ANSI NANOTECHNOLOGY STANDARDS PANEL (ANSI-NSP)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ASTM, IEEE, IEST, UL, ASME, SEMI, NEMA, AIHA, USP
Technical Committees:	ISO/TC 229 (established after initial ANSI-NSP meeting)
Other Partnering Organizations:	NGOs (EDF, PETA), Legal entities, Academic institutions (Rice University)
Government Organizations:	NNCO, OSTP, EPA, NIST, NIOSH, FDA, DoD, NASA, CPSC
Industry Sector(s) / Technology:	Nanotechnology, chemicals, semiconductors
Program / Activity Website URL(s):	www.ansi.org/nsp

STANDARDS DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In June, 2004, ANSI received a request from Dr. John Marburger, Director of the Office of Science and Technology Policy in the Executive Office of the President, to coordinate the development of standards (including nanotechnology terminology nomenclature) to be utilized by academics, industry, investment communities, and government. Dr. Marburger said, "As new materials, structures, devices and systems are developed that derive their properties and function due to their nanoscale dimensions, it will become increasingly important to the researchers, manufacturers, regulators, and other stakeholders to have agreed upon standards." In response, ANSI established its <u>Nanotechnology Standards Panel (ANSI-NSP)</u>, initially with three co-Chairs: Dr. E Clayton Teague, Director of the National Nanotechnology Coordination Office (Government), Dr. David Bishop of Lucent Technologies (Industry), and Dr. Vicki Colvin of Rice University (Academia).

PPP Goals:

The purpose of the ANSI-NSP is to serve as the cross-sector coordinating body and provide the framework within which stakeholders can work cooperatively to promote, accelerate, and coordinate the timely development of useful voluntary consensus standards to meet identified needs related to nanotechnology. These needs include: nomenclature and terminology, research, development, and commercialization.

The NSP does not develop the standards themselves; rather, it relies on relevant SDOs whose scopes of work may include nanomaterials and nanotechnology applications. As nanotechnology is a relatively new field, and as new materials and applications emerge, the NSP holds meetings and workshops of impacted stakeholders to discuss standards needs for topics as they are identified.

The NSP also works to promote various nanotechnology standards activities via news items to NSP membership as well as an <u>online standards database</u>, a freely accessible database that captures information about standards and associated documents (standards, best practices, guidelines) that directly relate to nanomaterials and nanotechnology-related processes applications and products.

NSP Terms of Reference:

- Coordinate and provide a forum for academia, industries, standards developing organizations, and governmental entities to identify and define needs, determine work plans, and establish priorities for updating standards or creating new standards.
- 2. Solicit participation from nanotechnology-related sectors and academia that have not traditionally participated in the voluntary standards system, and work cooperatively to achieve the mission of the ANSI-NSP and to address standards needs in the area of nanotechnology.
- 3. Facilitate the timely development and adoption of standards responsive to identified needs in the area of nanotechnology in general and nomenclature/terminology specifically.

- 4. Facilitate and promote cross-sector collaborative efforts between standards developing organizations to establish work plans and develop joint and/or complementary standards.
- 5. Where standards do not exist, obtain agreement from a standards developer to initiate and complete development of the standard in a timely manner.
- 6. Establish and maintain liaison with other national, regional, and international standards efforts addressing nanotechnology issues to create identical or harmonize existing standards.
- 7. Establish and maintain a database of nanotechnology standards, accessible from the Internet, and capable of generating updates, notices, and reports.

Public Sector Role & Participation:

The U.S. Government played an integral role in the development of the NSP. From the initial communication from Dr. Marburger requesting ANSI take on this activity, to the engagement of NNCO Director Dr. Clayton Teague as a NSP co-Chair from 2004 - 2011, the U.S. Government has been a leader in this initiative. As NSP co-Chair, Dr. Teague helped set the strategic direction of the NSP, and guided NSP members through the process of developing the U.S. position and technical inputs to ISO relative to the creation of ISO/TC 229 Nanotechnologies (for which Dr. Teague also acted as U.S. TAG Chair from 2005 – 2011).

Various U.S. government employees from a number of federal agencies continue to play a role in the NSP, participating in NSP workshops as panelists, speakers, and moderators and contributing technical input in workshop developments.

Implementation Methods:

The ANSI-NSP held its initial meeting September 29 – 30, 2004, at NIST in Gaithersburg, Maryland. (A meeting of the ANSI NSP Steering Committee, a subset of relevant stakeholders and experts, was held on September 28, 2004.) Prior to this meeting, ANSI sent out a call for participation to relevant stakeholders, including: SDOs, government agencies, academic institutions, NGOs, and industry representatives. In addition, a number of news items (both from ANSI and external sources) were shared to announce the purpose of the meetings and call for participants. During that initial meeting, a series of breakout sessions took place in which all were asked the same questions, from a variety of perspectives, including:

- Morphological, Geometrical, and General Terminology
- Inorganic nanomaterials
- Carbon nanostructures
- Top-down assembled structures and devices
- Hybrid nanostructures

ANSI developed an executive summary as well as recommended topics needed relative to nanotechnology standardization, which were distributed via ANSI to SDOs to request their consideration to develop relevant standards. The SDO responses to ANSI's call were presented in a subsequent meeting of the NSP Steering Committee, held in January 2005.

The trajectory of the NSP changed on January 20, 2005, when the British Standards Institute submitted a proposal to establish a new technical committee (TC) in Nanotechnology to ISO. At that time, the NSP worked on the development of the U.S. position on this new TC in terms of: the identification of the ISO/TC 229 TAG Administrator (ANSI); deciding which working group the U.S. would want to lead (health, safety, and environment); and connecting with relevant experts. Several of the NSP members also participated in the ANSI-Accredited U.S. TAG to ISO/TC 229 Nanotechnologies, which became the major focus of activity as it was developing specific standards.

However, the NSP remains a relevant and vital resource to the Nanotechnology community. Since 2005, the NSP has held workshops and meeting as needs and relevant topics are identified. Below is the list of NSP meetings and workshops that have taken place since 2005. All presentations and reports are available <u>online</u>.

- 2008 Focus on U.S. engagement in nanotechnology standardization and identification of scientific areas for U.S. leadership Reports of key areas for U.S. leadership shared with NSP members
- 2009 Information sharing relative to relevant U.S. domiciled nanotechnology standards activities
- 2013 Progression of nanotechnology standards: Was there focus on the right topics? Was there enough collaboration? A meeting report with recommendations (including the development of the NSP Database) was distributed
- 2017 Workshop focused on Graphene: Current state of the science, identification of relevant standards and if existing standards efforts met stakeholder needs?
- 2018 Workshop focused on Graphene (Part II): Consideration of existing standards documents in the areas of graphene; presentation from EPA relative to potential regulation of graphene materials
- 2019 Meeting to discuss the relationship between Nanotechnology Standards and Regulation
- 2020 Workshop to consider Advanced Materials Report shared with NSP members and meeting participants
- 2022 2nd Workshop to further consider Advanced Materials and needs relative to terminology, categorization, and regulation. Conclusions from the Workshop, including areas of categorization and standards needed, were shared with NSP members and meeting participants

The following future topics are being considered:

- Nanoplastics (proposed workshop for fall 2024)
- Nanomedicine

In addition to the meetings and workshops, the NSP has also:

- Developed a NSP quarterly newsletter (suspended in 2019)
- Launched <u>nanostandards.ansi.org</u> a community driven database
- Engaged SDOs in celebration of National Nanotechnology Day (websites/news items), including the following:
 - ANSI-developed Q&A of Nanotechnology experts (2021)
 - ANSI webpage devoted to celebrating 15 years of the ANSI NSP and a timeline of its development and activities (2019)
 - <u>ANSI webpage devoted to the various standards organizations developing nanotechnology-related</u> standards (2017)

Measurement of Success:

The initial goals of the NSP were achieved by the initiation of relevant standards in the three identified areas of initial interest: Terminology and nomenclature (ASTM <u>E56.01</u>, ISO/TC 229 <u>80004 series</u>), Measurement and characterization (ASTM <u>E56.02</u>, <u>IEEE</u>, <u>ISO/TC 229</u>) and Health safety and environmental standards (ASTM <u>E56.03</u>, <u>ISO/TC 229</u>).

Several of the standards that were developed have been identified and utilized by the U.S. Government, including:

- Identification by the <u>National Nanotechnology Coordination Office (NNCO)</u> as "Illustrative examples of documentary standards" in nanotechnology
- FDA has identified a number of these standards as "<u>recognized standards</u>," which are "national or international standard that medical device manufacturers can use to show that they meet a relevant requirement of the FD&C act."
- EPA has also referenced specific nanotechnology standards as part of their <u>TSCA Reporting and Recordkeeping</u> requirements.

A number of the SDOs that either participated in the initial NSP meetings or were established as a result of the NSP (ASTM, <u>NEMA</u>, ISO/TC 229, <u>IEC TC 113</u>) are still actively developing standards within this space, whether in the three originally identified priority areas, or in new areas that have developed as the technology has developed/additional data is established (such as material-specific standards for graphene and cellulose, product standards relative to nanomedicine, consideration of terminology for advanced materials).

The standards that have been developed by these various SDOs are a strong foundation for the industry to utilize and develop their sector-specific nanotechnology-related standards.

Key Takeaways:

- Engaging the government in PPPs is important, but just as important is the engagement and input from industry and other relevant affected stakeholders (as the users of voluntary standards). It is important to ensure that the private sector does not look to the government as the solution to the development of standards – industry, academic, and organization participation and support is critical to the success of standards efforts.
- 2. New topics always solicit excitement and engagement, but as technologies mature/change, the interest and participation dwindle. It is necessary to continue to outreach to interested parties to determine what standards needs exist and how the PPP can help.

Advice for Others:

It would be beneficial to find (at the most two) intelligent, effective, and engaged leaders/chairs to help drive the direction and work of the PPP. While there were initially three co-chairs to help recognize the importance of industry, academia, and government in the development of nanotechnology standards, this also caused difficulty, with competing philosophies and agendas trying to identify the direction of the group. This number has now been reduced to two co-chairs (government and industry) that are able to work together in a more cooperative manner.

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