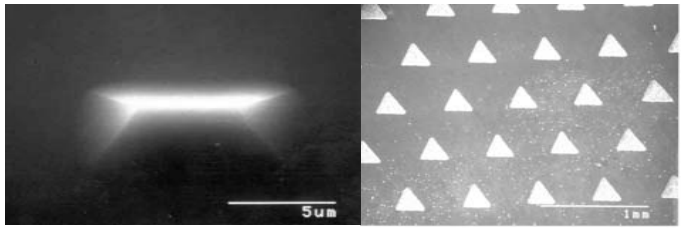


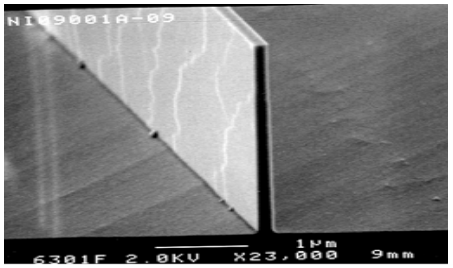




Nanomechanics and Tribology Measurements

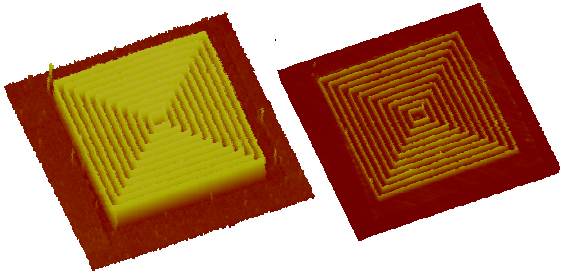
Surface Standards for Biomaterials





Linewidth Standards

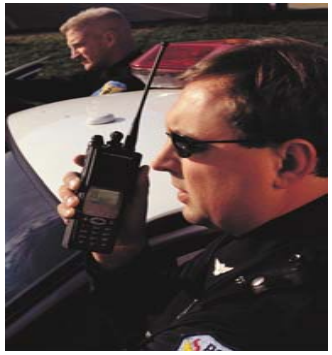
Nanoscale Dimensional Standards



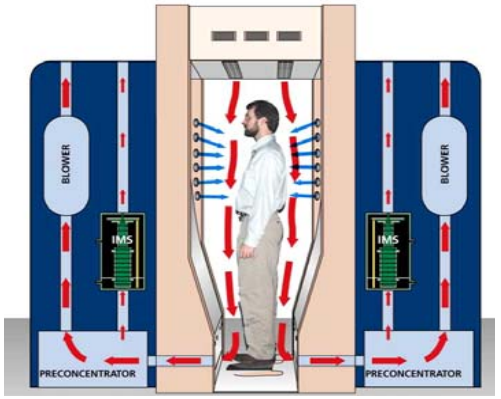
NIST research and measurement service activities

...improve public safety and security

gas mask performance standards



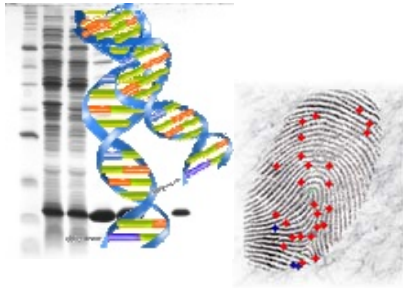
wireless interoperability stds. for first responders



assessment of trace explosives detection technology

mail irradiation technology

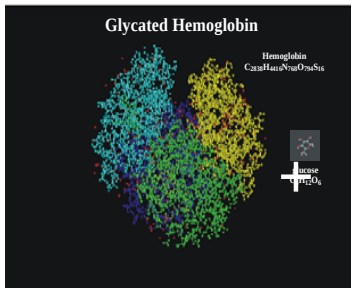
altimeter calibration



standards for body biometrics and body armor

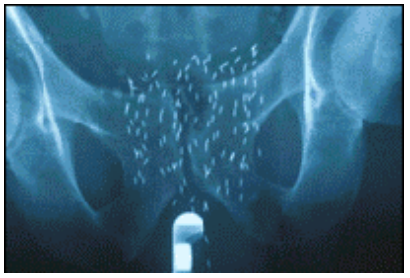
NIST research and measurement service activities

… improve disease prevention, diagnostics and treatment

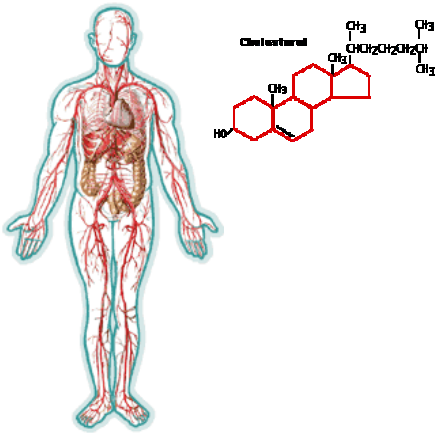


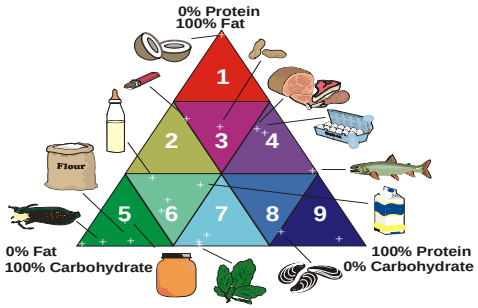
Standards for clinical diagnostics

QA water quality measurements

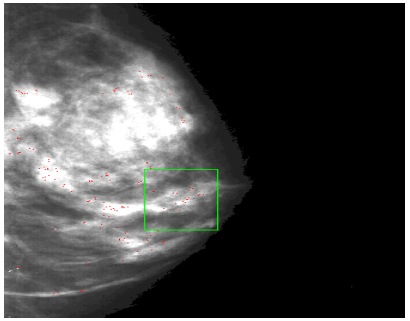


Dosimetry standards for prostate cancer treatment





Reference materials for nutritional labeling



Standards for mammography

NIST research and measurement service activities

...facilitate trade

secure automated banking

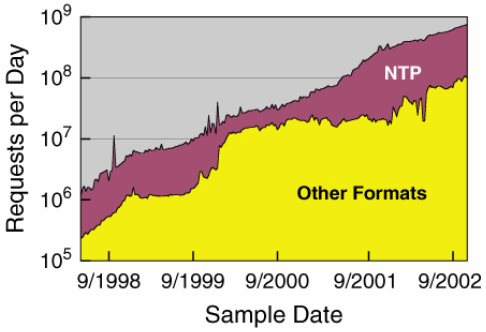
electric power metering

ASTM INTERNATIONAL

ISO International Organization for Standardization

international standards to counteract TBTs

volume and flow standards



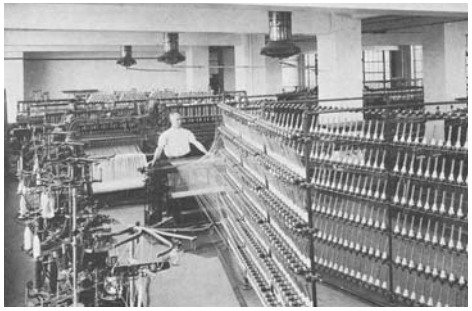
www.time.gov
billions of hits daily

CE

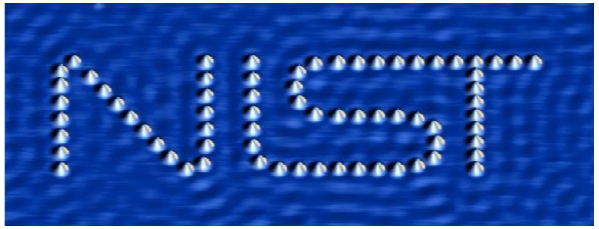
EU directive on in vitro diagnostic standards

NIST enables innovation in...

...manufacturing



1920
Experimental cotton mill



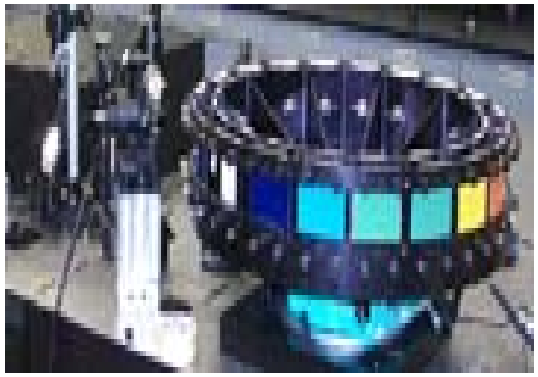
20xx
Automated and optimized assembly of single atom constructions

2004 Simulation technology for manufacturing operations

Testbeds

Interoperability and data exchange

…NIST provides many services and products



Calibration Services

Laboratory Accreditation

Commercial Metrology Guidelines

Standard Reference Materials and Data

NIST Security Configuration CHECKLISTS http://checklists.nist.gov CSD

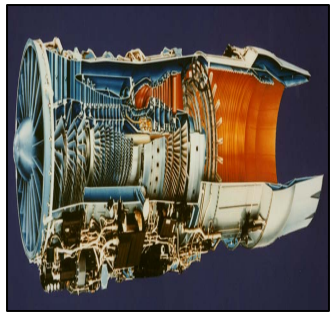
Cybersecurity Best Practices

Quality Guidelines

NIST Measurements and Standards

- **Measurement Research**
  2,100 publications/year
- **Standard Reference Data**
  90 types available; 5,000 units sold/ year
- **Standard Reference Materials**
  >1,200 products available; 30,000 units sold/year
- **Calibrations and Tests**
  3,200 items calibrated/year
- **Laboratory Accreditation**
  826 accreditations
- **Standards Committees**
  390 NIST staff, 450 committees
- **Metrology Training Courses**
  25 per year

We Provide Services to High Technology Industries ...

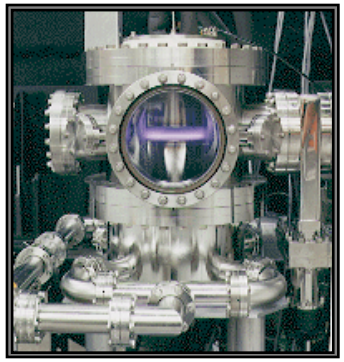


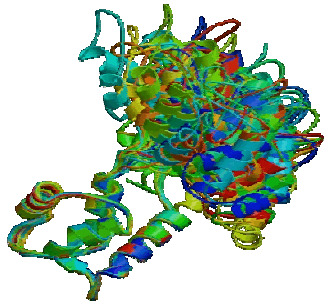
Aerospace and Transportation

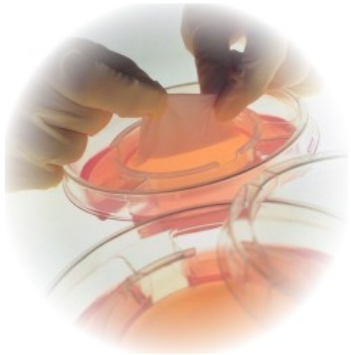
- Standards for low NO emissions from vehicles
- Thermophysical data on rocket propellants
- Cryogenic measurements for NASA's future space vehicles
- Properties of aircraft fire suppressants

Semiconductors

- SRMs for measuring P, As, and B in Si
- Thermometry and plasma process monitoring in semiconductor fabrication
- Electrical carrier density measurements
- Neutron transmutation in semiconductor doping







Biotechnology

- Proteomics
- DNA diagnostics
- Human identification
- Tissue engineering

… and Mature Industries

Chemical Processing

- Chemistry WebBook, MS Database, IR Database
- Thermal/physical properties of fluids, refrigerants, ionic liquids
- Molecular property data for chlorinated hydrocarbons
- Zeolite reference materials

Health and Food

- Reference methods and SRMs for clinical markers
- Methods and SRMs for dietary supplement safety
- Nutritional composition SRMs
- Environmental contamination SRMs

Energy

- SRMs for low-sulfur fuels
- Natural gas flow and composition standards
- Gas solubilities in steam for power generation

Constantly Balancing the "Old" with the "New"

SRM 1d - Argillaceous Limestone

Versions of SRM 1 have been provided by NBS/NIST since 1910. It is a critical natural resource as is building material, it is also used to manufacture lime for agricultural and chemical processes, cement and concrete, and iron and steel.

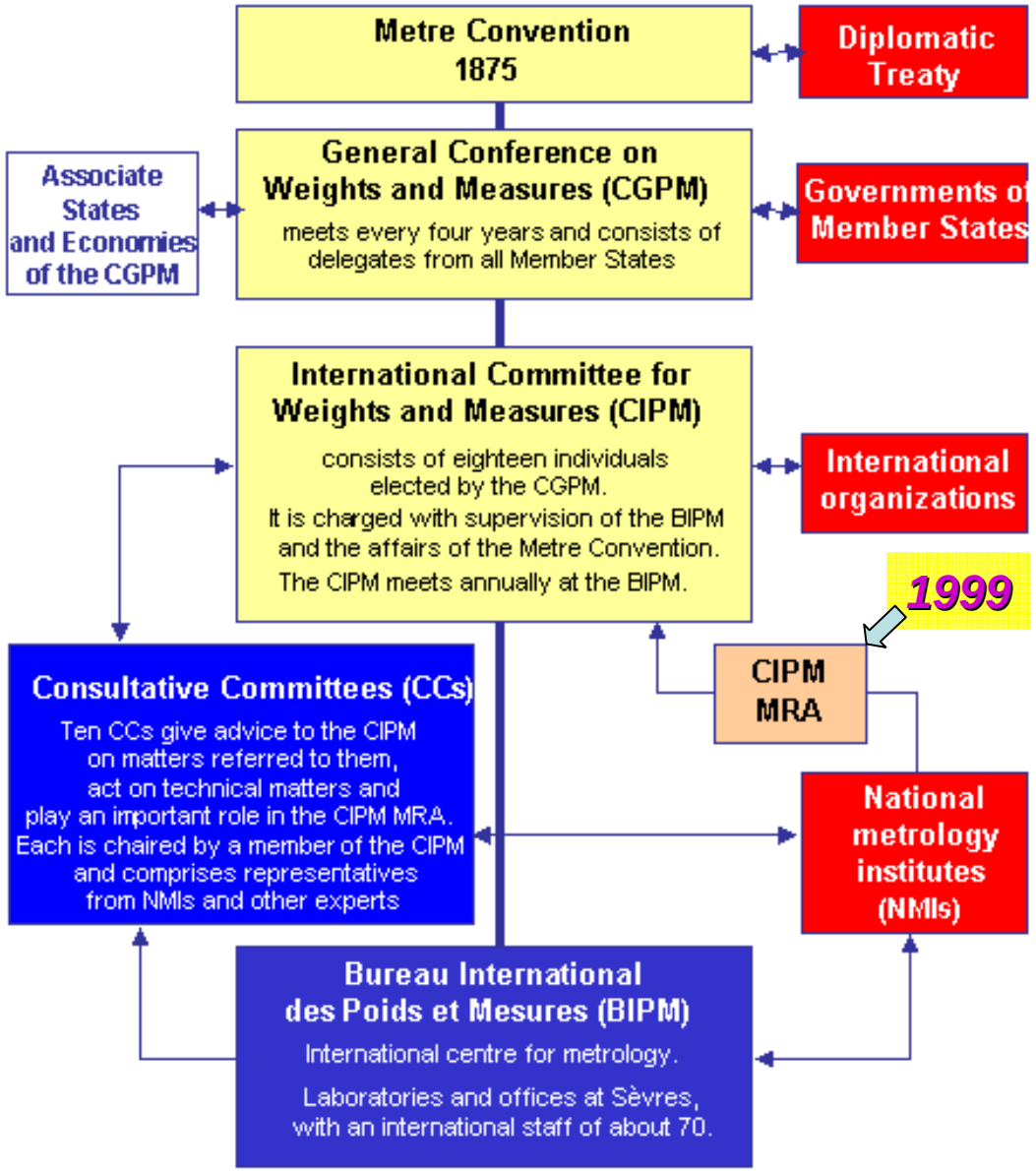
SRM 2399, Fragile X Human DNA Triplet Repeat Standard

And we support emerging industries and genetic testing laboratories in accurately counting fragile-X repeat sequences, NIST has developed a new reference material that can be used as a check on test procedures and for quality control. SRM 2399 consists of nine samples of DNA measured and certified by NIST for triplet repeats ranging from 20 to 118. **The triplet repeat standard joins more than 50 reference materials produced by NIST for quality control in clinical testing.**

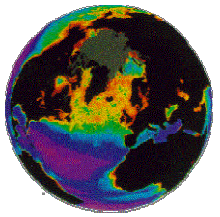
METRE CONVENTION

Provides the framework within which the international measurement system is maintained and made available to the whole world for:

- **national and international trade**
- **manufacturing**
- **human health and safety**
- **the protection of the environment, and**
- **all aspects of science and engineering**



Mutual Recognition Arrangement (MRA) developed by the CIPM



- **Signed by 38 NMI Directors in October 1999; 22 others since**
- **Provides:**
  - Open, transparent, and comprehensive scheme to give users reliable quantitative information on the comparability of metrology services worldwide needed for mutual recognition of national measurement standards and measurement certificates issued by national metrology institutes
  - Technical basis for wider agreements negotiated for international commerce and regulatory affairs
- **Requires:**
  1. Declaring and documenting calibration and measurement capabilities
  2. Evidence of *successful* participation in formal, *relevant* international comparisons
  3. Demonstration of system for assuring quality of each NMI's measurement services

Traceability to stated references and global confidence in this realization are the basis for mutual recognition and confidence in data used to facilitate and underpin international trade and decisions regarding health, safety, commerce, and scientific studies

Mutual Recognition Arrangement (MRA) requires:

1. Declaring and documenting calibration and measurement capabilities (CMCs)

   Over 1100 NIST CMCs for Chemical Measurements are included in ~3000 CMCs published in the CIPM MRA Appendix C.

2. Evidence of *successful* participation in formal, *relevant* international comparisons

Health
- clinical diagnostic markers
- electrolytes *(Na, K, Ca),* Pb in blood
- anabolic steroids in urine

Food
- Pesticides, antibiotics hormones
- vitamins and minerals
- drinking water *(EPA List)*
- ethanol in wine, sucrose

Environment
- air, soil, sediments
- biological tissues
- waste water *(EPA List)*

Advanced Materials
- semiconductors, alloys, polymers

General Studies
- pH and electrolytic conductivity
- purity assessment
- calibration solutions mixtures

Forensics
- drugs, breathalyzer *(ethanol-in-air)*
- explosive residues
- DNA profiling

Commodities
- emissions trading, sulfur in fossil fuels
- natural gas
- cement

Biotechnology
- DNA quantification
- GMO

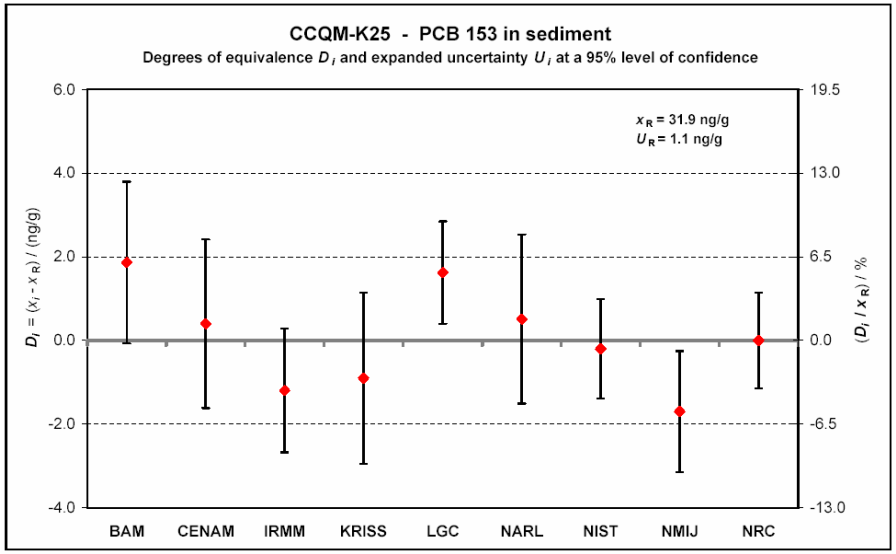
MRA Requirements:

2. Evidence of successful participation in formal, relevant international comparisons:

- **NIST has successfully participated in ~ 80 CCQM international comparisons to meet requirements of MRA during the past five years;**
- **NIST served / is serving as Coordinating Laboratory of >40 of these comparisons.**

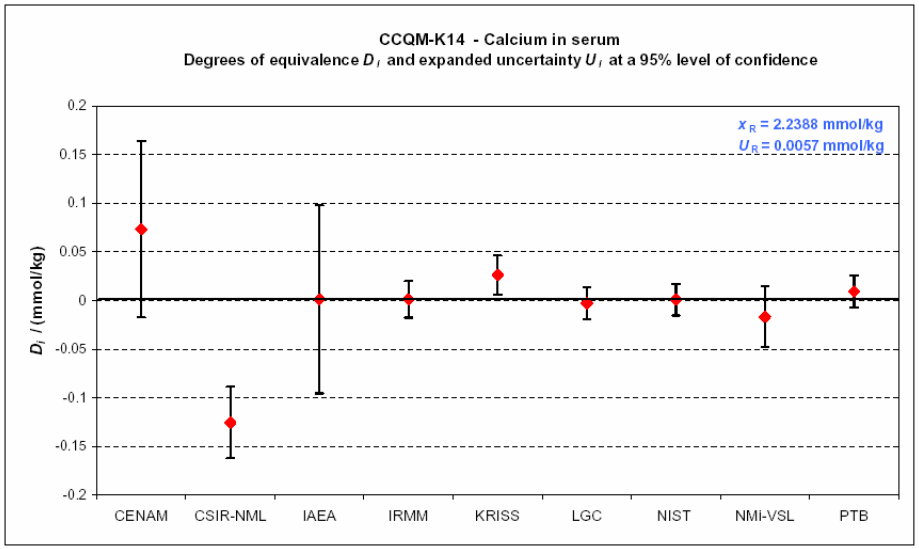
Recent Examples:

CCQM-K25: PCBs in Sediment
PCB 153



The BIPM key comparison database, December 2003

CCQM-K14: Calcium in Serum



The BIPM key comparison database, April 2004

Goals for NIST Measurement Service Activities

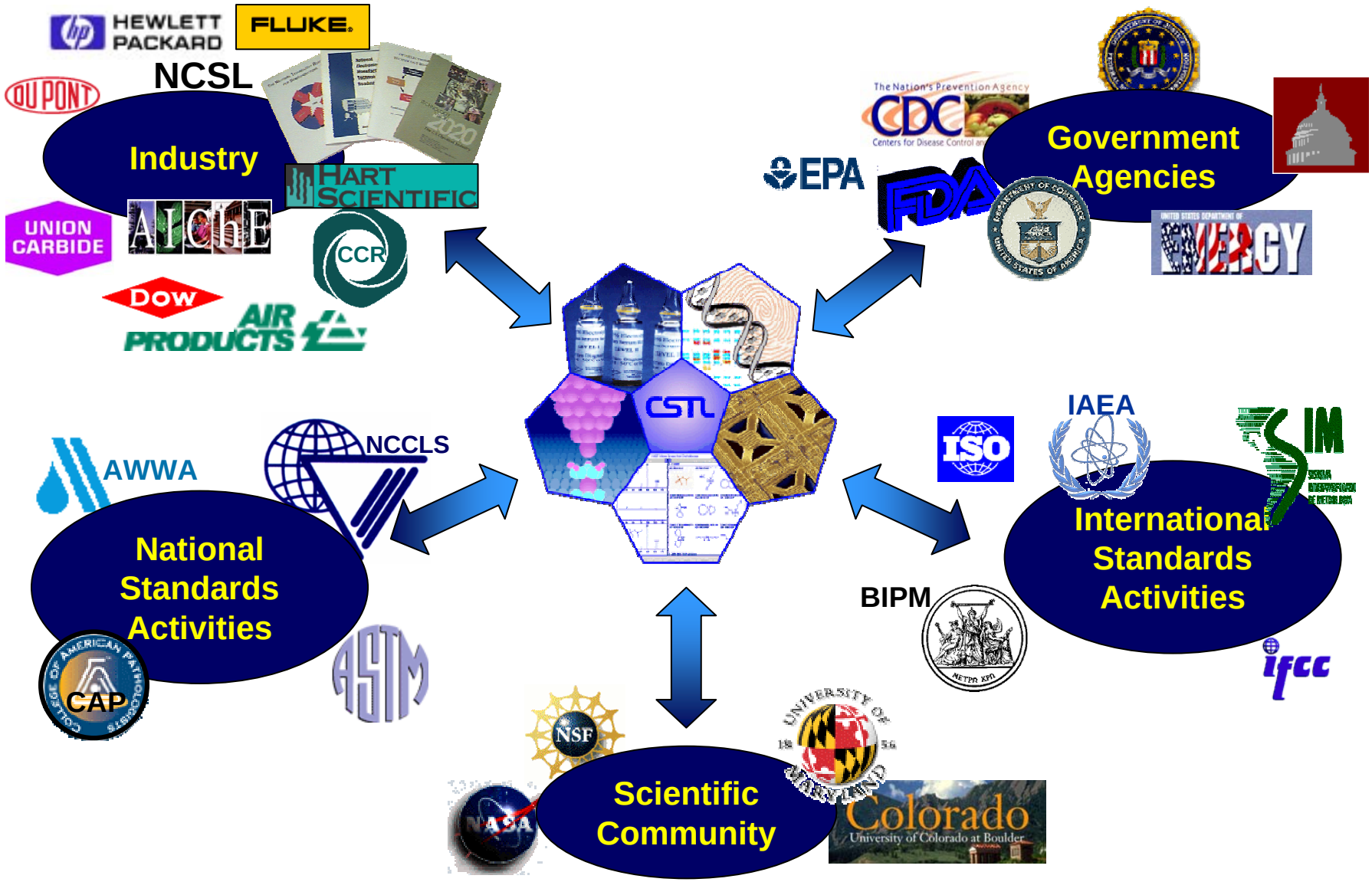
1) Improve effectiveness and efficiency of U.S. manufacturing by providing standards, technical information and services – helping the supply chain to work better
   - Broaden the extent and impact of NIST's activities to enable different parts of the manufacturing enterprise to interoperate more easily
   - Develop a plan for next generation MEP that helps smaller manufacturers to be high-performing elements of the supply chain
2) Promote international trade practices that are more fair and open
   - More effectively represent U.S. interests in selected global standards areas
   - Develop creative approaches for resolving problems faced by U.S. standards developing organizations in representing U.S. interests
   - Develop a more strategic approach for NIST's involvement in the standards process—including international standards affecting trade
3) Increase confidence between buyer and seller
   - Identify opportunities related to standards and assessing conformity
   - Help others in tackling technical aspects of issues of privacy and confidentiality

How are we keeping *our* priorities straight –

Are we on the proper course ???

How we are managing *our* load?

Impact of NIST Programs Enhanced through Interactions with Stakeholders



Programs Guided by Stakeholder Roadmaps and Needs Assessment

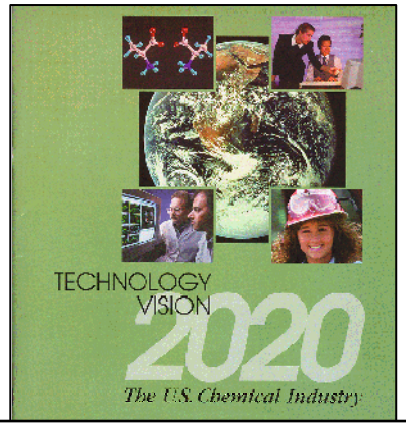
Semiconductor Industry Association

Optoelectronics Industry Development Association

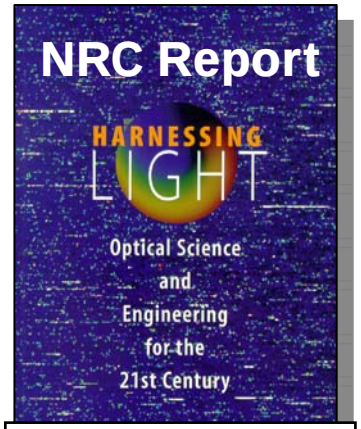
OIDA **Multiple Roadmaps**

President's Information Technology Advisory Committee

Roadmap



Chemical industry vision / roadmap



Optics needs

Working with Industry

Standards Developing Organizations

- Hundreds of staff are members of SDOs
- Many hold offices or are on several committees

Present on committees concerned with restricted substances

- ASTM F40 Declarable Substances
- IEC TC111 WG3 on Test Methods for RoHS
- IEC TC93 Design Automation
- ASTM D20 Plastics, ASTM E01 Metals
- IPC 2-18 Data Process Management
- Object Management Group (OMG)
- Standard for the Exchange of Product Data (STEP)
- Organization for the Advancement of Structured Information Standards (OASIS)
- Semiconductor Equipment Materials International (SEMI)

International Regulations on the Restriction of Hazardous Substances

European Union member nations are about to restrict the use of hazardous substances in electrical and electronic products and components.

China recently announced similar restrictions as part of their drive to reduce the problem of electronic waste in their country.

In **Japan**, electronics manufacturers recently set specifications to restrict the use of 24 substances by their suppliers and their own manufacturing facilities.

Many States in the US either have or are considering RoHS-like statutes

These regulations and specifications are aimed at products going to market.

RoHS is but one of many EU directives

- **IVD Directive**
- **Waste Electrical and Electronic Equipment**
- **Registration, Evaluation and Authorization of Chemicals**
- **End of life vehicles**
- **Packaging Directive**
- **Integrated Product Policy**
- **Batteries Directive**
- **Energy-Using Products**

Nutrition Labeling and Education Act of 1990

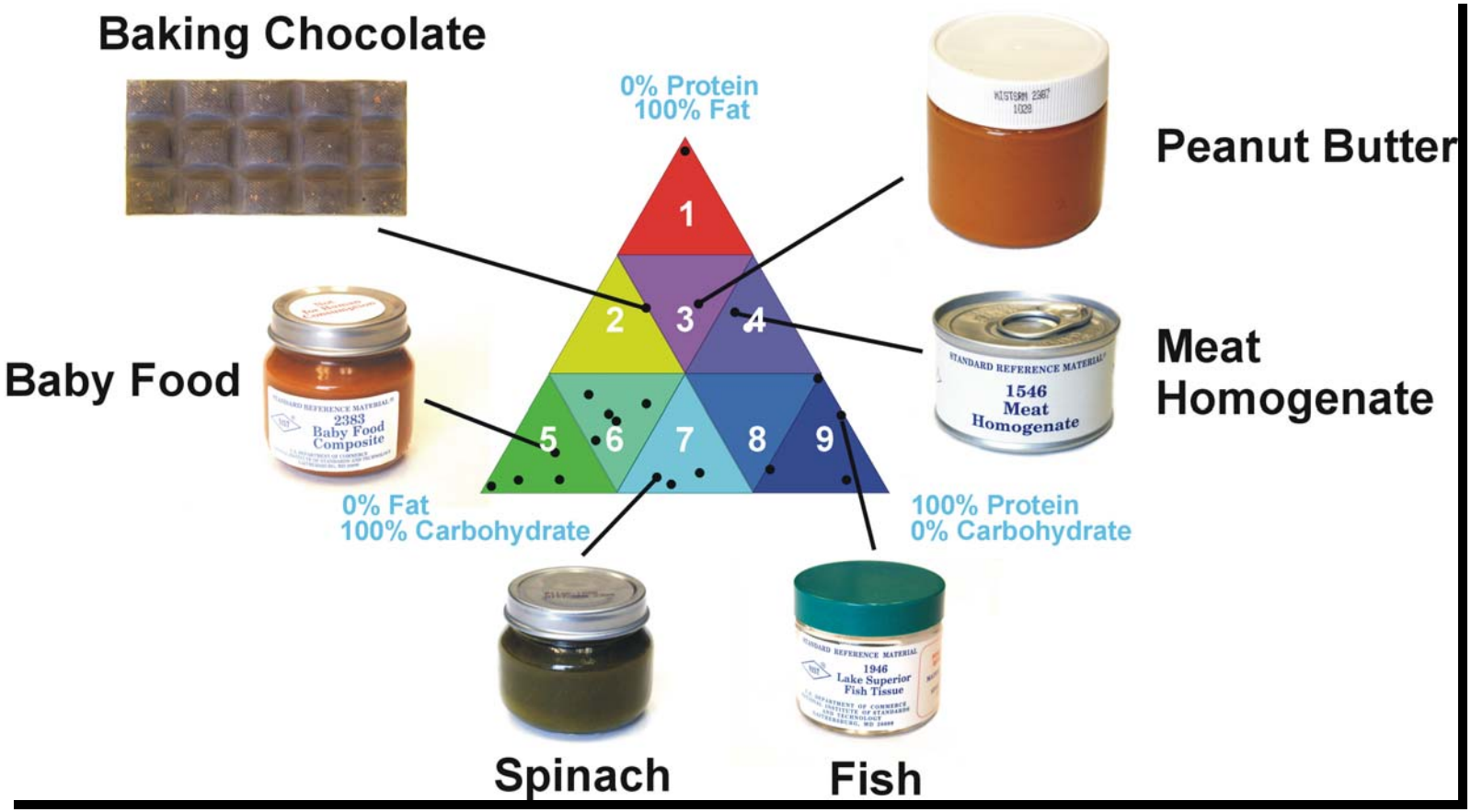
(Public Law 101-535)

Label on processed foods must specify:

- serving size in common household units
- number of servings per container
- total number of calories derived from all sources and derived from fat in each serving
- amount of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, other carbohydrates, total protein, vitamin A, vitamin C, calcium, and iron contained in each serving
- any other vitamin, mineral, or nutrient required to assist the consumer in maintaining a healthy diet

SRMs for Nutrients and Contaminants in Food

Examples of Food-matrix Standard Reference Materials by Sector

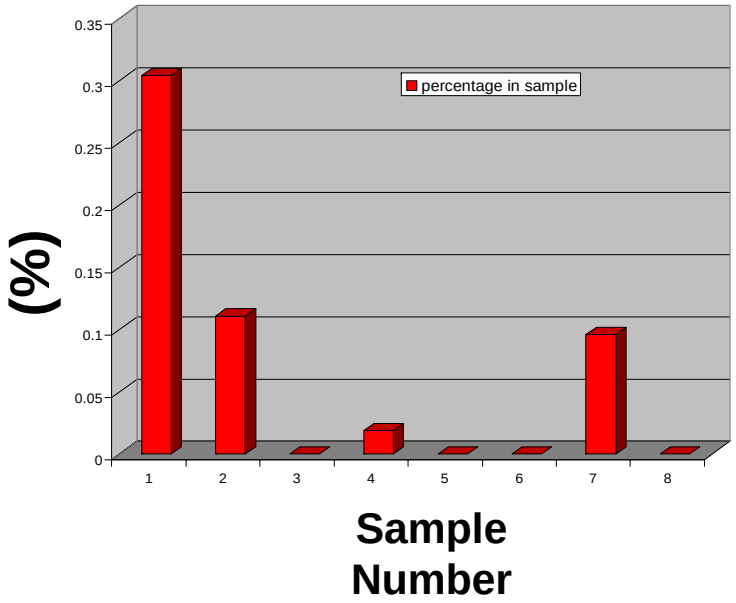


Most food analysis labs provide analyses for a similar set of analytes, but matrix Differences and concentration differences are the primary measurement challenges.
By providing SRMs across the major sections of the food triangle, NIST will have covered most of the field for the measurement of common food analytes.

Dietary Supplements and Functional Foods

Measurement Traceability increasingly required:

- to support label claims - truth in advertising
- **to facilitate regulatory control and/or compliance**
- to support public health and safety
- to assess conformance with import/export requirements



I. Khan, University of Mississippi

Eight commercial products sold as **Valerian Supplements** were analyzed in one Laboratory for valerenic acid content as shown below:

Standards for Dietary Supplements

US Senate Language FY2002

"NIH-ODS to allocate sufficient funds to speed up an ongoing collaborative effort to develop and disseminate validated analytical methods and reference materials for the most commonly used botanicals and other dietary supplements."

Matrix	***Targeted Physiological Agents***
• Ephedra	Alkaloids
• St. John's Wort	Hypericins, Hyperforin
• Saw Palmetto	Fatty Acids, Sterols
• Ginkgo Biloba	Flavonol glycosides, ginkgoterpenoids
• Green Tea	Catechins, Gallic Acid
• Multivitamin/mineral tablets	Vitamins and minerals

Priorities determined in consultation with NIH, FDA, USDA and AOAC

Standards for Mercury Emissions

EPA to regulate mercury emissions from coal fired power plants (Title II of the Clean Air Act of 1990)

- Original publication of regulations: December 2003
- Cap and Trade proposal issued February 24, 2004
  - New deadline publication for public comment: Spring 2004
  - 30 % reduction by 2008

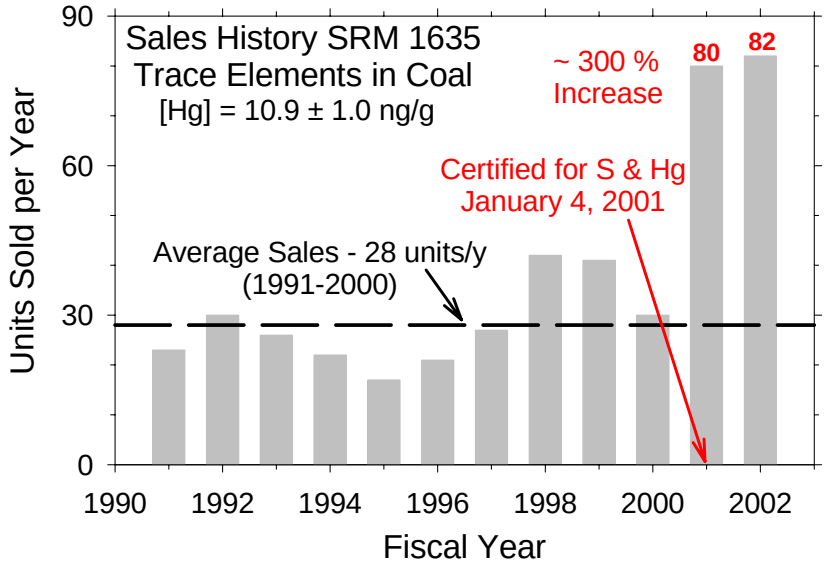
NIST Project Objectives

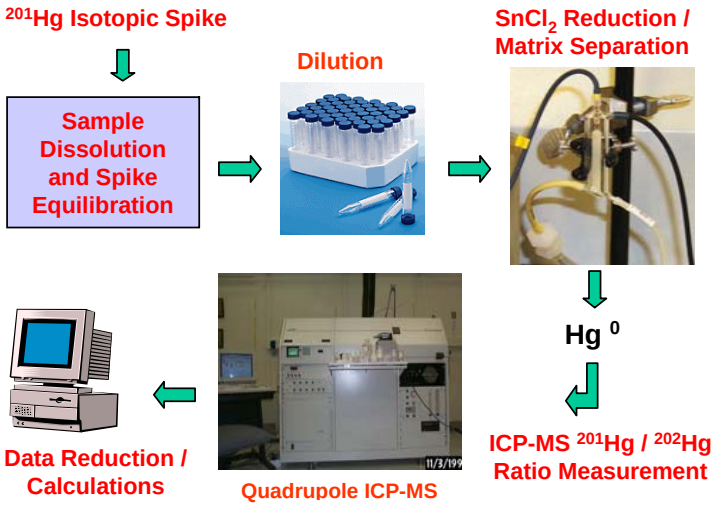
- **Provide traceability in elemental mercury emissions monitoring**
  - *Add Hg values to suite of existing Coal SRMs*
  - *Develop new gas mixture SRMs with NIST certified elemental mercury concentrations*

Certification of Mercury in Fossil Fuel SRMs by ID-CV-ICP-MS

Value added to existing SRMS

	ng/g of Hg	
SRM 1632c	93.8 ± 3.7	Bituminous
SRM 2682b	108.8 ± 2.9	Subbituminous
SRM 2683b	90.0 ± 3.6	Subbituminous
SRM 2684b	97.4 ± 4.7	Bituminous
SRM 2685b	146.2 ± 10.6	Bituminous
SRM 2692b	133.3 ± 4.1	Bituminous
SRM 2693	37.3 ± 7.7	Bituminous

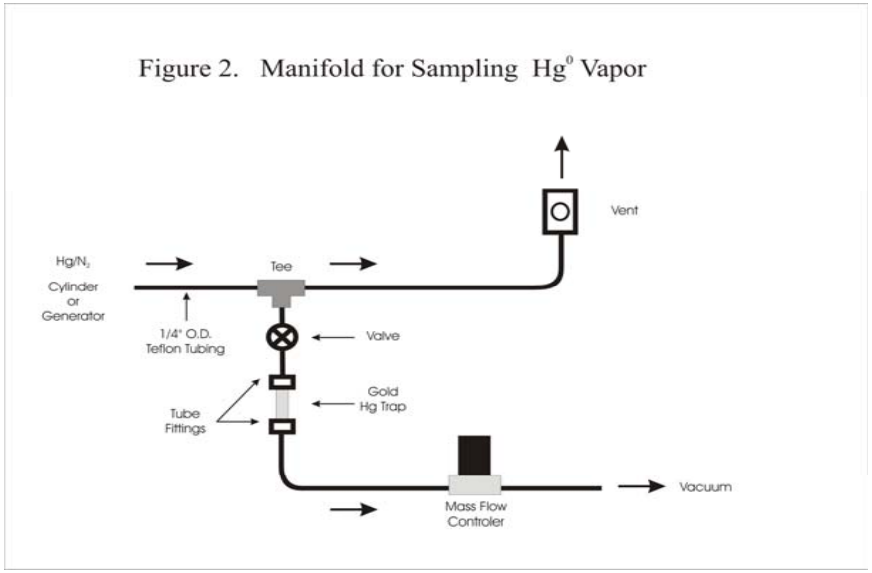




New method developed to meet industry need for low level Hg standards in coals

Mercury in Nitrogen Gas Standards

New Method: The first step is to develop a NIST traceable method for determining Hg^0 in nitrogen from two sources gas cylinders mercury generators (calibrators). This will be followed by the development of a NIST traceable standard for Hg^{++} in a flue gas.



Mercury Concentration of Cylinder Gas Mixtures

Cylinder Number	Concentration Hg (µg/m³)	Expanded Uncertainty	Percent Relative
CC-162841	2.13	0.14	6.6 %
CC-162896	2.50	0.16	6.4 %
CC-162918	2.25	0.16	7.1 %
CC-162789	5.99	0.36	6.0 %
CC-165910	6.31	0.38	6.0 %
CC-162915	4.48	0.28	6.3 %
CC-162824	21.4	1.3	6.0 %
CC-162881	22.8	1.4	6.0 %
CC-162911	22.9	1.4	6.0 %
CC-162828	55.6	3.4	6.1 %
CC-162887	64.9	3.8	5.9 %

Three sets of three cylinders each containing Hg^0 vapor in nitrogen were analyzed by NIST to provide traceable calibration gas mixtures. The nominal concentrations of Hg^0 in the sets are 2 µg/m³,5 µg/m³ and 20 µg/m³.

Calibration: SRM 3133 Mercury Standard Solution

".... the traceability of values assigned to calibrators and control materials must be assured through available reference measurement procedures and/or reference materials of a higher order ..."

EC-IVD Directive Annex 1 (3)

Approximately 60 % of the in vitro diagnostic medical devices (IVD MD) currently on the ~ $6 B/yr European market are imported from the US. (Worldwide, the in vitro diagnostic device market is ~$20B)

Health Care Measurements and EU IVD Directive

US IVD Manufacturers sought NIST help in meeting new traceability

NIST RESPONSE:

- **IVD Workshop held at NIST (Industry Driven), November 2000**
- **Follow-on Workshop, June 2002**
- **Webcast Workshop on Uncertainty in Clinical Measurements, March 2003**
- **Continuing updates with Industry at National Meetings**
- **Played leadership role in creating the Joint Committee on Traceability in Laboratory Medicine (JCTLM)**
- **Actively participating in ISO Technical Committees and other global SDOs.**

JOINT COMMITTEE on TRACEABILITY in LABORATORY MEDICINE

A global body, established in Paris on 12 June 2002, to meet the need for a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

The Declaration of Cooperation between the International Committee of Weights and Measures (**CIPM**), the International Federation for Clinical Chemistry and Laboratory Medicine (**IFCC**),and the International Laboratory Accreditation Cooperation **(ILAC**) for establishment of the **JCTLM** can be found at
http://www.bipm.org/en/committees/jc/jctlm/declaration.html

Joint Committee on Traceability in Laboratory Medicine

NIST was asked to lead WG-I of this International body is charged with:

Establishing a process for identifying, and reviewing against agreed upon criteria "higher order" Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.

Publishing a List of "higher order" Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.

Priority Analyte Areas

Review Teams established with worldwide representation in order to facilitate a fair and transparent review process

- *Lab Accreditation Organizations*
- *National Metrology Institutes from the US, Germany, UK, etc.*
- *Professional Societies, such as AACC, JACC*
- *the IVD Industry*

Review Team Areas:

Blood Grouping/ Typing

Blood Gases
Coagulation Factors
Drugs
Electrolytes
Enzymes

Hormones
Metabolites and Substrates
Microbial Serology
Non-Electrolyte Metals
Nucleic Acids
Proteins
Vitamins and Micronutrients

BIPM - database - Mozilla Firefox

File Edit View Go Bookmarks Tools Help

file:///h:/BIPM%20-%20database.htm

Customize Links Free Hotmail Windows Marketplace Windows Media Windows Yahoo! Bookmarks

BIPM
Bureau International des Poids et Mesures

JCTLM database: Laboratory medicine and *in vitro* diagnostics: Database of higher order reference materials and reference measurement procedures

JCTLM-DB summary
- General information
- Preamble
- JCTLM List I
- JCTLM List II
- Nomination of materials and procedures for review
- JCTLM Quality Manual

JCTLM
- Background information

Direct access
- USEFUL LINKS
- ACRONYMS
- CIPM MRA
- KCDB
- MEETINGS
- BIPM STAFF DIRECTORY
- PRACTICAL INFORMATION
- *METROLOGIA*
- FUNDAMENTAL PHYSICAL CONSTANTS

in French: *La base de données du JCTLM*

List I: Certified Reference Materials and Reference Measurement Procedures for well-defined chemical entities or internationally recognized reference method-defined measurands.

Reference Materials and Measurement Procedures included in this category are those that provide values that are traceable to the SI units; e.g., electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones and some proteins

Preamble for JCTLM List I of higher order reference materials and reference measurement procedures

JCTLM List I (resulting from the Cycle I nomination process)

List II: Reference Materials value-assigned using an internationally agreed-upon protocol

(e.g. reference materials for blood typing, coagulation factors, microbial serology, nucleic acids and some proteins).
The values of the measurands in the reference materials on this List are not SI-traceable and/or no internationally-recognized reference measurement procedures exist. List II also contains a group of purified substances that due to the absence of reference measurement procedures should not be directly used for calibration unless commutability is established.

JCTLM List II (resulting from the Cycle I nomination process)

- Quality manual for the listing of higher order reference materials and reference measurement procedures
- Open call (Cycle II) for the nomination of reference materials and reference measurement procedures for review by the JCTLM
- JCTLM WG review teams and members
- Contact the JCTLM secretariat

A searchable database of the published lists will be available after December 2004.

http://www.bipm.org/utils/en/pdf/jctlm_preamble.pdf

Start | JCTLM_REMCO 2005 | BIPM - database - Mo... | JCTLM_Wielgosz | /export/home/chemistry/... | EN 16:19

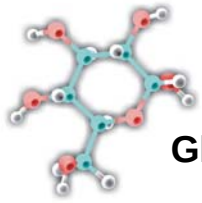
NIST has maintained Standards for 12 Health Status Markers for 20-years

Reference Systems are Currently in Place for Many Well-Defined Markers that are:

- **Relatively small well-defined molecular or elemental species**
- **Typically, can be determined using well-established ID/MS –based methodology**
- **Such as the following:**

Marker	*Disease State*
Calcium	Cancer, Blood Clotting
Chloride	Kidney Function
Cholesterol	Heart Disease
Creatinine	Kidney Function
Glucose	Diabetes
Lithium	Antipsychotic Treatment
Magnesium	Heart Disease
Potassium	Electrolyte Balance
Sodium	Electrolyte Balance
Triglycerides	Heart Disease
Urea	Kidney Function
Uric Acid	Gout
Vitamins	Nutrition Status

Demand for these SRMs have increased dramatically since the EU IVD Directive was implemented in December of 2003.

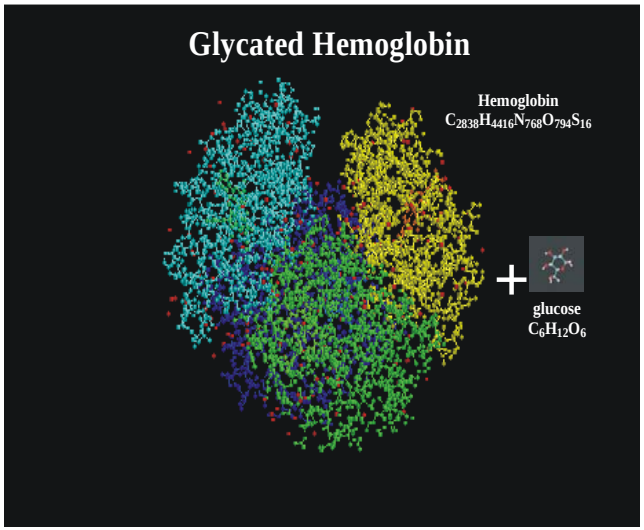


Glucose

NIST has Expanded its Standards Program to Support New IVD Industry Needs

Reference Systems Being Developed for New Markers that typically exhibit:

- High molecular mass (>20,000 daltons)
- Heterogeneity of analyte
- Low concentration
- Instability of analyte form
- Cannot all be determined using ID/MS or other definitive methodologies
- Such as the following:



Marker	***Disease State***
Troponin-I	Myocardial Infarction
C-Reactive Protein	Risk of Heart Attack
Homocysteine	Risk of Heart Disease
Glycated Hemoglobin	Diabetes Status
T3, T4 and TSH	Thyroid Function
Speciated Iron	Hemochromatosis
PSA	Prostate Cancer
Cadmium & Mercury	Toxic Metal Poisoning
Folates	Neural Tube Defects
HER2	Breast Cancer
Fragile X	Mental Retardation

Drivers for NIST Activities:

- Standardization necessary before full medical diagnostic benefit can be realized
- EU IVD Directive
- Well-articulated US “Other-Agency” Needs (FDA, NCI, CDC etc)

Joint Committee on Traceability in Laboratory Medicine

WG-I of this International body is charged with:

Establishing a process for identifying, and reviewing against agreed upon criteria "higher order" Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.

Publishing a List of "higher order" Certified Reference Materials and Reference Measurement Procedures required for IVD industry compliance with the EC IVD Directive regarding in vitro diagnostic medical devices.

Published 1 April 2004, the Current List contains:

- approximately 100 Reference Measurement Procedure entries for **58** different health status markers **NIST has Reference Methods for 30**
- approximately 150 Reference Material entries for **96** measurands **NIST has Reference Materials for 72**

http://www.bipm.org/en/committees/jc/jctlm/jctlm-db/

We're from the Government

and here to help !!

EU Directives on Restriction of Hazardous Substances

European Union member nations are about to restrict the use of hazardous substances in electrical and electronic products and components.

China recently announced similar restrictions as part of their drive to reduce the problem of electronic waste in their country.

In Japan, electronics manufacturers recently set specifications to restrict the use of 24 substances by their suppliers and their own manufacturing facilities.

These regulations and specifications are aimed at products going to market.

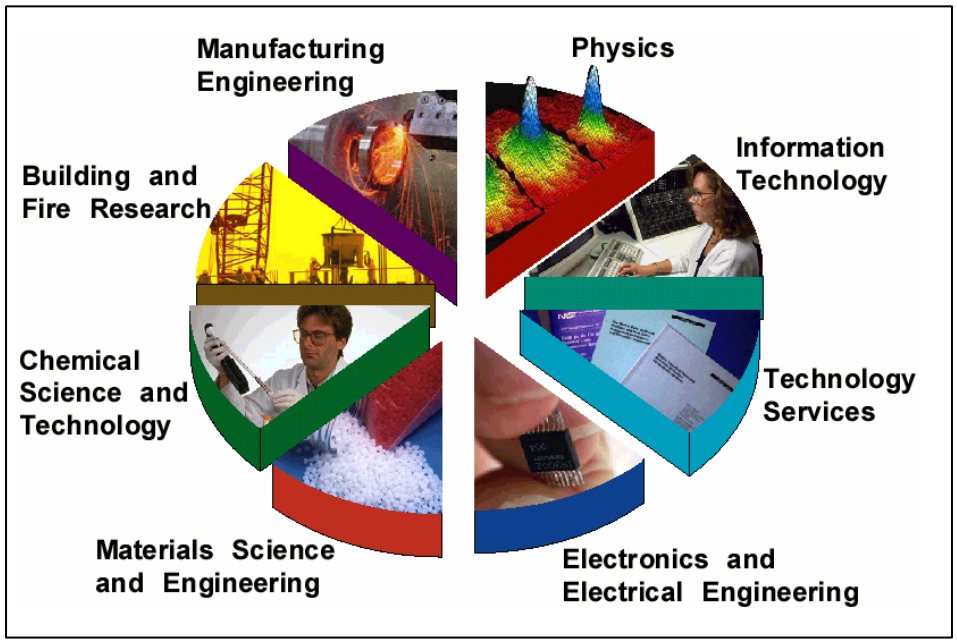
EU Directive 2002/95/EC, Restriction of Hazardous Substances (RoHS)

- **Restricts *Cd, Pb, Hg, Cr6+, Flame retardants*** *(PBBs, PBDEs)*
- **Requires *manufacturers to implement testing procedures* for raw materials and finished products to ensure compliance with these mandates**

How can NIST Help?

- **Develop and critically evaluate *test procedures***
- **Develop wide *variety of SRMs*** with certified values for restricted substances
- **Represent US on *SDO committees*,** e.g. IEC TC111 and ASTM F40
- **Standardize *declaration protocols***

NIST Laboratories



NIST's work enables

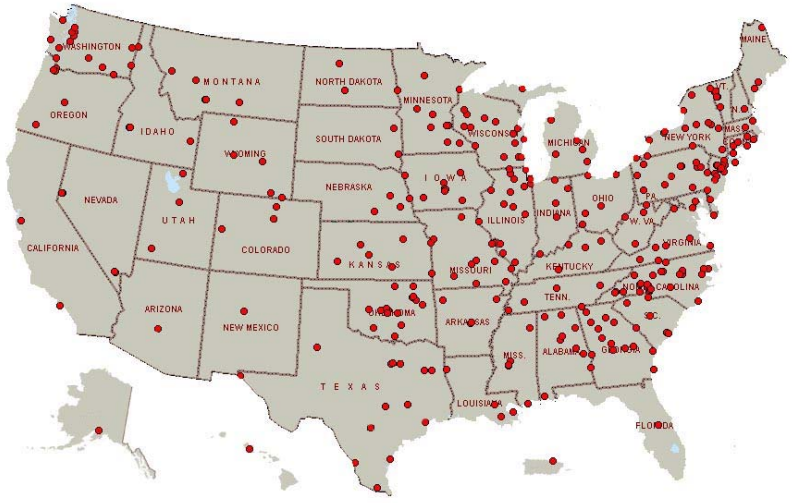
- **Science**
- **Technology innovation**
- **Trade**
- **Public benefit**

NIST RoHS-related measurement and standards interests, capabilities, and activities are very broad:

- **CSTL**
- **MSEL**
- **EEEL**
- **BFRL**
- **TS**

Manufacturing Extension Partnership

"Strengthening the global competitiveness of US-based manufacturing by providing information, decision support, and implementation assistance to smaller manufacturing firms in adopting new, more advanced manufacturing technologies, techniques, and business best practices."



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- ✓ **Leverage local, state & national partnerships**
- ✓ **Federal, State, Industry and Client Funded**

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and
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END