

Strengthening NIST's Standard Reference Materials Program

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Overview of NIST SRM Program

20 Divisions in 3 NIST
Laboratories

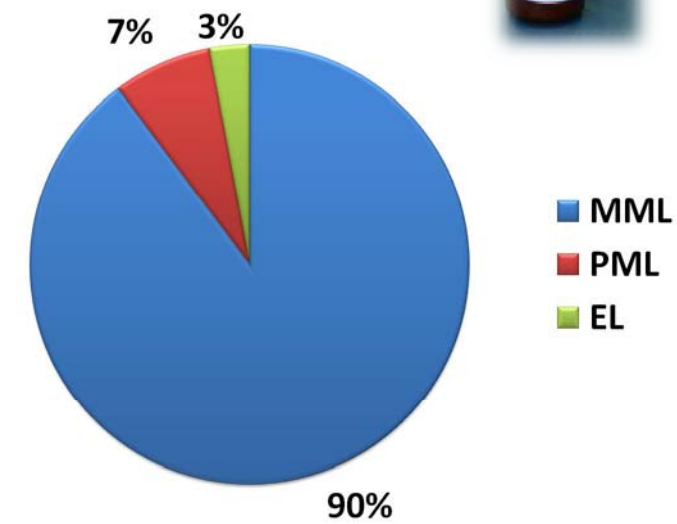
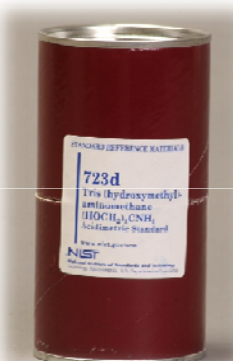
3 major categories

- Chemical composition, physical properties and engineering properties

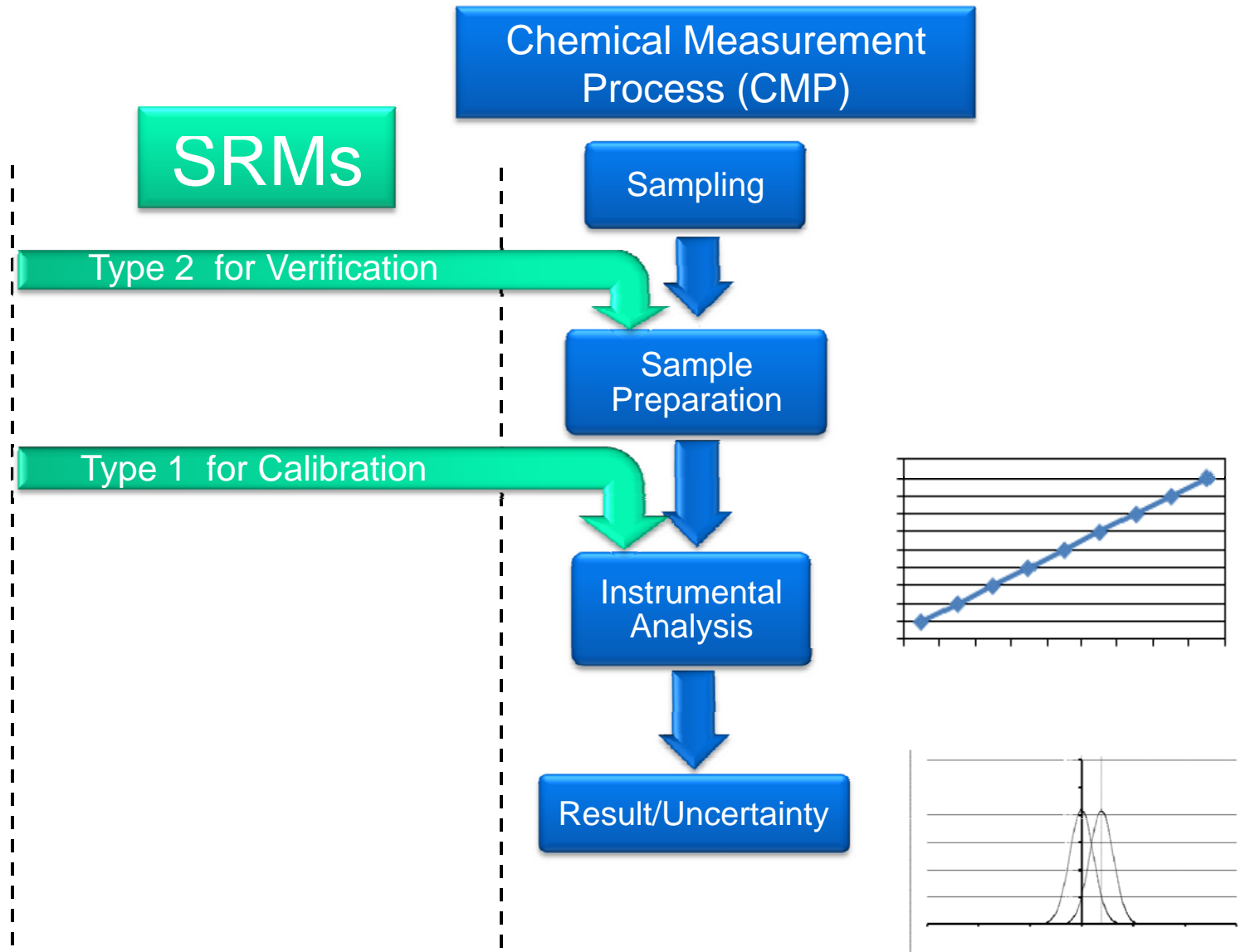
~ 1300 products

~ 32,000 units sold/year

\$12.6 M cost recovery income



How are SRMs Used?

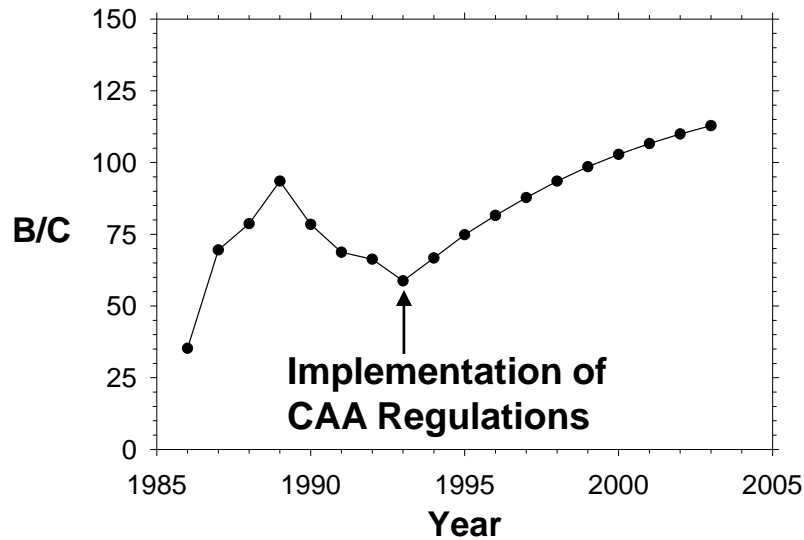


Importance of NIST SRMs

Sulfur in Fossil Fuels

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

Current Status of the Program

Some on-target examples of planning and program implementation

- Assessment of national priorities, measurement accuracy needs
- Convening important stakeholders
- Considering “Why NIST?” and “Why SRMs?”
- Success measured by stakeholder response, market acceptance (sales), economic impact
- Service delivery quality measured NIST-wide

With the exception of service delivery, the approach is uneven across the institute

- Driven locally with little or no coordination at the NIST level
- Driven by potential size of market
- No assessment of relative importance of major national initiatives

On-Target Example 1



National Priority – Clean Air Act

- NIST consults with EPA and the California Air Resources Board to define needs for accurate emissions testing and fuel quality
- NIST SRM response
 - Expansion of the primary gas SRM program
 - NIST Traceable Reference Materials (NTRMs)
 - Sulfur and lead in fuels
- Performance measured by economic impact

Gas-Mixture NTRM Program

Driver:

- Clean Air Act amendment created pollution credits program, which required the use of NIST-traceable reference materials

NIST status:

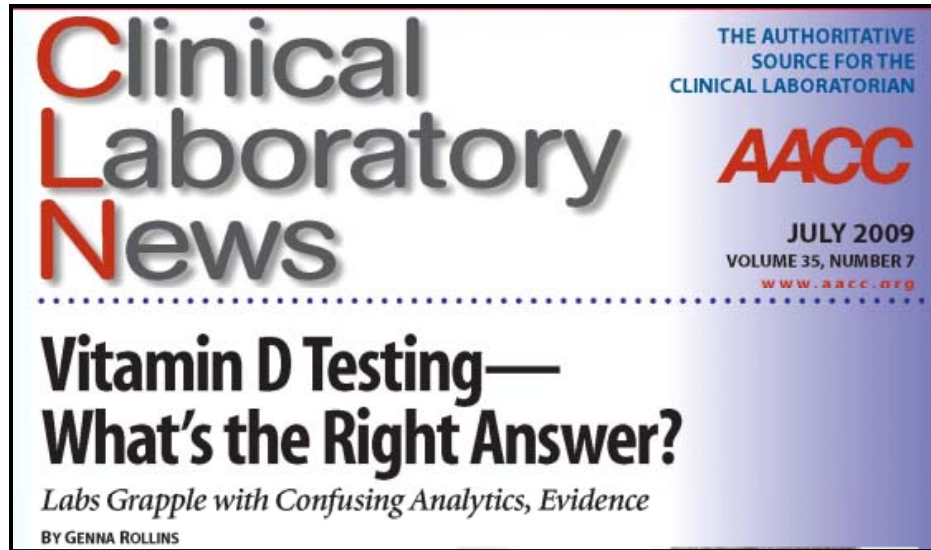
- Over 80 gas SRMs - take 1.5 to 2 years to develop each batch

NIST Response:

- NIST develops partnership with the specialty gas companies to link high-production lots of commercial gas mixtures to NIST primary standards
- In the first nine years of the program, 8624 NTRM cylinders were produced by 15 SGCs, resulting in the production of 500,000 EPA Protocol Gas Standards, valued at \$140,000,000
- Economic benefit-to-cost ratio measured in 2001 at 24:1



On-Target Example 2



Adults still risk vitamin D deficiency

The New York Times

Quest Acknowledges Errors in Vitamin D Tests

The Washington Post

Millions of Children In U.S. Found to Be Lacking Vitamin D
Links to Diabetes, Heart Disease Examined



Vitamin D May Cut Cancer Risk

Researchers Say "Sunlight" Nutrient Cuts Risk Significantly; Skeptics Remain

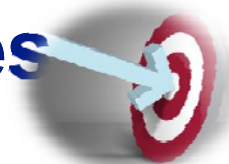
SRM 972 Vitamin D in Human Serum

National Priority – Healthcare

- New focus on the importance of vitamin D, but pervasive errors and variability in results from commercial diagnostic test kits
- National Institutes of Health Office of Dietary Supplements turns to NIST to resolve the problems
- NIST response
 - Development of an LC-MS method to fully resolve vitamin D metabolites that confound currently used diagnostic test kits
 - Production of a multi-level vitamin D metabolite SRM
- Performance measured by market acceptance
 - Nearly 1000 units sold since July 2009
 - QUEST Diagnostics has purchased over 50 % of the units



Research and Measurement Services



Development of "C30 Carotenoid Column"

Publications (15)

Technology transfer to private sector

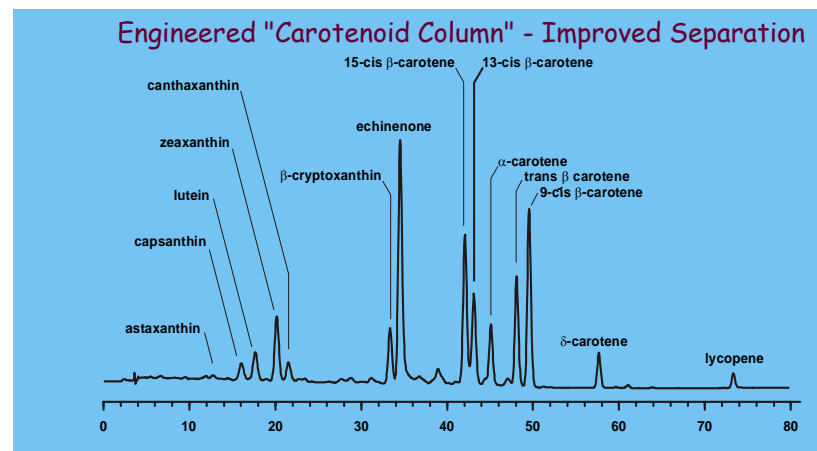
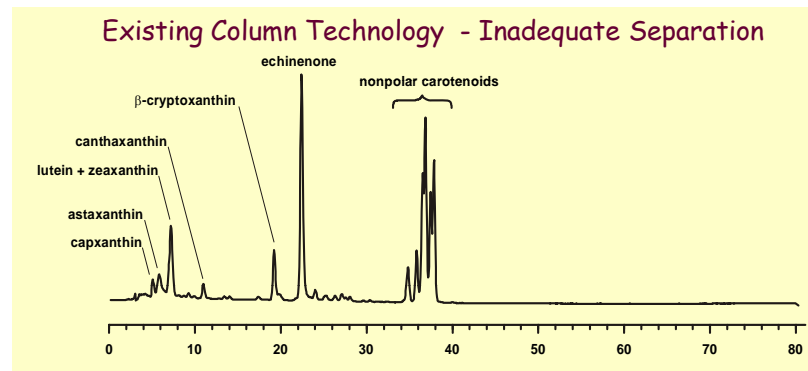
- 6-8 companies using NIST technology

Used for certification of carotenoids – deemed to be a beneficial dietary component:

- SRM 1849 Infant Adult Nutritional Formula
- SRM 2385 Slurried Spinach
- SRM 3250 Serenoa repens (Fruit)
- SRM 3251 Serenoa repens Extract
- SRM 3276 Carrot Extract in Oil
- SRM 3278 Tocopherols in Edible Oils
- SRM 3280 Multivitamin/Multielement Tablets

Used for certification of brominated flame retardants, hexabromocyclododecanes (HBCDs) – finding their way into the environment:

- SRM 1941b Organics in Marine Sediment
- SRM 1944 New York New Jersey Waterway Sediment
- SRM 1945 Organics in Whale Blubber
- SRM 1946 Lake Superior Fish Tissue
- SRM 1947 Lake Michigan Fish Tissue
- SRM 1974b Organics in Mussel Tissue (*Mytilus edulis*)
- SRM 2585 Organic Contaminants in House Dust



L. C. Sander, K. E. Sharpless, N. E. Craft, and S. A. Wise. *Anal. Chem.* 66:1667-1674, 1994.

Service Delivery



Comprehensive Dashboard of Measures

- Standard process flows with data-driven performance measure sensor points
 - Sales accuracy
 - One-day shipping
 - Return rates
- Measures of customer satisfaction
 - Transactional survey cards and web application

SRM One-Day Shipping

One Day Shipping for SRM Sales

↑ Better

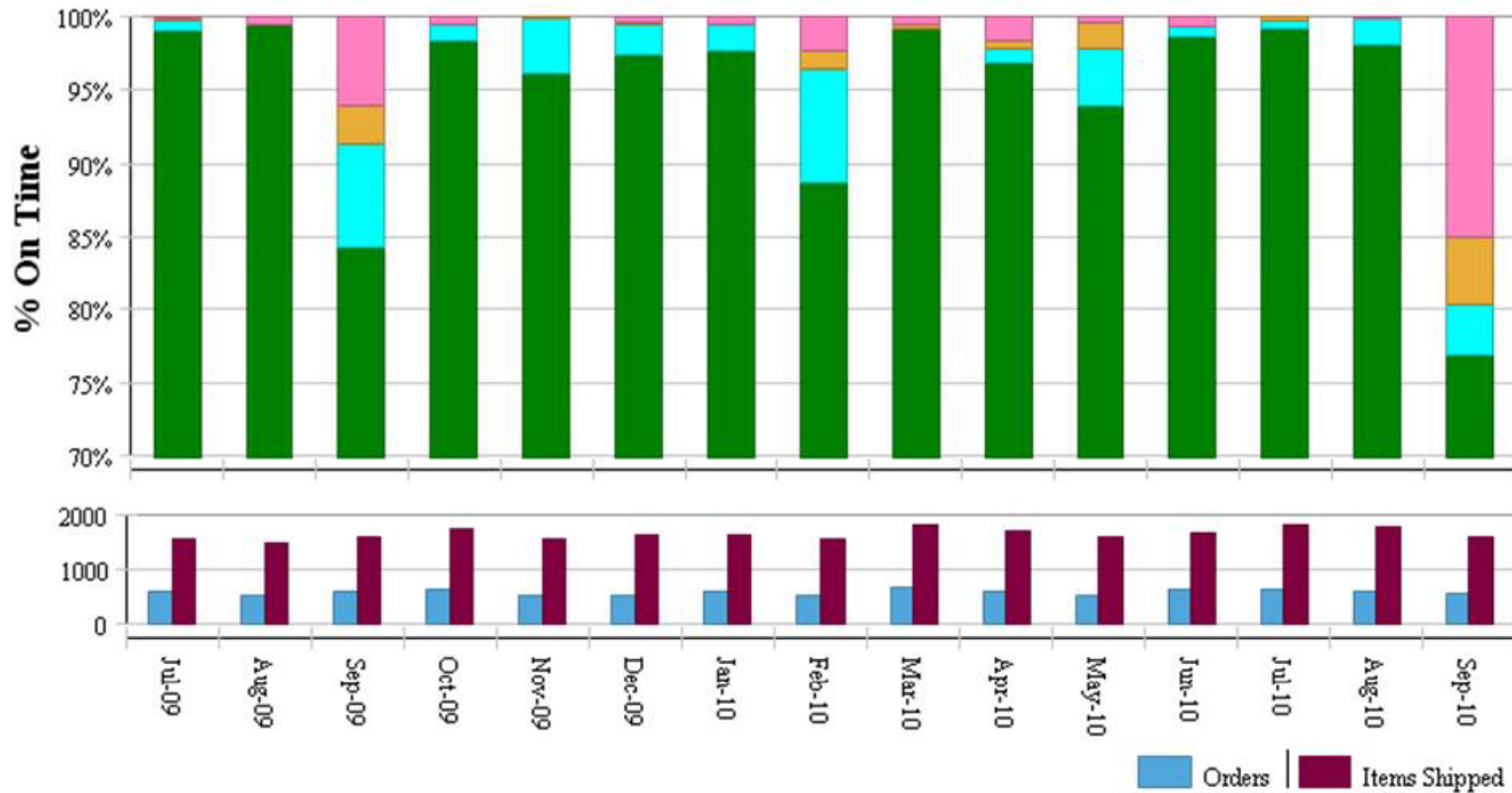
Process: [SRM Order Process](#)

Start: B

Created On: Oct 12, 2010

End: C

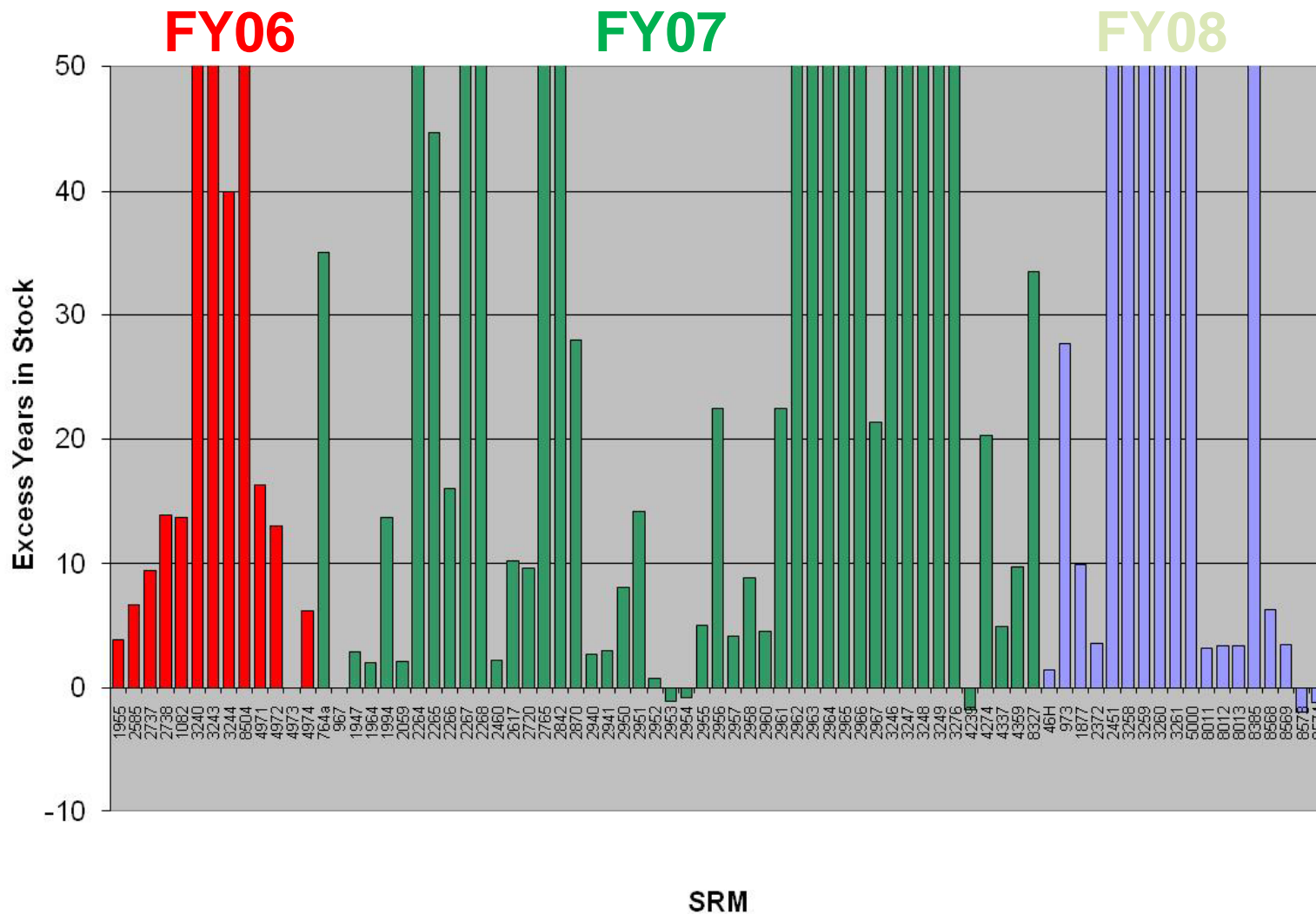
■ Never Shipped |
 ■ > 3 Days |
 ■ <= 3 Day |
 ■ <= 2 Day |
 ■ <= 1 Day



Missing the Mark



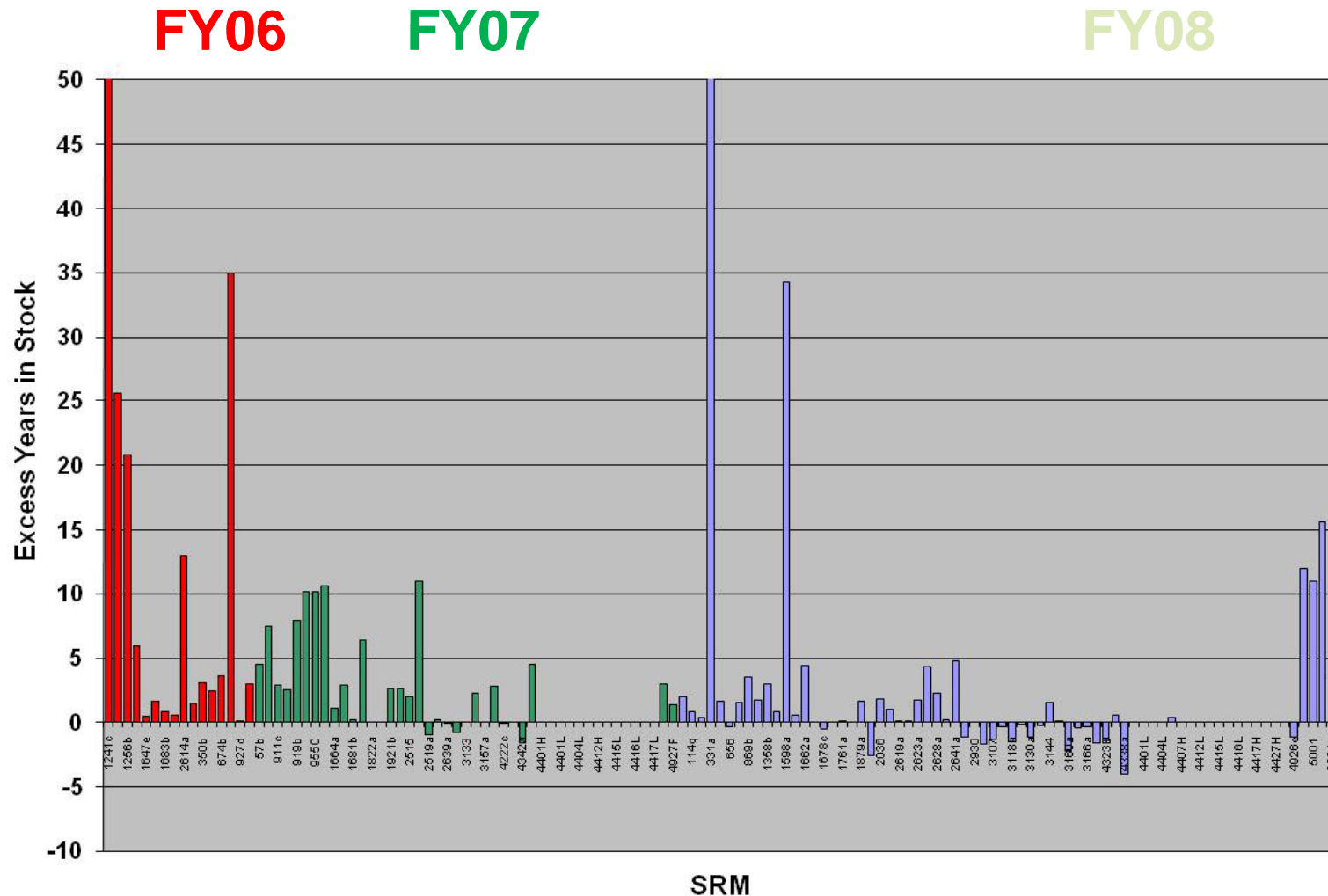
Excess stock for new SRMs introduced in:



Missing the Mark



Excess stock for renewal SRMs introduced in:



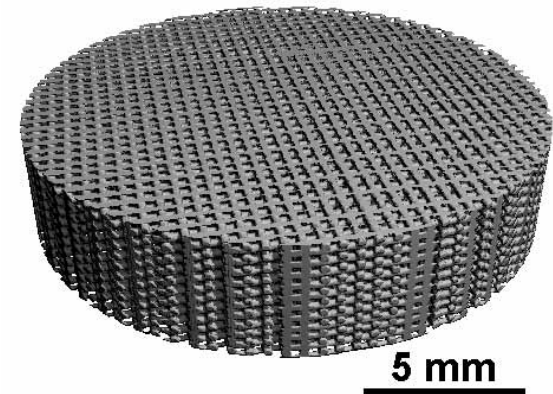
Missing the Mark



Cellular Response to 3D Tissue Scaffolds

National Priority – Healthcare

- **Good stakeholder input**
 - ASTM F04.42 Biomaterials and Biomolecules for Tissue Engineering Medical Products
- **Solid research foundation connected to measurement service delivery**
 - Combinatorial methods to detect cellular response to 2D substrates for extension to 3D models
- **High-quality reference material produced**
 - RM 8395, 8396, 8397 varying in strut diameter, spacing and porosity
 - **Not one has sold since they were put into inventory April 2009**
 - Missed price point - \$547 each



Ideas for how will things improve post-realignment

Adoption of a NIST-wide SRM Planning Process

- Consistent consideration for priority input sources:
 - Administration's S&T priorities
 - Legislative mandates (national and international)
 - Other Federal Agency needs to support regulations
 - Customer sector workshops/groups
 - Standards Committees (e.g., ASTM)
 - Professional Organizations/societies (e.g., AOAC, GMA)
- Use of stakeholder forums and workshops to define needs and refine NIST's possible role

Example of Stakeholder Input

Formal communication from the Association for Molecular Pathology

- Consideration of four areas in need of reference standards
 - Example 1: Targeted therapeutics and tumor markers
 - Example 2: Companion diagnostic tests
 - Example 3: Transplant follow-up care and quantitative standards
 - Example 4: Reference gene sequence database
- Calls upon NIST to develop 21 SRM types, identifying immediate, near term (1 year), and long-term (1-3 years) priorities

Planning Process (continued)

Stakeholder input to include performance measures

- Needs assessment and NIST's role to meet the needs must include measures of success
 - Measurement improvement outcomes
 - Sales

Consistent evaluation of "Why NIST?"

- Within the scope of its mission
- Taking advantage of its core competencies

Consistent evaluation of "Why SRM?"

- Development time, cost could indicate that other measurement service solutions could be better to meet the need

Documentation of both technical and business cases in SRM project submission

Measurement service perpetuation plan

Cost, Resources, and Performance

Improvements in program flexibility

- Meeting the needs of stakeholders is market-driven
 - Service scope and price need to match the need and NIST's position among NMIs
 - Service costs borne by fees and appropriated funds

Resources

- Do we have the right mix of personnel?

Performance evaluation

- Hybrid science and service quality assessments
 - NRC panels for science quality
 - Stakeholder community to evaluate effectiveness of measurement service quality and delivery
 - Review by international peers from other NMIs

Evaluation Process

The efficiency and effectiveness of the OU's market analysis, the program plan and operational plan will be evaluated using three principal tools:

Technical Quality Assessment

How good is our research program and how relevant it is to the NIST mission?

- Examine the technical appropriateness of the OU's S&T portfolio
- Peer-reviewers best suited for the assessment of programs
- Peer-reviewers could be internal or external, national or international, paid for or pro bono
- Peer-reviews could be run by NIST or another organization.

Customer Satisfaction Evaluation

How well are we serving our customers?

- Customer focus panels
- Customer workshops
- Formal customer surveys
- Informal customer surveys
- Customer suggestions/complaints
- Etc.

Data Collection and Evaluation

How efficient and effective are we at producing and disseminating our products and services?

- Activity-based metrics
- Operational metrics
- Outcome-based metrics
- Leading indicators
- Predictive metrics

QUESTIONS?