
Technical and Economic Considerations for the Development of Certified Reference Materials



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Metrology Impacts ...

- *Quality of life*
- *Market access and equity in trade*
- *Industrial competitiveness*
- *Sustainable manufacturing*



Everyday Life

Fossil Fuels

- gasoline
- jet A
- coal
- natural gas



Drinking Water

- flow metering
- quality



Altimeter Calibration



Thermometry

- healthcare
- process metrology



Food and Nutrition

- labeling
- measures

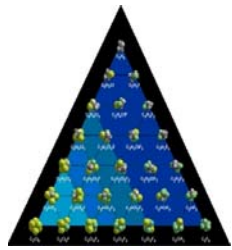


Refrigerants

Environmental Measurements

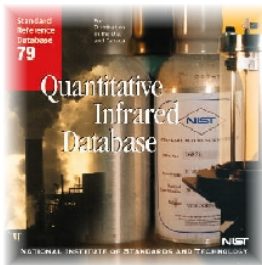
Global Market for Environmental Technologies Estimated at \$530 Billion

Standard Reference Data



REFPROP

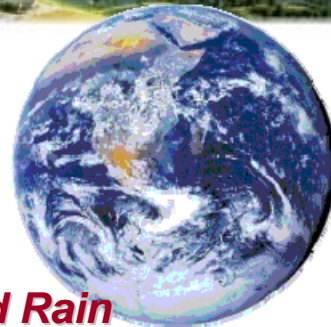
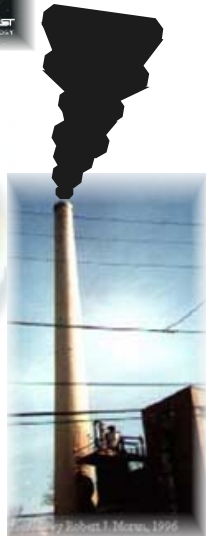
FTIR Database



Quantitative Infrared Database



Source Apportionment

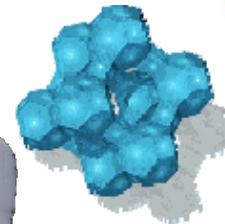


**Acid Rain
Emissions Trading
Catalyst Poisoning**

Fossil Fuels



Catalysts



Gas Mixtures



Standard Reference Materials



Sediments, and Dust



Standards for Proficiency Testing

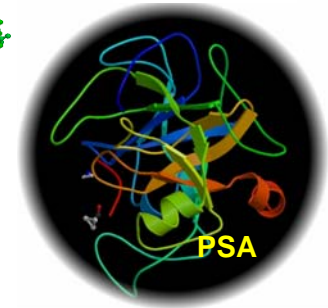
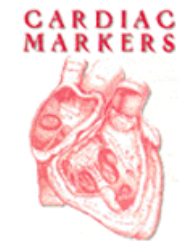
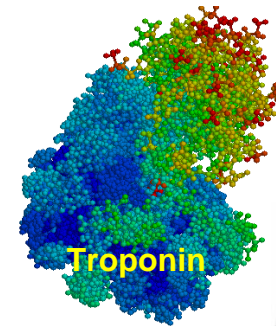
Healthcare Measurements

Healthcare costs amount to ~ 14% of the GDP, an estimated \$1.5 trillion

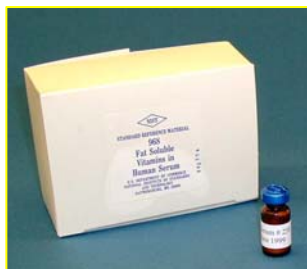
Prevention



Diagnosis



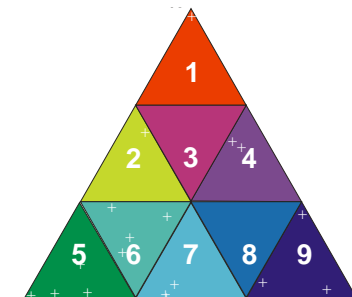
Treatment/Therapy



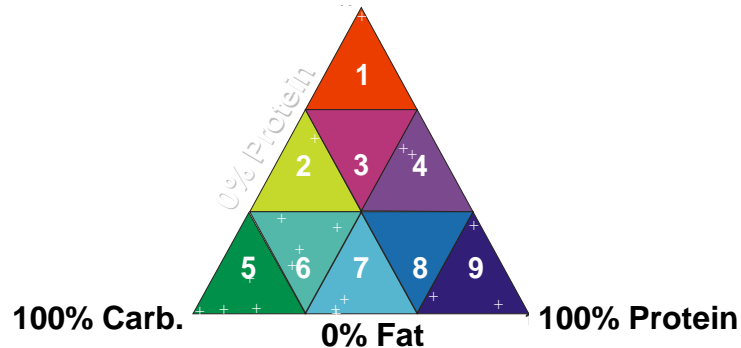
CSTL Maintains and Refines Definitive Methods for 12 Health Status Markers

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

Nutrition



Food and Nutrition



“Nutrition Labeling is Mostly Accurate on Packaged Food”

“However, 46 percent of foods contained less Vitamin A . . . than their labels claimed, and the labels were accurate for iron just 69 percent of the time.”

US FDA

Washington Post 1/1/97

Quality Assurance: Interlaboratory comparisons involve 20 laboratories from NFPA, plus other collaborating labs

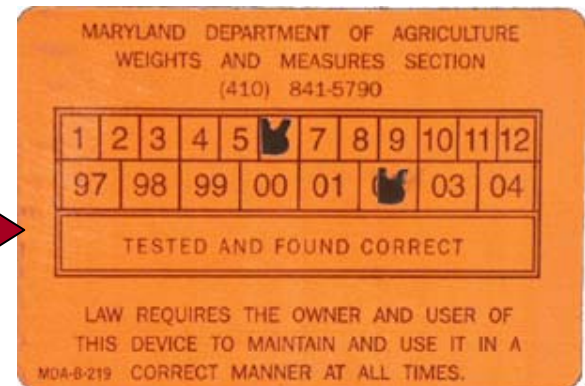
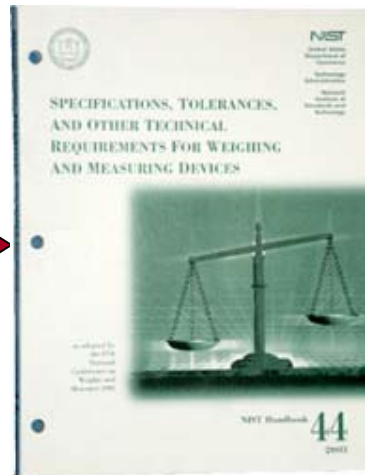
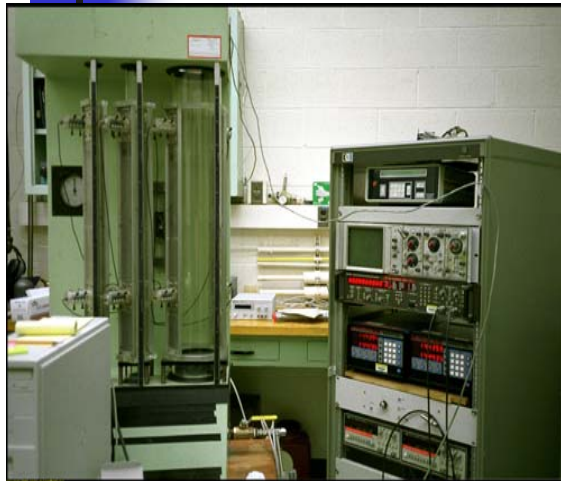
Populating the AOAC Food Triangle

- Sector 1** Cholesterol and Fat-Soluble Vitamins in Coconut Oil, SRM 1563
- Sector 2** Baking Chocolate
- Sector 3** Peanut Butter, proposed
- Sector 4** Meat Homogenate, SRM 1546
- Sector 5** Baby Food Composite, SRM 2383
- Sector 6** Frozen Diet, SRM 1544, Infant Formula, SRM 1846, Typical Diet, SRM 1548a
- Sector 7** Frozen Spinach, SRM 2385
Juncture, Fish Tissue, SRM 1946
- Sectors 4,8,9**

Food SRMs facilitate:

- compliance with nutritional labeling laws
- traceability for food exports needed for international trade
- the provision of accurate labeling information

Equity to the Marketplace



From laboratory, primary fluid-flow and volume standards

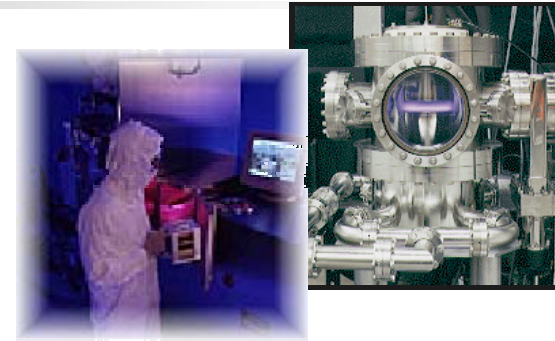
To assisting the States in their Weights and Measures regulation

- DOE Hydrogen Codes and Standards Coordinating Committee (HC&SCC) has delegated to NIST the lead role in weights and measures standards for vehicle systems and refueling facilities
- Responsible for coordination with Standards Development Organizations, such as the American Petroleum Institute (API) and the American Society of Mechanical Engineers (ASME), and the National Conference on Weights and Measures (NCWM)

Industrial Competitiveness



Aerospace & Transportation



Semiconductors



Chemical Processing



Health and Food



Global Sustainability

- Lead-free solder
- Green Liquid Fire Suppressants
- Green Solvents
- Fuel Cell development
- Green Building Design
- Sulfur in Fossil Fuels Standards
- Lead in Environmental Standards
- Advanced Isotope Ratio Measurements
- Alternate Refrigerants Research





Technical Drivers

- State of measurement practice is challenged by current or future accuracy requirements
- User community depends on compatibility of measurements
- Comparability of measurement results is required among all stakeholders

Measurement Comparability

- Needed to substantiate
 - Seller's specification claims
 - Conformance to regulations
- Important for harmonizing scientific and technical data from different research groups
- Essential for tracking trends in scientific and technical data
- Requires, wherever possible, an anchor point – a realization of an SI unit



Comparability vs. Traceability

- Comparability through consensus
 - Can be achieved with a quality control RM
 - Cannot be extended beyond consensus base or beyond the life of the QC RM
 - Subject to long-term drift
 - No anchor point



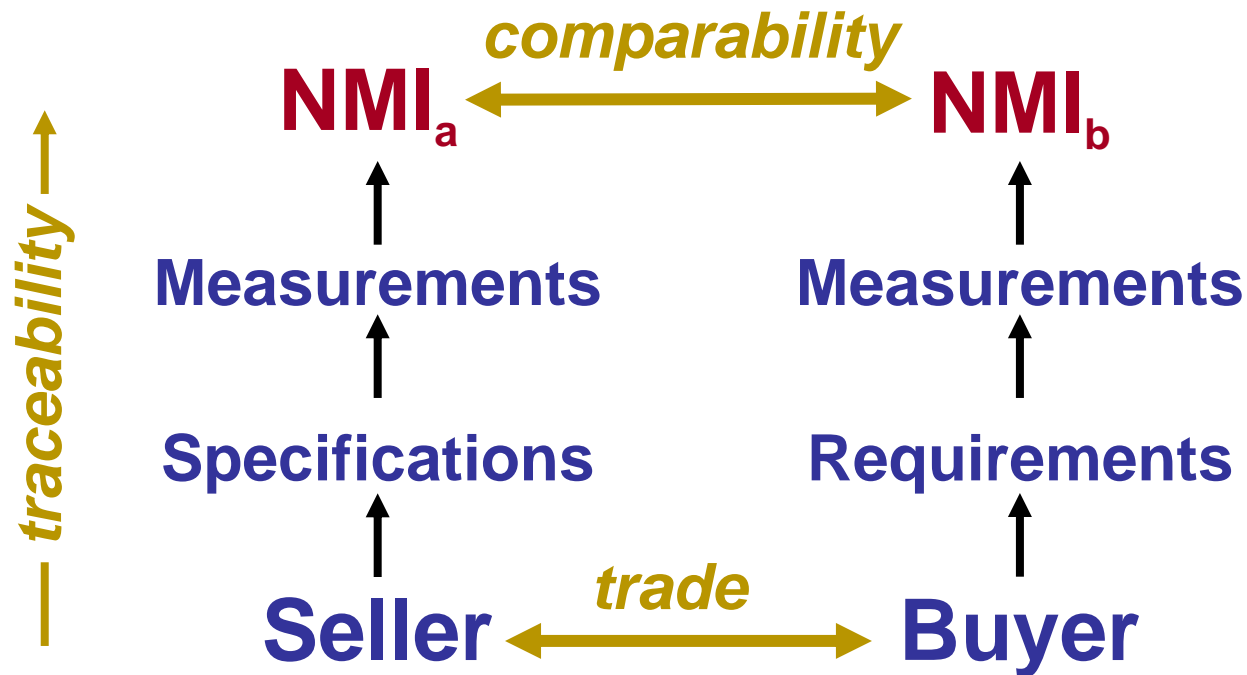
Comparability vs. Traceability

- Traceability
 - Achieved by the use of a CRM
 - Comparability based on a standard: SI Units or well-defined method-dependent unit
 - Extended beyond consensus group through realization of the SI
 - Anchored to ensure stability



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International Trade Requires Traceability *and* Comparability



NMI: National Measurement Institute

Technical Design of CRMs

- Assess specific measurement challenges to be addressed
 - Regulations
 - Stakeholder input
- Matrix, critical measurands and target uncertainties
- Measurement certification plan
- Material processing and packaging





Measurement Certification Plan

- Source of material
- Processing for homogeneity, stability, preservation of analytes
- Use principles of experimental design
 - Sampling plan
 - Measurement protocol
 - Controls
- Acceptance testing methods
- Certification methods
 - Degree of independence
 - Ability to fulfill uncertainty specifications



NIST Modes of Certification

For a CRM to be an SRM[®]

- Definitive or primary methods at NIST
 - High accuracy and precision
 - Specialized Instrumentation
 - Errors thoroughly investigated and corrected
- Two or more independent methods at NIST
 - Commercial instrumentation
 - Calibration based
 - Differing sources of systematic errors
- Collaboration with selected lab(s) and at least one NIST method
 - Multiple methods with designed independence
 - Requires execution of exact NIST protocol
 - NIST SRMs used as controls
 - Uncertainties greater than for other two modes

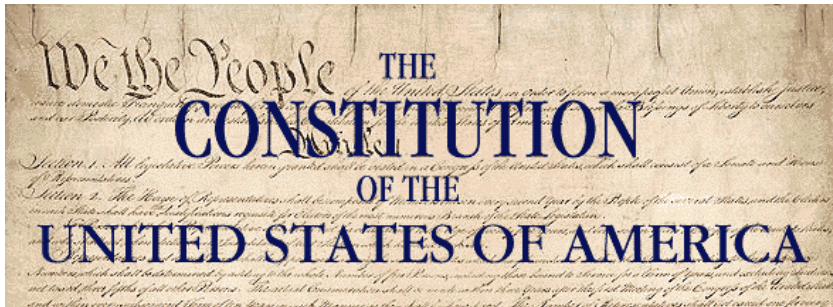


NIST Cost Recovery

- Appropriated funds
 - Measurement research
 - Establish infrastructure
 - Develop capability
- Development funds
 - Test feasibility
 - Identify candidate materials and methods
- Production funds
 - Actual execution of the certification plan including data analysis
 - These funds must be recovered in five years through sales
- It helps to be a Federal Lab

U.S. Federal Role in Metrology

The Constitution of the United States



Section 8. The Congress shall have the power ... To coin money, regulate the value thereof, and of foreign coin ... and fix the standard of weights and measures ... (1787)

“Foreign traders had begun to voice concern that goods might not be assigned a proper quantitative value at American custom-houses and that, as a result, assessed duties might be unfair and uneven from port to port.”

John Quincy Adams (1817)

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



Director Stratton.

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 assistants, to be appointed by the Secretary of the Treasury: One physicist, at an annual salary of \$3,500; one chemist, at \$3,000; two assistant physicists or chemists, at an annual salary of \$2,500; one laboratory assistant, at \$1,800; one laboratory assistant, at \$1,500; one secretary, at \$2,000; one messenger, at \$1,200.

Fulfilling the Public Trust

- NIST validates the efficacy of its investments in R&D
 - Business data related to the delivery of measurement services
 - Systematic collection of customer satisfaction data
 - Direct interaction with specific stakeholders
 - Formal economic impact studies for specific services/programs

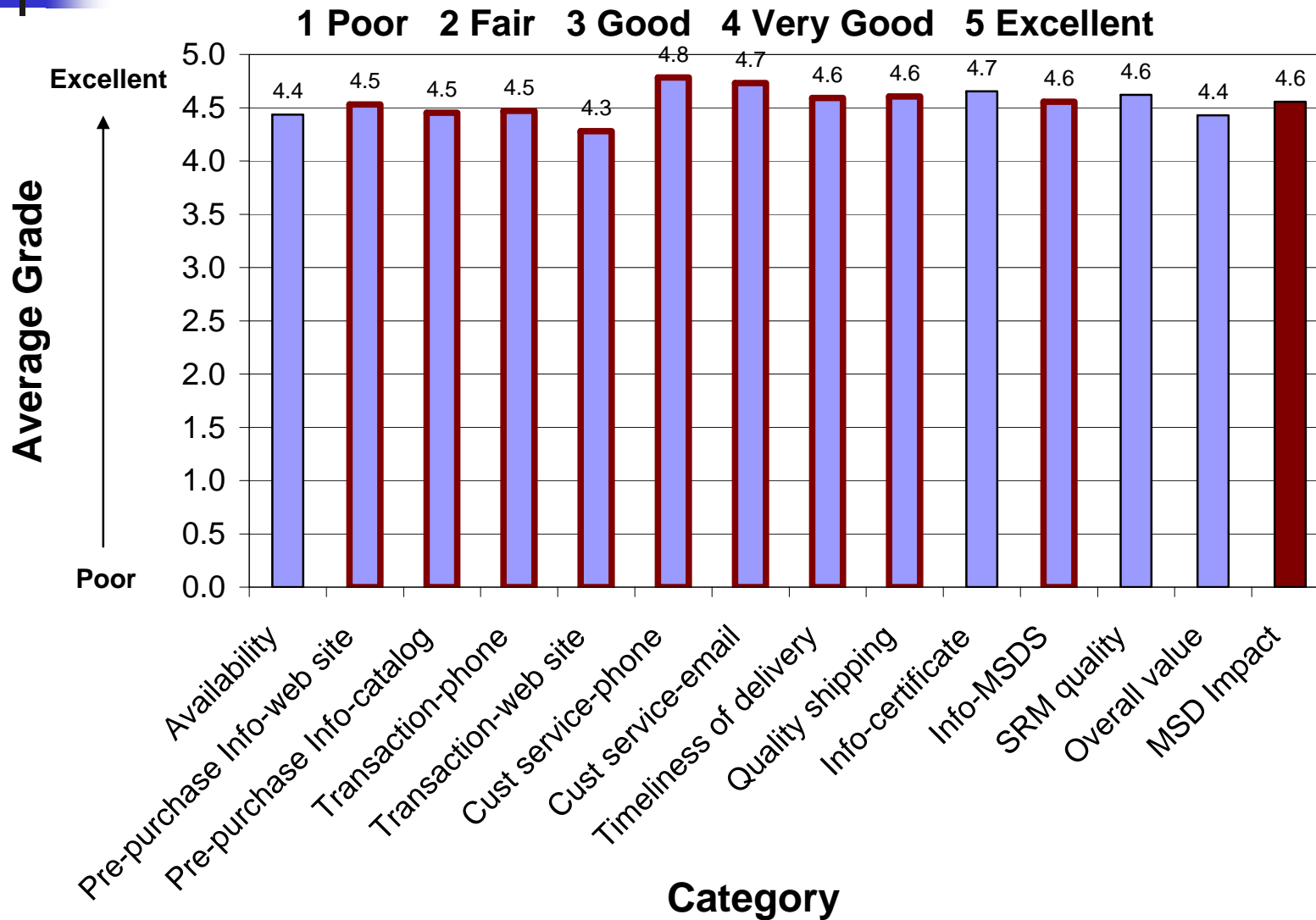


Standard Reference Materials

- 20 Divisions in 6 NIST Laboratories
- 3 major categories
 - Chemical composition, physical properties and engineering properties
- ~ 1285 products
- Approx. 33,000 units sold/year, with \$12M income



SRM Customer Satisfaction





Economic Impact Studies

- Identify customer base of the measurement service (MS)
 - Usually limited to a single level
- Survey base for the benefit derived from a NIST MS program
 - Use a counterfactual premise: What would it cost you to attain the same position without the NIST “-----”
- Establish the NIST costs to develop and deliver the specific MS
- Estimate social rate of return (SRR) and benefit-to-cost ratio (BCR)

Gas-Mixture NTRM Program

Stakeholders:

- Specialty Gas Companies
- End Users: Electric Utilities, Transportation Equipment Firms, Petrochemical Firms, Commercial Labs, Government Agencies



NTRM

Results through 2001:

Social Rate of Return	225 %
Benefit to Cost Ratio	24:1

NTRMs produced by commercial Specialty Gas Companies (SGCs)

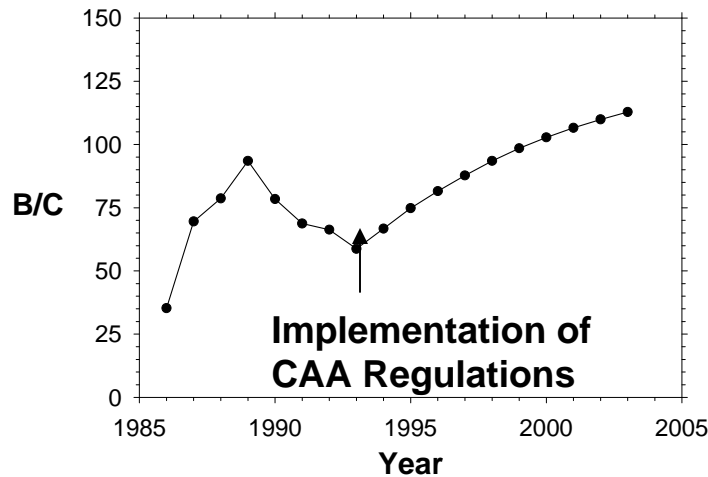
AGA
Air Liquide
Air Products
Airgas
BOC Gases
MG Industries
Praxair
Matheson TriGas
Scott Specialty Gas
Spectra Gases
Specialty Gas Products

From 1992 through 2001, **8624** NTRM cylinders have been produced by **15 SGCs**, resulting in the production of **500,000** EPA Protocol Gas Standards, valued at **\$140,000,000**. Since 2001 there have been 3887 more NTRM cylinders produced; the economic impact has not yet been assessed for these.

Sulfur in Fossil Fuel SRMs

Industries Impacted:

Transportation	Diesel, Gasoline
Energy	Coal
Steel	Coke



29 SRMs
45,673 units
2954 customers over 17 years

Benefit-Cost Ratio 113
Social Rate of Return 1,056 %

Certification of NIST SRMs for sulfur in fossil fuels uses a definitive method, developed at NIST, that virtually eliminates bias and significantly reduces the measurement uncertainty ... which translates to improved production efficiency

Cholesterol SRMs



Title: SRMs for Cholesterol Measurements

Products:

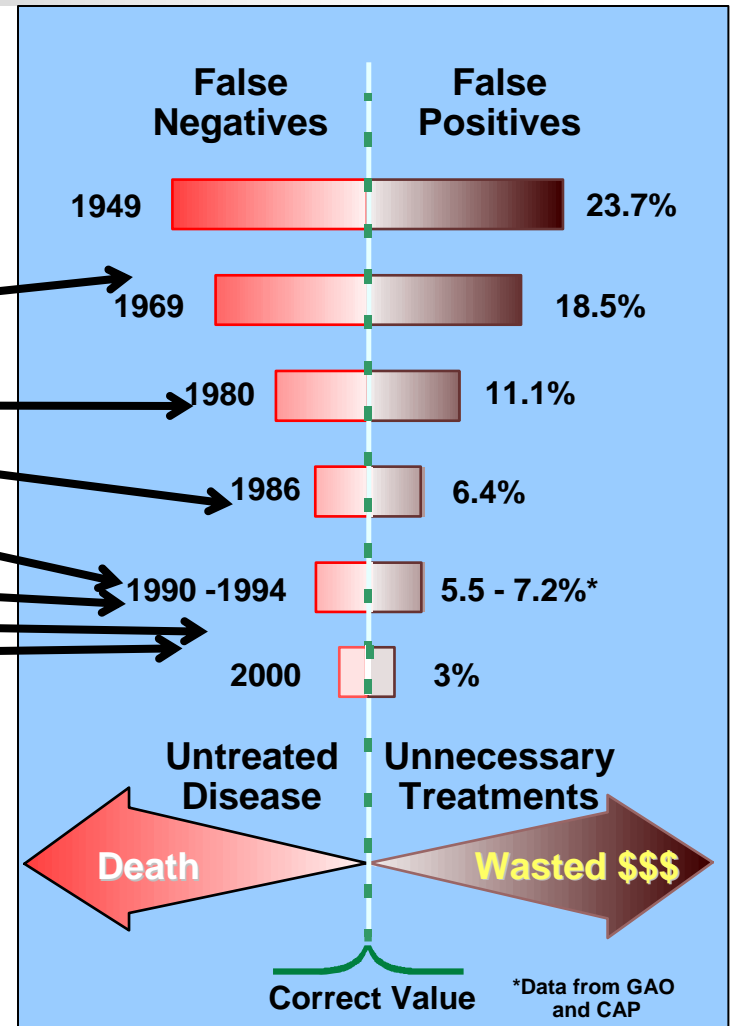
- SRM 911 Cholesterol
- SRM 909 Human Serum
- SRM 1951 Lipids in Frozen Human Serum
- SRM 1952a Cholesterol in Human Serum
- SRM 909a
- SRM 909b
- SRM 1951a

Users Impacted:

- Instrument and reagent manufacturers
- Network laboratories
- Clinical labs and hospitals

Results:

- **Social Rate of Return** **154%**
- **Benefit to Cost Ratio** **4.5:1**



Radio Pharmaceuticals

- Tens of millions of diagnostic and therapeutic x-ray procedures per year
- In 1973, there were no standards for about 75 percent of the more than 100 radionuclides then produced by industry
- Nuclear Energy Institute (NEI) and NIST (then NBS) established a Measurement Assurance Program in the early 1970s



28 SRMs

Benefit-Cost Ratio	97
Social Rate of Return	65 %

Dosage is critical: too little radiation the procedure will often have to be redone, particularly for a therapeutic procedure. If the patient receives too much radiation, injury or death could result.



NIST Formal Impact Studies

Industry:	Project	SRR	BCR
Semiconductors:	Resistivity	181%	37
	Thermal conductivity	63%	5
	Wire Bonding	140%	12
	Electromigration	117%	12
	Software for design automation	76%	23
Communications:	Electromagnetic interference	266%	
	ISDN	156%	
	Data encryption standards	267-272%	58-145
	Role-based access control, security	44%	109
Automation:	Real-time control systems	149%	
	Machine tool software error compensation	99%	118
Manufacturing:	Standards for product data exchange	32%	21
Photonics:	Optical fiber	423%	
	Spectral irradiance	145%	13
	Optical detection calibration	72%	3
	Laser & fiber optic power calibrations	43-136%	3-11

***lower transaction costs - lower compliance costs - energy conservation
increase R&D efficiency - increase product quality - enable new markets***



NIST Formal Impact Studies (Cont'd)

<i>Industry:</i>	<i>Project</i>	<i>SRR</i>	<i>BCR</i>
<i>Energy:</i>	Electric meter calibration	117%	12
<i>Computers:</i>	Software conformance	41%	
<i>Electronics:</i>	Josephson voltage standard	87%	5
<i>Materials:</i>	<i>Thermocouple calibration</i>	32%	3
	Phase equilibria for advanced ceramics	33%	10
<i>Pharmaceuticals:</i>	<i>Radiopharmaceuticals</i>	65%	97
	<i>Cholesterol</i>	154%	4.5
<i>Chemicals:</i>	<i>Alternative refrigerants</i>	433%	4
	<i>Sulfur in fossil fuel</i>	1,056%	113
	<i>Gas Mixture NTRMs</i>	225%	24
<i>Construction:</i>	Building codes	57%	
	Roofing shingles	90%	
	Fire safety evaluation systems	35%	

http://www.nist.gov/director/planning/impact_assessment.htm

Metrology: a Good Investment

Accurate and reliable measurements:

- Enable new technology
- Promote equity in trade
- Support industrial competitiveness
- Boost economic growth



and

- Enhance quality of life world-wide