Draft Meeting Report
ANSI Nanotechnology Standards Panel

February 4, 2013
King and Spalding, LLC
Washington, DC

1.0 Welcome and Opening Remarks

Co-Chairs Dr. Shaun Clancy of Evonik Corporation and Dr. Ajit Jillavenkatesa of the National Institute of Standards and Technology (NIST) welcomed participants to this 5th meeting of ANSI's Nanotechnology Standards Panel (ANSI-NSP).

Dr. Clancy began by reminding participants of the origins of this ANSI Panel. The ANSI-NSP was established in 2004 to facilitate standards development in the area of nanotechnology, initially focusing on the areas of terminology and nomenclature, to assist in the development of a common language with which all interested stakeholders could communicate. Nanotechnology isn't just "one thing," it covers many different industry sectors; as such, standards are an important element to facilitate commerce.

One goal of today's meeting is to examine where, if any, opportunities for improvement exist. Some questions to consider include:

- How is the community doing with regards to nanotechnology standards development?
    - Are the activities focusing on the right topics?
    - Are the activities focusing in areas that are of a lower priority? And if so, what are they?
    - Is enough collaboration between activities taking place and with the relevant stakeholders?

On behalf of the NSP community, the following individuals were acknowledged for their efforts to advance this activity:

- Dr. Celia Merzbacher. Previously at the Office of Science and Technology Policy (OSTP) in the Executive Office of the President, worked with then NNCO Director Dr. Clayton Teague to set in motion the establishment of the ANSI-NSP.
- Dr. Clayton Teague. As NNCO Director, Dr. Teague played a critical role in the launching and direction of the NSP. As initial NSP Chair, Dr. Teague presided over the development of the U.S. position with respect to the ISO Proposal to establish a new field of Technical Activity in the area of Nanotechnologies – ISO/TC 229.
- Mr. Travis Earles. Formerly with the OSTP, Mr. Earles was a strong early supporter of the ANSI-NSP initiative and of the development of relevant and science-based nanotechnology standards.

- Dr. Altaf Carim. Dr. Carim, in his former position at the U.S. Department of Energy, was an early supporter of nanotechnology standards activities and in his current role in OSTP, continues to be a key figure advocating for active U.S. participation in, and support of these efforts.

Today's meeting provides an opportunity to hear these individuals' perspectives on the current state of nanotechnology standardization efforts, including if they feel that the nanotechnology standards community is focusing on the right areas of work and developing useful and valuable documents.

Dr. Jillavenkatesa recognized ANSI for its leadership and its maintenance of the ANSI-NSP as a mechanism to help bring relevant bodies together to facilitate the development of voluntary consensus standards in this important area.

In addition to the questions identified earlier, the following questions were posed for consideration:

- In light of the current economic climate, how can the ANSI-NSP help continue to build more effective partnerships, including public and private partnerships, to further the development of useful and science-based nanotechnology standards?
- How can the NSP continue to be effective and maintain U.S. leadership in this space? What challenges does the NSP face in terms of needs-relevant standards development and how can the standards community effectively address these challenges?

Dr. Clancy and Dr. Jillavenkatesa thanked everyone for their attendance and noted that they looked forward to the day's discussions.

2. ANSI Panels and Standards Coordination Activities: An Introduction

ANSI Senior Vice President and Chief Operating Officer Fran Schrotter provided an overview of ANSI's various panels and standards coordination activities. **Document: ANSI-NSP 081-2013**

ANSI is responsible for serving as the United States' voluntary consensus standards coordinating institution. This role requires ANSI to be dynamically responsive to national needs, to further voluntary standards initiatives and to assure that the interests of the U.S. public are effectively addressed.

When talking of systems integration and converging technologies, standards efforts underway require far more collaboration than years ago. ANSI is able to act as a bridge between the public and private sectors to promote the development and compatibility of standards programs.

As noted, the ANSI-NSP was established in response to a request from then OSTP Director Dr. John Marburger for ANSI to facilitate the development of nanotechnology standards, particularly in the area of nanotechnology terminology. Membership on the ANSI-NSP is open to all interested parties and meetings are convened as needed. The goal of this Panel is to be a valuable information resource for the nanotechnology community.

In response to an inquiry as to how the ANSI-NSP currently measures the success of the existing nanotechnology standards, Ms. Schrotter responded that it is up to the user community to determine a standards success by the utilization of the documents. That being said, Ms. Schrotter recognized the successful efforts of the ANSI-Accredited U.S. TAG to ISO/TC 229 *Nanotechnologies'* to ensure development of a nanolabeling document under the leadership of ISO instead of a regional standards body. The original nanolabeling document coming out of the European Committee on Standardization (CEN) would have been very detrimental to U.S. interests. The efforts of the United States to have this document developed under ISO, and the technical input that the U.S. experts have provided on this topic, have worked to ensure that the final product will not negatively impact U.S. trade.

Participants also recognized the success of the ISO/TC 229 Series of Nanotechnology Vocabulary documents – the "80004" series, for developing a core set of nanotechnology terms and definitions.

Ms. Schrotter thanked the participants for their attention and noted that she looked forward to the days' Panel sessions.

3. Federal Government Perspective on Nanotechnology and Standards

Dr. Altaf Carim, White House Office of Science and Technology Policy, provided a government perspective on nanotechnology and standardization.

The National Nanotechnology Initiative (NNI), which is the nanotechnology coordination and collaboration body for the U.S. government, defines nanotechnology as *the understanding and control of matter between approximately 1 to 100 nanometers where unique phenomena enable novel applications*. The U.S. has maintained this consistent definition of nanotechnology since 2004 and federal agencies are required to ensure that their utilization of the term is consistent with this definition.

Dr. Carim commented that nanotechnology standards activities have been supported within the U.S. Government, noting the NNI structure includes a designated standards-liaison to the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the National Science and Technology Council's (NSTC) Committee on Technology. Dr. Clayton Teague acted as coordinator until his retirement; Dr. Jillavenkatesa is now the official liaison.

A question was posed about the size scale contained in the existing NNI definition of nanotechnology. With the advent of biomedical devices and other products and tools in the nanobio space, should the size range currently contained in the definition be revised to accommodate the biological impacts of larger size particles?

Dr. Carim noted that interest and involvement with nano-bio interface has been part of the NNI since its inception; the current 1-100 nanometer (nm) size range included in the NNI definition does not exclude those particles that are 150 nm or larger. He added that a number of federal agencies such as the FDA often elaborate on the existing definition by providing clarification as it relates to their agency's specific mission.

As to how the federal agencies are coordinating internally relative to nanotechnology standardization, Dr. Jillavenkatesa noted that many U.S. government staff from various agencies participate in inter-agency groups such as the nanotechnology sub-group of the Emerging Technologies Interagency Policy Committee (ETIPC), and the Global Issues in Nanotechnology sub-group of the NSET within which there is a good deal of consideration of standards issues. Through their participation in these various groups, these staff are able to raise awareness and foster discussion about nanotechnology standardization related developments.

Dr. Carim concluded his comments noting that the U.S. government is interested in continuing support for the various nanotechnology standardization initiatives and making sure that the standards developed do not result in trade barriers that would impact the competitiveness of the United States.

4. Panel: Stakeholder perspectives on nanotechnology standardization

Moderator: Dr. Celia Merzbacher, Semiconductor Research Corporation

Panelists:
Dr. Jay Ansell, Personal Care Products Council (PCPC)
Dr. Richard Canady, ILSI Research Foundation
Mr. Travis Earles, Lockheed Martin
Dr. Jozef Kokini, University of Illinois
Dr. Treye Thomas, Consumer Product Safety Commission (CPSC)
Dr. Jay West, American Chemistry Council (ACC)

Dr. Merzbacher began the session by recognizing the efforts of the late Dr. John Marburger, who was instrumental in the establishment of the ANSI-NSP, and by thanking Dr. Clayton Teague for his leadership.

Panelists were asked to consider the following questions:

- How are existing nanotechnology standards being utilized?
- Are the current standards meeting real world needs and key priority areas?
- What, if any, impact do existing nanotechnology standards have on research and development?
- Are there industry-specific standards already in existence that can be modified or tailored for nanomaterials?

With respect to chemicals regulatory and policy-making, consistent terminology is a critical need for not only enhancing commerce but understanding the scope of the conversation of nanotechnology. Within the nanotechnology arena, stakeholders struggle to stay up to date with various regulatory requirements that each rely on a different definition for nanomaterials. The European Union recently implemented a statutory requirement to label materials which are "nano", utilizing a definition that is different from definitions contained in other regulatory requirements. The cosmetic community as well is being forced to adhere to multiple and sometimes conflicting definitions from different sources.

Panelists added that the European Union will be requiring "nano" labels on foods starting in 2014 and that the definition of "nano" utilized for food will be different from the definition in the cosmetics directive. This multiplicity of definitions goes to the question of whether the existing standards are meeting real world needs? While the ISO definitions offer a baseline for communication, six or seven additional definitions exist that attempt to deal with sector- specific areas of interest. Could the solution to this problem be the development of sector-specific standards to meet the needs of each particular community?

When asked if there are issues beyond the concerns relative to the development and use of consistent terminology, Dr. Thomas commented that for the CPSC, which is a small but broadly influential regulatory agency, the challenge is how to address nanomaterials safely? Do reliable methods exist for assessing the potential exposure and toxicity of nanomaterials? More robust data is needed.

Panelists commented that measurement techniques are currently a significant need in terms of standardization. Remarks indicated that none of the standards that are in existence today are very useful for nanomaterials and validated measurement methods are necessary.

Noting that there are a number of standards organizations developing documents in this space, participants asked if a single repository of information regarding all relevant standards activities exists? Dr. Clancy suggested that it might be possible for ANSI to offer such a repository and ANSI staff agreed to investigate this suggestion further.

Funding of standards activities was also discussed and various models noted. Panelists agreed that both public and private funding is important, including greater government support for nanotechnology standardization efforts. In addition, it is essential that the various standards activities are effectively coordinated to ensure the most efficient use of limited financial and human resources.

Dr. Merzbacher thanked the panelists and identified some of the key outputs from this Stakeholder Panel:

- In terms of specific standards needs, the following topics were identified:
    - Characterization of materials and relevant methods
    - Standards for exposure and release
- In terms of general needs for the standards community, greater visibility is needed for nanotechnology standards that are already published and available for utilization

- A potential mechanism for increasing awareness of existing documents could be the development of a freely accessible, online database of relevant standards activities (to be hosted by ANSI)

Dr. Clancy and Dr. Jillavenkatesa thanked Dr. Merzbacher and the panelists for their input.

5. Panel: Value proposition for participation in nanotechnology standardization

Moderator: Dr. Clayton Teague, Former Chair, ANSI-NSP

Panelists:
Mr. Chris Bell, Sidley Austin, LLP
Dr. Eric Grulke, University of Kentucky
Dr. Debra Kaiser, National Institute of Standards and Technology (NIST)
Dr. Subhas Malghan, U.S. Food and Drug Administration
Mr. Andrew Salamon, PerkinElmer
Dr. Joanne Shatkin, CLF Ventures

Dr. Teague thanked Dr. Clancy and Dr. Jillavenkatesa for their leadership and reiterated the importance of the ANSI-NSP.

The second panel discussed the benefits for organizations and experts to participate in nanotechnology standardization activities. Panelists were asked to respond to the following questions:

- Why do individuals participate in standards?
- What is the value of participation for institutions?

Panelists noted that one major benefit of participating in such activities is the networking opportunities and professional relationships people develop, which often transition beyond the standards meetings into day-to-day business. That being said, one major difficulty for some communities, such as the environmental community, is that participation on standards activities can be difficult due to budget constraints. There exists a lack of understanding about the value of participation as well as a lack of awareness of the work underway. The need for more effective and broader communication of the benefits and outputs of participation was confirmed.

In addition to relationship building, another benefit identified was the greater understanding of the existing marketplace and awareness of new technologies that are coming into commerce.

The FDA recommends that industries not only participate in the standards efforts themselves, but also to utilize the documents that are developed. The ISO 10993 series was identified as a set of standards that are particularly useful for the medical community.

Some Panelists noted that they approach standards from a policy and economic perspective. Standards by definition have the potential for massive economic impact; as such, it is of upmost importance to write solid, science based documents to enhance communication. Participation in standards activities can sometimes comes from the "do no harm" perspective, as some countries and organizations may seek to utilize standards writing as a vehicle for furthering narrow agendas, or to enhance national competitive advantage. It is beneficial to participate in standards activities to ensure interests are supported and advanced.

In response to the question of effective engagement of stakeholders in nanotechnology, panelists stated that the lack of funding is a major barrier for participation, especially within academia. Further engagement via professional societies was identified as a way to allow for greater participation of individuals from different disciplines.

Panelists added that the value of individuals' participation in standards activities is not always effectively communicated to their parent organizations. Identification of effective mechanisms for communicating the value of participation in nanotechnology standards would be a beneficial output from today's meeting.

It was noted that ANSI's Standards Boost Business, http://www.standardsboostbusiness.org/ initiative could be utilized as a model for how to showcase the benefits of participating in nanotechnology standardization. The Standards Boost Business initiative is a marketing plan, using the testimony from top CEOs as well as a collection of case studies, to present the benefits of participating in standards activities to companies and organizations' bottom lines.

With regards to opportunities for greater collaboration, Dr. Kaiser noted that in her capacity as Chair of the ASTM E 56 Nanotechnology committee, she is interested in exploring mechanisms for more effective coordination with the ANSI-Accredited U.S. TAG to ISO/TC 229 *Nanotechnologies*. While their different business models have to be factored when defining means of collaboration, both organizations have begun discussing mechanisms for increased sharing of information and documentation.

Dr. Teague thanked the panelists for their input and identified the following key outputs from this discussion:

- In terms of the value of participating in nanotechnology standardization efforts, panelists noted that a key benefit is enhanced knowledge about the state-of-the art technology as well as the development of professional relationships.
- Panelists also identified potential barriers to participation, in particular, securing financial and other resources needed to participate effectively, can be a challenge. It would be beneficial for the NSP members to consider mechanisms to more effectively promote support for individuals' participation in standards development activities.

Dr. Clancy and Dr. Jillavenkatesa thanked Dr. Teague and the panelists for their input.

6. Open discussion

Based on the day's discussions, Dr. Clancy and Dr. Jillavenkatesa asked participants to reconsider the questions posed at the beginning of the meeting:

- Are the activities focusing on the right topics?
- Are the activities focusing in areas that are of a lower priority? And if so, what are they?
- Is enough collaboration between activities taking place and with the relevant stakeholders?

Within the ISO/TC 229 activity, there are instances where the U.S. takes a reactionary position to projects that are brought forward from other national bodies that are scientifically premature and/or not validated methods. These projects can consume a good deal of time and effort on the part of U.S. experts that could be utilized more effectively. It would be beneficial for the U.S. to take a more proactive approach to development of science-based nanotechnology standards, to ensure the proposals put forward are of the highest quality.

With regards to mechanisms for improvement, participants commented that not enough is being done to promote the various standards efforts. A potential path forward could be for the development of a set of core standards that could then be utilized by various industry sectors as the basis from which to develop their own sector specific standards.

Participants agreed on the importance of the following to the long-term success of nanotechnology standardization initiatives: effective outreach to potential stakeholders; effective mechanisms that encourage participation in the various standards activities; necessary support from the public and private sectors; and increased awareness and utilization of the existing standards.

7. Concluding Remarks

Dr. Jillavenkatesa and Dr. Clancy identified the following recommendations from the day's discussions:

- Greater visibility is needed for those nanotechnology standards that are already published and available for utilization. ANSI will explore the development of an online database of relevant standards activities
- The community should enhance outreach efforts to those relevant stakeholders potentially impacted by nanotechnology standardization.
- Mechanisms for promoting support for individuals and organizations participating in the standards development processes would be beneficial. ANSI's Standards Boost Business Initiative could be used as a role model.

In terms of next steps, the NSP Co-Chairs agreed to work with ANSI to develop a robust meeting report and to include relevant action items for consideration by the Panel prior to distribution to the larger community.

On behalf of Dr. Jillavenkatesa and ANSI, Dr. Clancy thanked participants for their contributions and reiterated the ANSI-NSP leadership's interest in continuing these important and timely discussions.

8. Adjournment

The meeting was adjourned at approximately 5:30 pm.

List of Attendees – See Annex A

ANNEX A – LIST OF ATTENDEES – FEBRUARY 4, 2013

Title	First Name	Last Name	Organization
Dr.	Jay	Ansell	Personal Care Products Council
Mr.	Chris	Bell	Sidley Austin LLC
Ms.	Heather	Benko	American National Standards Institute
Dr.	Herb	Bennett	National Institute of Standards and Technology
Mr.	Steve	Brown	Intel Corporation
Ms.	Anne	Caldas	American National Standards Institute
Dr.	Richard	Canady	International Life Sciences Institute
Dr.	Christopher	Cannizzaro	U.S. Department of State
Dr.	Altaf	Carim	White House Office of Science and Technology Policy
Mrs.	Marjorie	Chertok	Tyco Fire Protection Products
Dr.	Shaun	Clancy	Evonik Corporation
Dr.	Amy Jo	Clippinger	People for the Ethical Treatment of Animals
Dr.	Raymond	David	American Chemistry Council
Dr.	Nicholas	Dagalakis	National Institute of Standards and Technology
Mr.	John	DiLoreto	NanoReg
Mr.	Travis	Earles	Lockheed Martin
Ms.	Kathleen	Eggleson	University of Notre Dame
Dr.	David	Ensor	Institute of Environmental Sciences and Technology
Dr.	Heather	Evans	National Institute of Standards and Technology
Dr.	Stephen	Freiman	Freiman Consulting
Mr.	Tom	Goldberg	American Technology Specialists, LLC
Dr.	Eric	Grulke	University of Kentucky
Dr.	Angela	Hight Walker	National Institute of Standards and Technology
Dr.	Ajit	Jilla	National Institute of Standards and Technology
Ms.	Robin	Jones	U.S. Department of Justice
Dr.	Debra	Kaiser	National Institute of Standards and Technology
Mr.	Marc	Kelemen	NanoSynopsis Consulting
Mr.	James	Kim	Office of Management and Budget - Executive Office of the President
Dr.	Fred	Klaessig	Pennsylvania BioNano Systems LLC
Dr.	Jozef	Kokini	University of Illinois
Mr.	David	Leech	National Institute of Standards and Technology
Mr.	Mike	Leibowitz	National Electrical Manufacturers Association/IEC TC 113
Dr.	Subhas	Malghan	U.S. Food and Drug Administration
Ms.	Kate	McClung	ASTM International
Dr.	Celia	Merzbacher	Semiconductor Research Corporation
Ms.	Elizabeth	Nesbitt	U.S. International Trade Commission
Ms.	Christine	Petitti	Occupational Safety and Health Administration
Mr.	Erik	Puskar	National Institute of Standards and Technology

Mr.	Dan	Ratner	American National Standards Institute
Ms.	Pat	Rizzuto	Bloomberg BNA
Dr.	John	Rumble	R&R Data Services
Mr.	Andrew	Salamon	PerkinElmer Health Sciences
Ms.	Fran	Schrotter	American National Standards Institute
Dr.	Jo Anne	Shatkin	CLF Ventures
Dr.	Lewis	Sloter, II	U.S. Department of Defense
Dr.	Clayton	Teague	Former Chair, ANSI NSP
Dr.	Treye	Thomas	Consumer Product Safety Commission
Dr.	Kim	Tuminaro	U.S. Department of State
Dr.	Nina	Veas	Michelin Research North America
Dr.	Jay	West	American Chemistry Council
Dr.	Michael	Winchester	National Institute of Standards and Technology
Dr.	Jianchao	Zeng	U.S. Food and Drug Administration
Dr.	Vince	Hackley	National Institute of Standards and Technology
Dr.	Mike	Kiley	National Nanotechnology Coordination Office