

ANSI-Nanotechnology Standards Panel Break-out Group Report

1. Name of Breakout Group: Hybrid Nanostructures Group

2. Date of Report: September 29, 2004

3. Scope of Break-Out Group:

Hybrid Nanostructures Definition:

Engineered nanostructures that involve hybrid materials—including biological components, or involve assemblies of disparate nanoscale materials.

At least one component should be less than 100 nm and the hybrid nanostructure must exhibit some novel property.

4. Facilitator: Brij M. Moudgil

5. Scribe: Barbara Karn

6. Break-out Group Participants: Submitted to ANSI NSP

These issues and questions are posed specific to the scope of this breakout group.

I. Brainstorming session related to nomenclature standardization

1. What are the most critical nomenclature issues that require discussion and resolution?

Nano-naming problems magnified with hybrids

Basis for developing nomenclature:

Structure, function, behavior?

Size, function, primary building blocks vs. bulk/aggregate, etc., intended use hierarchy?

Patent position first is called primary e.g. multiwalled nanotubes patented earlier than doublewalled

System should be open to add-ons (start from inside and work out to surface)

Need consistent/user friendly name, common community terms e.g. *dendrimer*

Drug vs. device controversy, may be legal distinction, not necessarily technical. (In FDA Office of Combination Products—decision is made there—case-by-case basis)

Wet/dry, wet/wet, dry/dry—synergies, interfaces—architecture standpoints, carrier (organic/inorganic/biological)

Life cycle aspects—transformations through cycle—nomenclature dependent throughout

Hierarchical system - Nano composition, structure, property 1, property 2...

II. Discussion of implementation questions

- 1. What standards work is underway; who is involved and is any group or individual considered the "leader"?
- IUPAC, NCCLS, ISO
- European Nanotechnology Forum
- ACS
- VDI group report, Particle Technology Association in Japan AAPI
- 2. Are any stakeholders missing from this group?
- Need to add more industry to missing entities to this group
- Biologists-cell molecular biologists, Angela Belcher, Carlo Montemagno, Chad Mirkin, James Heath, biomimetic
- Tissue engineering community
- 3. Are there any crosscutting issues with other breakout groups? If so, please identify.
 - a. Do we need a more complete nomenclature system developed by other groups e.g., Group 1?
 - b. Should we consider structures made up of 100 nm size substructures to be also defined as "Nanostructures?"
 - c. How to promote global acceptance of ANSI developed nomenclature standardization?

- 4. What are the possible impediments to the generation and acceptance of a universal nomenclature?
- Lack of communication with other groups engaged in similar issues; vested stake in terms of industries, groups, crossdisciplines
- Anti-global view
- NGO objections to new technologies
- Precautionary principle vs. risk assessment—e.g., GMO issue—public perception
- Micro/nano size connections
- 5. Provide recommendations on appropriate venues in which to address the needs identified and any individuals or organizations who should be contacted to serve as project leaders.

Nanotechnology conferences, journals, professional societies

Government and industry groups

Professional journal/publications editors

Workshops

III. Brainstorming broader issues of nanotechnology standardization needs

1. Are there other areas in nanotechnology that would benefit from standardization?

Following items are in order of priority based on voting by the participants.

- 1. Reference standards, physical standards (physical artifact)
- 2. Standard methods of analysis, nano-sized materials standards, particle size measurements, Characterization procedures
- 3. Risk assessment: medical, biological, environmental e.g., changes in reaction to different sized materials

standardized ways to assess risk, Hazard characterization, risk assessment, GLP

- 4. Quality control in manufacturing/ product—anything specific to nano? What properties to measure to determine quality/consistency of product? May vary from sector to sector GMPs, Specifications of materials, Intermediate products—production and handling, safety
- 5. Problems in buying and selling nanomaterials—adequate decision information? Measures of product quantity, e.g., including matrix? Should it be on activity? Some forms on % weight; some on conductivity within polymers. Consistency of product.
- **6.** Conformity assessment systems, Need for accrediting/certification ISO guidelines, ANSI--

Other stakeholders benefiting from this exercise:

DOD

Industry groups—pharma, avomed, small businesses, SBIR

Media esp. scientific

Regulatory agencies

PTO

Consumer groups

Environmental groups

Labor

Non-regulatory government agencies

Insurance companies

IEEE nano council. ASME nano institute

WTO

CEN

Graduate students, academic researchers

- 2. Are there stakeholders in these areas that should be involved in future discussions? Please identify.
- Need to add more industry to missing entities to this group
- Biologists-cell molecular biologists, Angela Belcher, Carlo Montemagno, Chad Mirkin, James Heath, biomimetic,
- Tissue engineering community

IV. General Comments

1. Comments/observations/suggestions

The group strongly recommends organizing a new ISO group for ANSI to establish a global priority position in the nanotechnology standardization/nomenclature area.

2. Thoughts on next steps

Engage media to help with propagation of "nanoclature"

Create data dictionaries, execute terminology agreements

3. Is there a need for a future meeting of this breakout group?

The group voted to meet at least one more time.