Nanotechnology Activities and Standards

Remarks by Mary C. McKiel EPA Standards Executive

Nanotechnology

Nanotechnology refers to research and technology development at the atomic, molecular, and macromolecular levels aimed at creating and using structures, devices, and systems that have novel properties and functions because of their small size.

Nano Sightings

- National Nanotechnology Initiative
- Nanotechnology Standards Panel
- U.S. Technical Advisory Group to the Nanotechnology Technical Committee (TS-229) in the International Organization for Standardization (ISO)
- ASTM International technical committee
- ISO Technical Committee 229
- Organization for Economic Cooperation and Development - OECD

Government Venues

- Nanotechnology Research and Development
- National Science and Technology Council (NSTC) ... coordinated by Office of Science and Technology Policy
- National Nanotechnology Initiative (<u>www.nano.gov/html/about/nnistructure.html</u>)

Departments and Agencies

OSTP	NIST	DOE	EPA
OMB	NASA	NSF	DHS
NIH	DoD	DOT	USDA
DOJ	ITC	CPSC	DOL
FDA	NRC	DOED	DOI

Organization for Economic Cooperation and Development-OECD

- The Organization for Economic Co-operation and Development (OECD) held a Workshop on the Safety of Manufactured Nanomaterials (hosted by U.S., Dec. 7-9, 2005, Washington, DC) covering:
 - Definitions, nomenclature and characterization
 - Environmental and human health effects
 - Information exchange on Voluntary and Regulatory frameworks
- 39th meeting of the Chemicals Committee (Feb. 15-17, 2006, Paris) agreed to establish a Working Party on Manufactured Nanomaterials
- Will help share the burden among members and make approaches more consistent, which should reduce burden on industry, facilitate global markets and improve understanding
- First Working Party meeting will take place 26-27 October 2006 in London, chaired by the United States
 - EPA Contact: Charles Auer, OPPT

Jim Willis, OPPT

Government Roles

- Nanotech Research and Development
- Technology Development and Transfer
- Interagency Coordination
- Provide Grants
- US Global Leadership
- Environment, Safety and Health Applications
- Legal and Ethical Issues

EPA Interests

- Chemical manufacturing and applications
- Pesticides
- Terminology and definitions
- Nano particles in Air and Water
- Land Contamination
- Research and technology transfer
- Risk Management

(See various EPA web sites)

OPPT Chemical Control Division

- Voluntary stewardship program for engineered nanomaterials – planned for establishment in about 10 months.
 - Collect and generate information engineered nanomaterials
 - Characteristics of nanomaterials and impact on envioronment
 - Peer consultations to be held before program launched.

Contact: Jim Willis, Director Chemical Control Division (See BNA Article from 10/20/06)

Private Sector and AcademicVenues

- American National Standards Institute
 - Nanotechnology Standards Panel
 - U.S. Technical Advisory Committee to ISO Technical Committee 229 for Nanotechnology
- ASTM
 - Standards development in Nanotechnolgy
- University of California at Santa Barbara
- Rice University
- Cadmus
- Environmental Defense and Dupont

Standardization Activities

- American National Standards Institute ANSI
 - National Standards Panel est. August 2004
 - Stakeholder group to promote, accelerate and coordinate the timely development of voluntary consensus standards that are intended to meet identified needs related to nanotechnology research, development and commercialization.
 - U.S. Technical Advisory Group for international technical committee on nanotechnology under the International Organization for Standardization
 - Mirror group to the international activity
 - Stakeholders develop US positions and language for input to the international standards work

Standards Panels

- Multi-stakeholder/ Promotes Cross-Sector Collaboration
- Expert-driven/ Liaison with other efforts
- Do not develop standards
- Hosted by ANSI
- Investigates needs, existing resources and gaps
- Current panels include:
 - Homeland Security
 - Health Care Information Technology
 - Identity Theft
 - Nanotechnology

Nanotechnology Standards Panel

- Six Broad topics
- Four urgent 0-1year timeframe
 - General terminology for nanoscience and technology
 - Systemic terminology for materials composition and features
 - Toxicity effects/environmental impact/risk assessment
 - Metrology/Methods of Analysis/Standard Test Methods

ASTM International E56 Committee

- Formed in 2005
- Scope of work: 1) Development of standards and guidance for nanotechnology and nanomaterials, and 2) the coordination of existing ASTM standardization related to nanotechnology needs.
- Subcommittees include:
 - Terminology & Nomenclature
 - Characterization: Physical, Chemical and Toxicological Properties
 - Environment, Health and Safety
 - International Law & Intellectual Property
 - Liaison & International Cooperation
 - Executive
 - Strategic Planning and Review

ASTM E56 WK8051: Terminology for Nanotechnology

Scope

This standard contains terms and their definitions as used in the field of nanotechnology; multiple scientific fields and disciplines, both existing and emerging, are contained herein. This standard is broad by design, and may include terms from existing disciplines that have been redefined for specific nanotechnology application. This standard is a living document that will be amended as new scientific disciplines evolve, and may be referenced and/or adopted, in whole or in part, depending o the requirements of the individual user. This standard is intended to facilitate communication among members of the academic, regulatory, legal, industrial communities as well as the public at-large, both within the U.S. and internationally. No such document currently exists. Potential users include members of the academic, scientific, regulatory, legal, and industrial communities.

(See ASTM.org)

International Standardization

- International Organization for Standardization (ISO)
 - ISO established a new technical committee <u>ISO/TC</u> <u>229</u>, <u>Nanotechnologies</u> in late 2005, which is hosted by the ISO member for the United Kingdom, the British Standards Institute, to develop International Standards for nanotechnologies. Future tasks and the initial structure for the work include developing standards for:
 - Terminology and nomenclature
 - Metrology and instrumentation
 - Test methodologies
 - Modeling and simulation
 - Science-based health
 - Safety
 - Environmental practices

Private Sector Interests

- Trade and commercialization
- Worker safety
- Manufacturing processes
- Intellectual property
- Development of new technologies
- New markets

U.S. Involvement in ISO

- ANSI is U.S. Official Member and Access
- Technical Advisory Groups (TAGs) formed as venue to international work
- Dr. Clayton Teague is chair of the US TAG to ISO's nanotechnology committee.
- Current Workgroups under the committee:
 - WG2 Measurement and Characterization
 - WG3 Health, Safety and Environmental Aspects

National Technology Transfer and Advancement Act of 1995

- Directs federal agencies to use, and participate in the development of voluntary consensus standards. (The law makes no distinction between national and international standards.)
- Requires an annual report and justification on the use of government-unique standards in lieu of using existing, applicable consensus standards.
- (See Public Law 104-113, sec 12[d] and Office of Management and Budget Circular A-119)

Questions Include:

- Which venues are most important to EPA and EPA's mission?
- Is there a way to determine effective crosswalking between national and international outcomes in policy and standards arenas?
- Would EPA and the public benefit from greater Agency participation in standards setting bodies?
- How can we effectively transfer EPA technical expertise into private sector venues?