Meeting of NIST Visiting Committee on Advanced Technology
Theme: NIST's Roles in Innovation and NIST's Strategic Plan
Session III: NIST's Strategic Plan

"Update on Biosciences Strategic Planning Activities"

October 29, 2008

Key Questions for VCAT

- Are we addressing the right technology sectors, societal needs, and NIST needs?
- Is NIST missing other opportunities?
- Is NIST using the right metrics to evaluate program performance?
- Are there other metrics that NIST should use?

Outline

- Update on Strategic Planning Process
- Preliminary Findings of Meeting
- Path Forward

June 10, 2008 *Briefing to VCAT*
"Strategic Planning for Biosciences at NIST and the Role of the October 2008 Biosciences Conference"

At last meeting -

Outline for Briefing

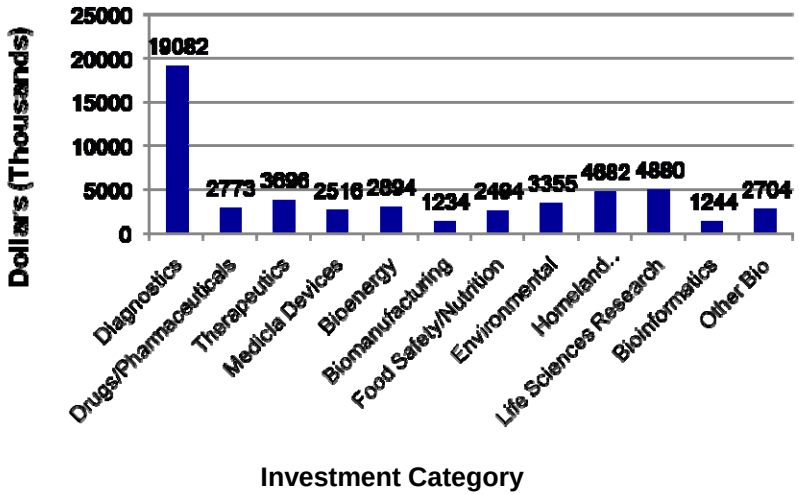
- **NIST's Growing Role in the Biosciences**
- **Current Portfolio of Activities in Bioscience and Health and Need for More Effective NIST-wide Planning**
- **Short Term Plans for Biosciences Program Growth**
  - FY07 Budget Increase
  - FY09 Request
  - Future Plans
- **Developing a Strategic Plan for Longer-Term Biosciences Program Growth**
  - Current and Near-term Activities
  - October 2008 Conference
  - Outline for Strategic Plan
  - Vetting Draft Plan with Stakeholder Community

Need for Strategic Plan for NIST Bioscience Activities

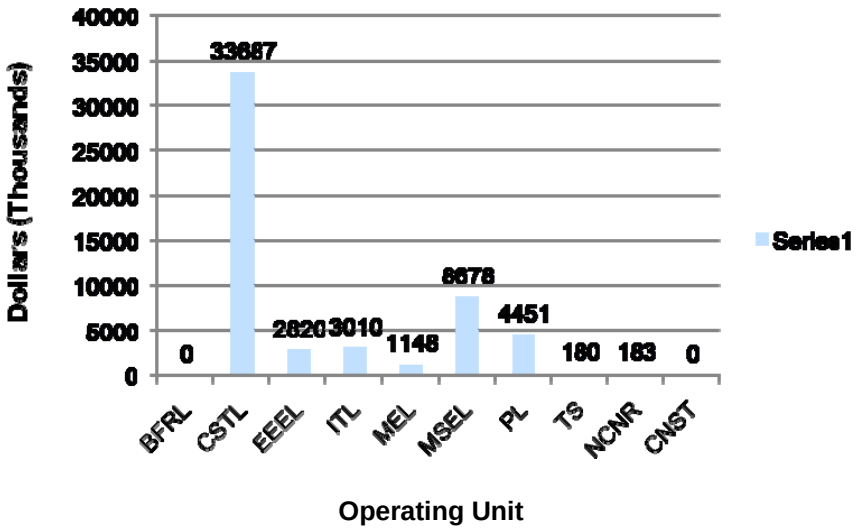
- Biology and biotechnology-based applications are having a growing impact on multiple sectors of the (energy, national security, the environment, manufacturing, food and nutrition and healthcare, etc.)
- Current NIST programs (totaling $54.2 million in FY08) are not enough to address the growing number of measurement needs.
- Current programs are spread across NIST, and are not fully coordinated leading to gaps in coverage of need and some duplication of effort.
  - Bulk of current NIST programs focused on Healthcare specifically measurements and standards supporting diagnostics (including imaging), drug and therapeutic development, and medical devices
- The development of a NIST level Strategic Plan for NIST's growth is needed to:
  - Ensure existing resources are optimally targeted
  - Provide a basis for coordinated expansion of bio-related programs
  - Identify opportunities for partnerships and expanded outreach
- This strategic planning process was initiated in 2007 as a top-level, NIST-wide effort with input solicited from both external and internal sources.

Breakout of Current NIST Bioprograms

By Research Focus



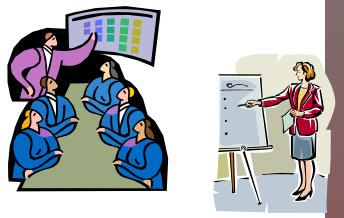
By OU



NIST Biosciences Strategic Plan Development Process

Current Activities

- Summarized relevant input from past needs assessments
- Updated inventory of current NIST activities in the biosciences – currently quality assuring
- Convened **October 2008 Conference** to identify measurement, standards, and technological needs to inform and guide research and biosciences program growth at NIST
- Summarizing needs identified during just concluded **October 2008** Conference



Planned Activities

- Perform gap analysis
- Develop implementation plan with timelines for addressing identified gaps
- Develop and implement longer-term plan for continuing to assess and validate needs

NIST Strategic Plan for Biosciences Program Growth

Past Outreach and Assessment Of Needs

- Over the past 5 years NIST has participated in or hosted a number of conferences and workshops to identify measurement and standards needs. Examples include:
  - **"Development of Biologic Drugs: Scientific Issues in Assessing the Similarity of Follow-on Protein Products",** Conference cosponsored by FDA, NIST, and the New York Academy of Science, December 12-14, 2005, Brooklyn, NY.
  - **National Biofuels Action Plan Workshop,** November 28-29, 2006 Washington, DC
  - **Strategy for Health Care through Bio and Information Standards and Technologies,** Conference held September 24-25, 2007
  - **Council on Ionizing Radiation Measurements and Standards (CIRMS) meeting,** October 22 – 24, 2007, Brachytherapy Subcommittee of the AAPM meeting, July 27, 2008
  - **NIST/NOAA Aquaculture Workshop**: **Overcoming Technical Barriers to the Development of Competitive Marine Aquaculture in the United States**, February 12-13, 2008, Orlando, FL
- The USMS identified need for better biological measurements in 9 of the 11 sectors. Examples of key areas of need include clinical diagnostics (medical imaging and laboratory medicine), biocompatibility of nanomaterials in the body, biological threat detection and biosurveillance
- Many of the needs identified were near term in focus and targeted at the interest of specific groups at NIST.
- Wanted to conduct a forward looking external assessment of measurement needs across a broad spectrum of bioscience applications

International Conference: October 20-22, 2008

"Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges"

Objective:

- **To identify and prioritize measurement, standards and technology barriers to realization of optimal economic and broad societal benefit from new discoveries in the following focus areas:**

– Medicine	→	improving health through measurement of complex biological signatures
– Energy	→	obtaining sustainable energy from biological sources
– Manufacturing	→	obtaining higher quality products through better bioprocess measurements
– Agriculture	→	increasing yield, quality, & safety in the world's food supply
– Environment	→	understanding our planet through linking molecules to ecosystems

Expected Outcome:

A listing of measurement, standards, and technology needs to inform and guide research at NIST and the measurement and standards community worldwide

Format:

- **Plenary Symposium with lectures from visionary bioscience thought-leaders discussing future trends and measurement, standards and technology needs in the Conference focus areas**
- **Workshop to identify & prioritize measurement and standards challenges impeding innovation in the five focus areas plus a parallel "Hot Topics" session to capture broader needs within the biosciences**

Participants:

- **National and international experts from industry, academia, and government focused on the broad spectrum of measurement and standards needs in the biosciences**

Output of Technical Breakout Sessions

AGRICULTURE: ***Increasing yield, quality, and safety in the world's food supply***

15 Panelists (3 Academic, 3 Industry, 8 Government, 1 International)

Critical Barriers

- Need improved methods for Sampling
- Lack of adequate analytical technologies
  - –Multiplex platforms
- Lack of real-time measurements
- Need improved bioinformatics tools and infrastructure

ENERGY: ***Obtaining sustainable energy from biological sources***

16 Panelists (2 Academic, 6 industry, 7 Government, 1 International)

Critical Barriers

- Need improved analytical measurement techniques
  - –Field ready
- Better Thermochemical, and thermophysical data
- Performance standards
- Standards to document environmental impact (GHG emissions, sustainability, etc.)

ENVIRONMENT: ***Understanding our planet through linking molecules to ecosystems***

17 Panelists (2 Academic, 1 Industry, 11 Government, 3 International)

Critical Barriers

- Lack of systems interoperability
- Lack of appropriate diagnostics
  - –Sampling and processing, and systems level measurements
- Lack of common definitions

Output of Technical Breakout Sessions

MANUFACTURING: ***Obtaining higher quality products through better bioprocess measurements***

17 Panelists (2 Academic, 10 Industry, 5 Government)

Critical Barriers

- Improved Process/Platform Measurements for Cell-based manufacturing
  - –Genotypic drift
  - –Glycosylation
  - –In line measurements (pH, O2, etc.)
  - –Systems biology-based predictive tools
- Improved tools and standards for characterization of raw materials
- Improved tools and processes for product quality measurements
  - –Assessing potency, purification generated modifications, etc.

MEDICINE ***> > > Improving health through measurement of complex biological signatures***

24 Panelists (9 Academic, 11 Industry, 4 Government)

Critical Barriers

- Dynamic Measures over time
- Improved methods and procedures for sample processing, storage, and handling
- High throughput multiplex measurement systems
- Standardization across diagnostic platforms and systems

"Hot Topics" Session

Addressing Unrecognized, Overlooked, Underestimated and Ignored Measurement Needs in:

- Stem Cell Therapies
- Bioremediation
- Emerging Microbiological Threats
- Gene Therapy
- Antibiotic and Antiviral Drug Resistance
- Transgenic Plants and Animals as Biopharmaceutical Sources
- Synthetic Biology
- Marine vs Terrestrial Bioenergy

Biomedical Topics

- Keith Yamamoto – University of California San Francisco and NAS
- Kathy Hudson – John Hopkins University
- Ann Reid – National Academy of Science
- Renee Reijo-Pera – Stanford University School of Medicine

Non-Medical Topics

- Gregory Petsko – Brandeis University
- George Pierce – Georgia State University
- Feng Chen – UMBI, Center of Marine Biotechnology
- Robert Wall – U.S. Department of Agriculture
- Joseph Spence – U.S. Department of Agriculture

Crosscutting Needs

- Better methodologies and practices for sample handling
- More robust protein measurements
- High throughput multiplexed measurements
- Improved tools and standards for bioinformatics
  - Data collection, analysis, modeling, archiving, etc.
- Improved tools and methods to ensure confidence in data and enable comparability across multiple platforms
  - Whether medical imaging, clinical assays, environmental sensors, etc.

Needs Identified by the Conference Provide Validation for Current NIST Plans Biosciences Program

- FY07 Budget Increase — Calibration and IT standards for MRI, CT, PET and cellular imaging
- FY09 Budget Request — Technology and standards for individual and multiplex measurements of biochemical health status markers
- Under Discussion — Support for development of advanced tools for visualization of structural and biochemical changes associated with disease

	FY07 + $3M	FY09 + $10M	Under Discussion
Medical Imaging	➢ Standards for MRI contrast agents ➢ Phantoms for PET/CT		➢ Standards tools to enable enhanced image analysis, data comparison and feature extraction
Cellular and Biomolecular Measurements	➢ Standards and techniques to enable quantitative fluorescence microscopy and cellular imaging.	➢ Quantifiable measurements of individual biomolecules and biomarkers ➢ Development of multiplexed measurement platforms	➢ Technologies and standards for quantitative protein measurements, ➢ structure function analysis, ➢ manufacturing and process monitoring
Computational Tools	➢ Software validation for image analysis and extraction	➢ Uncertainty analysis ➢ Collection and exchange of data ➢ Validation of modeling tools	

Key Conference Outcomes and Opportunities

- Generated input on key measurement and standards challenges
  - Important to follow up further flesh out with the relevant industry sectors
  - Need to assess how NIST can best use existing resources and target new resources to have the most impact
- Provided an opportunity to introduce a broad section of the biosciences community to NIST
  - Many were unaware of or had a limited view of the role of NIST
  - Need to follow up and continue to build trust and recognition of NIST in the biosciences community
  - To address challenges effectively we need to identify opportunities for partnerships
- Provides the opportunity to educate policy makers on the importance and magnitude of the measurements and standards challenges facing the biosciences community
- Will serve as the cornerstone of an international effort to address the measurements and standards needs of the biosciences community
  - Significant international attendence – NMI leadership from: Australia, Canada, Brazil, EC, UK, Netherlands, Japan, China, Korea, and Germany, and the executive secretary of CIPM

Timeline for Post-Conference Activities

- Complete Executive Summary — **December 08**
- Complete first draft of Strategic Plan and share draft with stakeholders — **January 09**
- Complete draft Conference Report — **January 09**
- Complete final Conference Report — **April 09**
- Commence meetings with bioscience industry leaders and OA stakeholders to discuss: — **March-August 09**
  - current NIST activities in the biosciences
  - draft plan for NIST biosciences program growth
  - measurement and standards needs not being addressed
  - Opportunities for partnership

- Complete Strategic Plan version.1 — **October 09**

Key Questions

- Are we addressing the right technology sectors, societal needs, and NIST needs?
- Is NIST missing other opportunities?
- Is NIST using the right metrics to evaluate program performance?
- Are there other metrics that NIST should use?