

U.S. Department of Commerce

New Health Care-Related Budget Initiatives and Stimulus Spending under the American Recovery and Reinvestment Act of 2009

Michael D. Amos, Ph.D.
Biosciences Advisor
Director's Office
Chemical Science and Technology Laboratory
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899
301-975-8631
mamos@nist.gov
<http://www.cstl.nist.gov/>





COMMERCE NEWS

U.S. Department of Commerce
Washington, D.C. 20230

Office of the Secretary
www.commerce.gov

FOR IMMEDIATE RELEASE

**CONTACTS: Karen Cowles Pullen/
Areaka McFadden**

February 25, 2009

202-482-4883

Commerce Department Receives \$7.9 Billion in Recovery Act Funding Essential to U.S. Job Creation and Economic Growth

<u>National Telecommunications and Information Administration</u>	\$5.4 billion
<u>Bureau of the Census</u>	\$1 billion
<u>National Oceanic and Atmospheric Administration</u>	\$830 million
<u>National Institute of Standards and Technology</u>	\$610 million
<u>Office of Inspector General</u>	\$6 million



National Institute of Standards and Technology

Through the Recovery Act, NIST is provided a total of \$610 million, including:

\$360 million to address NIST's backlog of maintenance and renovation projects and for construction of new facilities and laboratories, including \$180 million for a competitive construction grant program for funding research science buildings outside of NIST;

\$10 million in funds is provided to help develop a comprehensive framework for a nationwide, fully interoperable smart grid for the U.S. electric power system.



National Institute of Standards and Technology

\$20 million in funds transferred from the Department of Health and Human Services for standards-related research that supports the security and interoperability of electronic medical records to reduce health care costs and improve the quality of care;

\$220 million for NIST laboratory research, measurements, and other services supporting economic growth and U.S. innovation through funding of such items as competitive **grants**; research **fellowships**; and advanced measurement **equipment and supplies**;

Spending Plan Pending

Snapshot of NIST's 2008 Investment in Healthcare

	Healthcare				Healthcare Total
	Diagnostics	Drugs/ Pharmaceuticals	Therapeutics (Non-drug)	Medical devices (non-diagnostic)	
NIST Laboratories: FY08 Total by Category	\$19,484	\$3,113	\$3,703	\$3,685	\$29,986
STRS (appropriated funds)	15,300	1,608	1,411	3,156	\$21,475
SRM Production (reimbursable)	654	0	0	0	\$654
Other Agency/ Non-Fed Govt/CRADA	2,168	1,147	1,708	313	\$5,337
Other Reimbursable	1,362	358	584	217	\$2,520
Special Invested Equipment Allocation from Initiative	0	0	0	0	\$0

Of the ~ \$15M of Congressionally appropriated funds being spent on HC Diagnostics-related activities, only ~\$5M was appropriated specifically for this purpose

2002: \$2.0 M Standards for *In vitro* Diagnostics and Tissue Engineering

2007: \$3.0 M Bioimaging

New Health Care FY09 Budget Initiative

FY 2009 Omnibus Appropriations Bill

\$27M for new NIST laboratory programs

\$3 Million - Standards to Support Current Generation Diagnostic Measurements
(Total \$18.3M spending on health care diagnostics out of \$819M total NIST appropriation)

Will improve health care quality and lower costs through:

Improved reliability of laboratory medicine testing, resulting in:

- Increased accuracy of laboratory testing
- Greater comparability over time and space
- Fewer misdiagnosis and unnecessary repeated tests

More “truth in and from” medical imaging data, resulting in:

- More accurate monitoring of disease progression and therapeutic response
- Earlier detection of disease facilitating more effective treatment decisions
- Improved reliability and accuracy of clinical trial data

Increased quality of the information that goes into the EHR, resulting in:

- Fewer medical errors
- Increased efficiency in healthcare delivery to mobile patients
- Greater confidence for patients and healthcare providers in the information used to make medical decisions



Laboratory Medicine: FY09 Program Plan

Develop the measurement science base to underpin the provision of “Higher Order” Reference Measurement Procedures, Standard Reference Materials, and Measurement Quality Assurance Programs to provide SI-traceability for Genetic Testing and measurement of blood protein health status markers.

Categories of Analytes for Diagnostics and Therapeutic Monitoring

Drugs of Abuse

Electrolytes

Metabolites/Substrates

Non-electrolyte Metals

Non-Peptide Hormones

Vitamins

Covered by current NIST base program

Nucleic Acids

Proteins

To be addressed with NIST FY09 investments

Blood Coagulation Factors

Blood Group Substances

Enzymes

Being addressed by other NMIs or DIs

JOINT Committee on Traceability in Laboratory Medicine

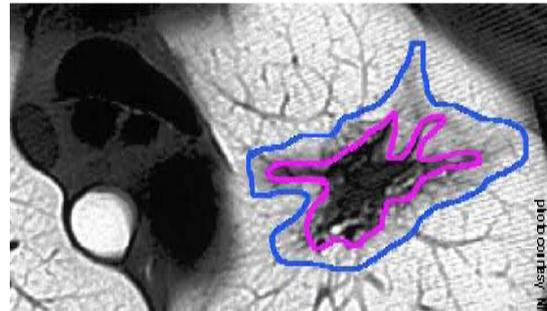


Medical Imaging: FY09 Program Plan

Quantitative Macroscopic Medical Imaging

New standards, methods and measurement quality assurance processes to enable traceable, quantitative imaging that both ensures the direct comparison of images across instruments and over time, and provides a means for ensuring instrument stability and reliability for:

- Magnetic Resonance Imaging (MRI)
- Positron Emission Tomography (PET)
- Computerized Tomography (CT)
- Medical optical imaging



U.S. Department of Commerce

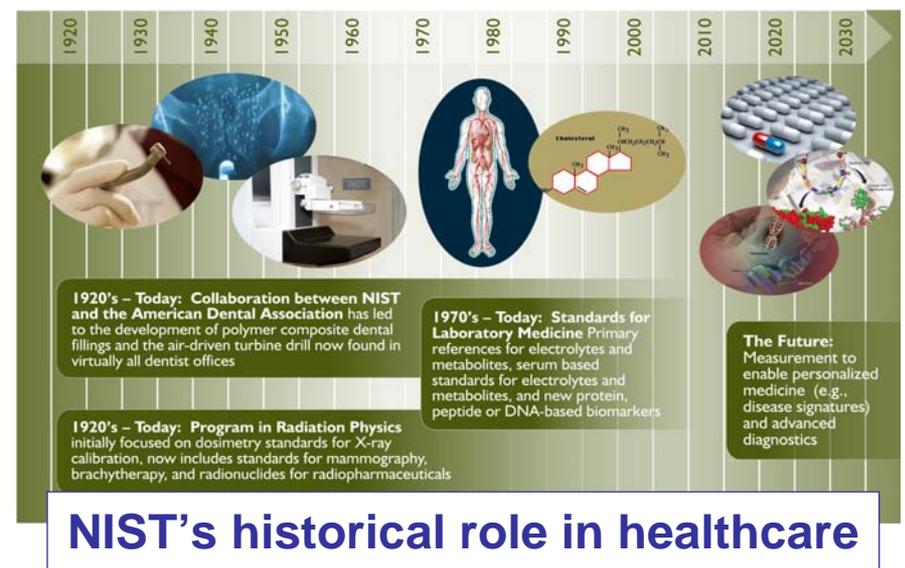
New Health Care-Related Budget Initiatives and Stimulus Spending under the American Recovery and Reinvestment Act of 2009

Michael D. Amos, Ph.D.
Biosciences Advisor
Director's Office
Chemical Science and Technology Laboratory
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899
301-975-8631
mamos@nist.gov
<http://www.cstl.nist.gov/>



Why NIST?

It is congruent with the NIST mission - and indeed our mandate - to address the measurement and standards barriers affecting the cost and quality of healthcare delivery



Why should NIST Increase Investments in Healthcare?

The nation is preparing to invest billions of dollars to computerize medical health records. Without a concurrent investment to improve the quality of the data, it is unlikely that simply computerizing the health records will have the desired impact on healthcare cost and quality

- Patients and doctors assume that test results are accurate, comparable over space and time, and interpreted in a reliable and consistent manner - **but this is not true**
- Patients and doctors are mobile; therefore, results must be transferable between institutions - **but measurement procedures give different results and reference ranges do not always take this into account**
- Effective use of the electronic health records to reduce HC costs will require long term comparability of results over the lifetime of the patient - **genotypic and phenotypic data entered into the electronic records and used to make medical decisions must be accurate and comparable over both space and time.**



What is the Problem?

The lack of a robust biomedical measurement standards infrastructure limits the quality of healthcare services and contributes to increased healthcare costs.

It is a stated goal of the new Obama Administration to improve the quality of our health care while lowering its cost by computerizing all Americans' medical records. ... "this will cut waste, eliminate red tape, and reduce the need to repeat expensive medical tests it will save lives by reducing the deadly but preventable medical errors that pervade our health care system".

- ✓ U.S. annual healthcare spending is reaching unsustainable levels (~\$2 Trillion) and is expected to consume 25% of GDP by 2015
- ✓ Lack of appropriate measurement tools and standards:
 - has resulted in fewer new drugs and diagnostics reaching the market place
 - has led to increased adverse drug events
 - has contributed to misdiagnosis and repeat diagnostic testing
 - will limit the positive impacts of the New Administration's healthcare goals

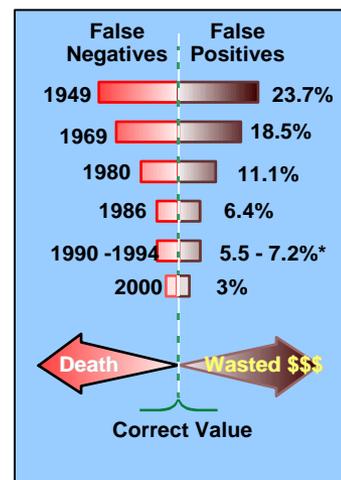
Major Healthcare Measurement Challenges:

- Laboratory medicine technology suffers from a lack of attention to standards – test results are neither accurate nor comparable over space and time
- Medical imaging software and standards are not adequate to enable physicians to extract quantitative data for determining medically relevant changes in tumor size or determine success of a drug in a clinical
- In drug development, a lack of measurement and modeling tools has resulted in poor predictive toxicology for many new drug candidates and resulted in costly recalls and mortality and morbidity
- Measurement infrastructure does not currently exist to support the innovation and effective utilization of the new measurement technologies necessary to facilitate the advent of personalized, predictive and preventative medicine



Significance of the Problem

- ~ 70% of health care decisions are based on clinical laboratory test results
 - Yet, standards exist for only 10% of the 700 routinely performed tests
- 60 million CT tests performed annually to measure changes in lesions are limited by ability to discern only large changes in size/metabolism
 - This is a direct consequence to lack of standards to monitor equipment performance
- The incidence of manufacturer-reported serious adverse drug events has increased 16-fold since 1990
 - The FDA's Critical Path Opportunities List calls out the need for enhanced evaluation tools and standards to support drug development



Improved accuracy in cholesterol measurements is estimated to save \$100M/yr in treatment costs

Data from U.S. Government Accounting Office and College of American Pathologists

Stakeholders have asked for our help!

NIST has conducted outreach to industry, academic and governmental stakeholders. We have identified more than 200 unmet or under-met measurement needs. Common themes were:

- *measurement standards for individual clinical biomarkers*
- *standards to support medical imaging platforms*
- *standards to support high throughput multiplex measurements*
- *standards to assure the integrity and quality of clinical samples*
- *robust and interoperable biocomputing tools*

