

# 1

## Introduction: An Overview of Nanotechnology and Nanomaterial Standardization and Opportunities and Challenges

Ajit Jillavenkatesa

National Institute of Standards and Technology (NIST), U.S. Dept. of Commerce,  
100 Bureau Drive, Gaithersburg, MD 20899, USA

### 1.1 Standards and Standardization

Standards and standards development activities are of increasingly significant interest as these and associated products directly impact trade, technology, innovation, and hence competitiveness. A 1999 OECD (Organization for Economic Cooperation and Development) report on Regulatory Reform and International Standardization<sup>1)</sup> cites a study that estimated that 80% of trade (estimated to be about \$4 trillion annually, at the time of the study) could be affected by standards or associated technical regulations. Given the growth in trade and number of countries that have joined the global trading system since this report appeared, it is clear that the impact of standards and their use as technical regulations have likely grown dramatically, and impacts trillions of dollars annually.

Standards have also national and local positive impacts, and multiple studies point to the benefits accruing from the development and use of standards and standardized approaches. An effort by the International Organization for Standardization (ISO) to compile studies on the economic benefits of standardization<sup>2)</sup> included studies that showed in the United Kingdom standards made an annual contribution of GBP 2.5 billion to the economy, and 13% of the growth in labor productivity was attributed to standards. More locally, companies that participate in and use standards reap direct benefits from standards. The benefits span a broad spectrum of technologies and organizations and can range from large multinational companies with tens of thousands of employees to small enterprises with 10 to 20 employees.

1) TD/TC/WP(98)36/FINAL OECD Working Party of the Trade Committee Report on Regulatory Reform and International Standardization, January 1999, <http://www.oecd.org/tad/benefitlib/1955309.pdf>.

2) ISO Standards: What's the Bottom Line, 2012, <http://www.standardsinfo.net/info/benefits/benefits.html>.

Standards play a critical role as they represent an agreed-upon approach, and also form the lingua franca that enables clear and precise communication of intent and expectation. Applying this common language in communication and in processes provides predictability in performance and enables interoperability. Standards also reflect consensus among experts and often embody the state of the art in technology. Thus, standards can help achieve public policy objectives such as consideration of health and safety consideration of materials or products, enable technology innovation by providing common platforms upon which competitors and product developers can provide further value-added products and services, and enable interoperability by defining where and how interoperability is needed and desired.

All these directly benefit consumers and users through better products, improved performance, and reduced costs. Evidence of these benefits of standardization is seen in products as mundane as motor oil used to lubricate automotive engines, safety glasses and ladders used by tinkerers and home improvement professionals, and smartphones used by just about everyone. Smartphones represent a rather remarkable story of the success of standardization as they have evolved from large brick-sized (and just as heavy) contraptions capable of making scratchy phone calls that could last only a few minutes to amazingly complex handheld computers with remarkable computing power that have completely transformed every facet of our lives and all in about two decades.

## 1.2 Nanotechnology Standardization

Standards development in support of nanotechnology has now been underway in a range of international, regional, and national organizations for over 10 years. For a relatively recent activity, the progress made in these organizations is noteworthy. Standards development activities involve the development of documentary standards, measurement protocols, test specifications, and reference materials. Prior to examining the trajectory of nanotechnology standardization, it is important to understand some of the broader trends relating to technology standardization as that can provide some additional context to understand and appreciate nanotechnology standardization.

### 1.2.1 Technology Standardization

Technology standardization has been underway as an organized activity for centuries. Examples of early technology standardization are seen in guilds and similar collectives in Europe, where the guilds established common practices for measurements and tools among guild members.<sup>3)</sup> Examples of common

3) Ruth A. Johnson in *All Things Medieval: An Encyclopedia of the Medieval World*, vol. 2, pp. 734–735.

measures and tools used to ensure equity in trade are seen in many museums in cities around Europe. Modern day standardization, as we know it, can be considered to have started more than a 100 years ago with the formation of formal groups to help develop common solutions to problems confronting technology deployment. An example of such a formally government-driven and government-organized activity was the convention in 1865 that established the predecessor to today's International Telecommunications Union to address challenges posed in exchange of telegraph traffic and associated tariffs. Another example of stakeholders organizing themselves into groups to address problems of engineering, production procurement through standards was the establishment of the International Association for Testing Materials, which organized working groups to discuss testing methods for iron, steel, and other materials supporting the railroad industry in the United States.<sup>4)</sup> This group paved the way for the formation of the American Section of the International Association for Testing Materials in 1898, which is the predecessor to today's ASTM International.

Today, technology standards development is underway in many organizations that develop standards and specifications using models that are responsive to the needs of their members or the unique characteristics of the industries that support the standards development. The strong interest in technology-related standardization is driven in large part by an expanded awareness and understanding of the strategic value of standardization. Increased participation in standards development by countries that have not been traditional leaders or major contributors to standards is changing the landscape of standards development in many bodies. Many emerging economies are looking to both lead and actively participate in the development of international standards, by suggesting new ideas for standardization, bringing forward technologies for standardization, and actively supporting the participation of their experts in the development of technology standards. This increased participation is ensuring that standards have greater global relevance and applicability, but in some instances it is also leading to tensions in standards development in light of varying cultural differences and expectations.

### 1.2.2

#### **Development of Standards for Nanotechnology**

Nanotechnology standardization is being driven by a combination of factors that create a push-pull dynamic. As nanotechnology and nanomaterials are increasingly being used in commercial applications, nanotechnology-related standardization is helping by developing common vocabularies and terminologies and by providing standardized testing techniques that can inform important decisions about potential risks relating to these materials. Simultaneously, developments in applying measurement existing techniques to assess materials and properties

4) ASTM 1898–1998: A Century of Progress, [http://www1.astm.org/IMAGES03/Century\\_of\\_Progress.pdf](http://www1.astm.org/IMAGES03/Century_of_Progress.pdf).

in the nanoscale range, and the advent of new techniques for measurement, are also informing the development of standards for nanotechnology and nanomaterials.

Though standards development activities in the size range considered to be nanoscale have been underway for many years, standardization specifically for the purpose of elucidating properties of nanomaterials and for enabling nanotechnology can be considered to have started in the early 2000s. This timing also tracks the development of many national initiatives focusing on nanotechnology such as the National Nanotechnology Initiative (NNI) in the United States, which was established in 2000. Two efforts in the development of international standards for nanotechnology and nanomaterials were initiated in 2005. ISO established Technical Committee (TC) 229, or ISO TC229, on nanotechnologies with initial efforts focused on developing standards for terminology and nomenclature, metrology and instrumentation, and environmental, health, and safety (EHS) practices.<sup>5)</sup> ISO TC229 later expanded its scope of activities to develop standards for material specifications relating to nanomaterials. ASTM International's Committee E56's initial efforts focused largely on standards both for physical, chemical, and toxicological measurements and for safe handling of nanomaterials.<sup>6)</sup> Later, E56 broadened its efforts to include common file formatting of nanomaterial data and education and workforce training for nanotechnology. In early 2007, the International Electrotechnical Commission (IEC) established Technical Committee 113 to develop standards for "technologies relevant to electronic products and systems in the field of nanotechnology."<sup>7)</sup> IEC TC113's initial scope of work included standardization for components and intermediate assemblies made of nanoscale materials, their properties and functionalities, final products that used these components, and standardization in various fields of activities that would see applications of nanotechnology.<sup>8)</sup> Recognizing the commonality in scope and potential for overlap in work in developing standards for terminology and nomenclature and standards for measurement and characterization, ISO TC229 and IEC TC113 established joint working groups for standardization in these two areas.

The framework of international standards development work established by these technical committees has provided an excellent start in addressing many questions relating to a common and agreed-upon vocabulary for nanotechnology and its applications, metrology and characterization, important EHS-related questions, and materials and device characterization. Some of these standards are now being considered for use by regulators, and some are already being referenced in rules, proposed rules, or other guidance supporting the implementation or regulations, such as those in the European Commission's

5) [http://www.iso.org/iso/iso\\_technical\\_committee?commid=381983](http://www.iso.org/iso/iso_technical_committee?commid=381983).

6) <http://www.astm.org/COMMITTEE/E56.htm>.

7) IEC Dashboard, IEC TC113: Nanotechnology Standardization for Electrical and Electronic Products and Systems, [http://www.iec.ch/dyn/www/?p=103:7:0:::FSP\\_ORG\\_ID,FSP\\_LANG\\_ID:1315,25](http://www.iec.ch/dyn/www/?p=103:7:0:::FSP_ORG_ID,FSP_LANG_ID:1315,25).

8) *Ibid.*

Recommendation on the Definition of Nanomaterial,<sup>9)</sup> the Environmental Protection Agency's Proposed Rule on reporting and record keeping requirements for chemical substances when manufactured or processed using nanoscale materials<sup>10)</sup>, or as part of the Food and Drug Administration's Recognized Consensus Standards Program<sup>11)</sup> and industry.<sup>12)</sup>

Nanotechnology standards development work in ASTM International<sup>13)</sup> E56 has resulted in 15 standards including test methods for physical and chemical characterization of nanomaterials and in support of EHS aspects of nanotechnology. Recent efforts have led to the establishment of work to address questions arising from the increased commercial availability of nanoenabled consumer products and the publication of standard guides and practices for workforce education. This work is unique in that it addresses an important need for worker training and credentialing.

Standards development activities in ISO TC229 are informed by experts from 36 participating countries and have resulted in nearly 50 products, including standards, technical specifications, and technical reports (as of June 2016).<sup>14)</sup> These products cover standards for terminology, nomenclature, measurement, characterization, metrology, EHS aspects, and material and product specifications. In addition, work in ISO TC229 has also focused on how consumer, societal, and sustainability aspects could be considered in the development of nanotechnology standards, given the confidence that nanotechnology can help in solutions to address many societal and sustainability challenges. Recently, the group has also been exploring possible standardization opportunities that may lie at the intersection of nanotechnology and biological systems.

IEC TC113 standardization work leverages expertise from 14 participating countries and includes 13 specifications, standards, and technical reports that cover test methods for measurement and characterization of electrical and electronic properties of various nano-objects and specifications to assist in different aspects of nanomanufacturing.<sup>15)</sup> These do not include terminology- and vocabulary-related standards that are developed in the joint working groups led by ISO TC229.

Governments have actively supported the development of international standards for nanotechnology. In the United States, the President's Council of

9) Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), *Official Journal of the European Union*, October 20, 2011 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF>).

10) EPA Proposed Rule on Chemical Substances When Manufactured or Processed as Nanoscale Materials: TSCA Reporting and Recordkeeping Requirements, April 6, 2015, [Regulations.gov](http://www.regulations.gov) Docket ID: EPA-HQ-OPPT-2010-0572-0001, [www.regulations.gov/#/documentDetail;D=EPA-HQ-OPPT-2010-0572-0001](http://www.regulations.gov/#/documentDetail;D=EPA-HQ-OPPT-2010-0572-0001).

11) <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/Search.cfm>.

12) Nano's Big Future, *ISO Focus*, 110, May–June 2015.

13) <http://www.astm.org/COMMIT/SUBCOMMIT/E56.htm>.

14) [http://www.iso.org/iso/home/store/catalogue\\_tc/catalogue\\_tc\\_browse.htm?commid=381983&published=on&includesc=true](http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=381983&published=on&includesc=true).

15) IEC TC113 standards and publications, <http://www.iec.ch/dyn/www/?p=103:22:0:::> FSP\_ORG\_ID,FSP\_LANG\_ID:1315,25.

Advisors on Science and Technology (PCAST) in their most recent (fifth) assessment of the National Nanotechnology Initiative called for continuing US federal agency participation in the development of international standards, particularly relating to EHS, as a necessary element for supporting the commercialization of nanotechnology.<sup>16)</sup> Similar sentiments acknowledging the important role of international standards and international engagement in the development of measurement tools and solutions were expressed in previous PCAST assessments of the NNI. The fourth PCAST assessment of the NNI (2012) recommended identifying an individual who could coordinate US federal agency efforts relating to nanotechnology standards development.<sup>17)</sup>

The European Commission, through two standardization mandates to the European Standards Organizations (ESOs), has expressed its belief about the importance of standards to meet the Commission's objectives with regard to nanotechnology. The Commission first articulated its approach relating to nanotechnology in 2004 in COM (2004) 338 "Towards a European Strategy for Nanotechnology" and the related strategy document "Nanosciences and Nanotechnologies: An Action Plan for Europe 2005–2009." To support the objectives laid out in these policy documents, the Commission issued Standardization Mandate M/409<sup>18)</sup> in 2007 charging the ESOs to undertake a landscape scan of existing nanotechnology-related standards activities, identify the need for new standards, identify other standards-related deliverables, and identify suitable stakeholders who could contribute to the development of such standards. In 2010, the European Commission issued the second nanotechnology-related standardization mandate M/461 that requested the ESOs to develop specific standards "as regards measurement and testing tools for the characterization, behavior of nanomaterials and exposure . . ."<sup>19)</sup>

### 1.2.3

#### Nanotechnology Standards Development in Europe

Nanotechnology-related standardization in Europe is actively underway in a hybrid model. National standards bodies in many European countries have organized national committees for nanotechnology standardization. Many of these national technical committees also act as mirror committees that represent their

16) Report to the President and Congress of the Fifth Assessment of the National Nanotechnology Initiative, Executive Office of the President's Council of Advisors on Science and Technology, October 2014 ([https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast\\_fifth\\_nni\\_review\\_oct2014\\_final.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_fifth_nni_review_oct2014_final.pdf)).

17) Report to the President and Congress of the Fourth Assessment of the National Nanotechnology Initiative, Executive Office of the President's Council of Advisors on Science and Technology, October 2012 ([http://www.nano.gov/sites/default/files/pub\\_resource/pcast\\_2012\\_nanotechnology\\_final.pdf](http://www.nano.gov/sites/default/files/pub_resource/pcast_2012_nanotechnology_final.pdf)).

18) M/409 Mandate Addressed to CEN, CENELEC and ETSI for the Elaboration of a Programme of Standards to Take into Account the Specific Properties of Nanotechnology and Nanomaterials.

19) M/461 Mandate Addressed to CEN, CENELEC AND ETSI for Standardization Activities Regarding Nanotechnologies and Nanomaterials, Feb. 2010.

nation's expertise in the standards development work in the development of international standards such as in ISO and IEC, and in regional standards such as those developed in the European Committee for Standardization, CEN. In addition, these technical committees also develop standards and specifications to address national needs. Examples of such activities include a range of Publicly Available Specifications (PAS) from the British Standards Institute.<sup>20)</sup> Simultaneously, work is underway in CEN, the lead organization among the ESOs, for standards development work relating to nanotechnology. CEN established Technical Committee 352 in 2006. Similar to the organization of work in ISO TC229, CEN TC352 has a working group each for measurement, characterization, and performance evaluation and for EHS aspects. In addition, CEN TC352 also has a working group to consider commercial and other stakeholder aspects. Due to the established working relationship between ISO and CEN and the ability of national bodies to adopt ISO (or IEC) standards as national standards, many of the standards developed in ISO TC229 have been adopted as European standards<sup>21)</sup> through CEN processes for regional adoption of standards. In addition, CEN/TC352 also has standards activities underway that are independent of the standardization activities in ISO TC229 and represent regional interest of the stakeholders.

#### 1.2.4

##### **Working with the Organization for Economic Cooperation and Development**

Another international organization that is playing an important role in developing protocols and specifications for measurement and characterization of nanomaterials is the Organization for Economic Cooperation and Development's Working Party on Manufactured Nanomaterials (OECD WPMN).<sup>22)</sup> The work of this group has focused on addressing questions about the safety of manufactured nanomaterials. Though OECD is not a standards developing organization, this OECD group works in collaboration with ISO TC229 and other standards, regulatory, and industry bodies in developing its guidance documents and specifications. Of particular note has been the collaboration between the OECD WPMN and the ISO TC229's Joint Working Group on Measurement and Characterization (JWG2) to accelerate the development of test protocols that are suitable for characterization of specific parameters (endpoints) for 13 manufactured nanomaterials that were identified by OECD WPMN as initial materials of interest. The list contains materials that are either already in mainstream commerce or are expected to be in wide-scale commercial use soon. Parameters of interest include chemical composition, aggregation/agglomeration, particle size distribution, crystalline phase, dustiness, specific surface area, water solubility/

20) <http://shop.bsigroup.com/en/Browse-by-Subject/Nanotechnology/>.

21) CEN/TC352: Nanotechnologies, published standards list at [http://standards.cen.eu/dyn/www/?p=204:32:0:::FSP\\_ORG\\_ID,FSP\\_LANG\\_ID:508478,25&cs=18E152154F73BA190A16C4D279047F5FD](http://standards.cen.eu/dyn/www/?p=204:32:0:::FSP_ORG_ID,FSP_LANG_ID:508478,25&cs=18E152154F73BA190A16C4D279047F5FD).

22) <http://www.oecd.org/science/nanosafety/>.



dispersability, zeta potential, photocatalytic activity, porosity, redox potential, radical formation potential, crystallite size, and surface chemistry. A report published in early 2016 discusses the techniques used to determine the above properties for the materials of interest.<sup>23)</sup> Other publications from the group that touch upon nanomaterials can be found at the publication's site for the series on the Safety of Manufactured Nanomaterials.<sup>24)</sup>

### 1.3 Nanomaterial Standardization

While the discussion so far has focused on documentary standards development activities, it is also important to note work underway relating to the development of physical standards that are very well characterized and commercially available to help users benchmark their measurement or material characterization processes, calibrate equipment, or help establish metrological traceability to a primary standard, such as a primary unit of measurement (SI unit). These materials, generally referred to as reference materials or certified reference materials, are produced typically by national measurement institutes (or national metrology institutes) and are made available with detailed information such as how the material was characterized, the characterized values and the associated uncertainty of those values, instructions for storage and use, and a time frame during which the stated values would be considered reliable.

The National Institute of Standards and Technology (NIST) in the United States has developed (certified) reference materials (trademarked by NIST as (Standard) Reference Materials, RM or SRM) with values specified for specific surface area (titanium dioxide),<sup>25)</sup> mass fraction of various elements encountered in the analyses of carbon nanotubes,<sup>26)</sup> and physical/dimensional characterization of nanoparticles (10, 30, and 60 nm gold nanoparticles<sup>27)</sup> and 2 nm Si nanoparticles<sup>28)</sup>). In addition, NIST experts have also developed reference materials that provide a common set of single-wall carbon nanotube dispersions of varying aspect ratios and purity<sup>29)</sup> to help with measurement comparisons. The NIST portfolio of reference materials also includes polyvinylpyrrolidone-coated silver nanoparticles<sup>30)</sup> that can be used as a benchmarking and investigative tool in the

23) OECD Environment Directorate Report "Physical-Chemical Properties of Nanomaterials: Evaluation of Methods Applied in the OECD-WPMN Testing Programme, ENV/JM/MONO(2017)7, Feb. 2016 ([http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono\(2016\)7&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2016)7&doclanguage=en)).

24) <http://www.oecd.org/env/ehs/nanosafety/publications-series-on-safety-of-manufactured-nanomaterials.htm>.

25) SRM 1898 [https://www-s.nist.gov/srmors/view\\_detail.cfm?srm=1898](https://www-s.nist.gov/srmors/view_detail.cfm?srm=1898).

26) SRM 2483 [https://www-s.nist.gov/srmors/view\\_detail.cfm?srm=2483](https://www-s.nist.gov/srmors/view_detail.cfm?srm=2483).

27) RMs 8011, 8012 and 8013 [https://www-s.nist.gov/srmors/view\\_detail.cfm?srm=8011](https://www-s.nist.gov/srmors/view_detail.cfm?srm=8011).

28) RM 8027 [https://www-s.nist.gov/srmors/view\\_detail.cfm?srm=8027](https://www-s.nist.gov/srmors/view_detail.cfm?srm=8027).

29) RM 8017 [https://www-s.nist.gov/srmors/view\\_detail.cfm?srm=8017](https://www-s.nist.gov/srmors/view_detail.cfm?srm=8017).

30) RM 8281 [https://www-s.nist.gov/srmors/view\\_detail.cfm?srm=8281](https://www-s.nist.gov/srmors/view_detail.cfm?srm=8281).



evaluation of potential EHS risks that may be associated with manufactured nanomaterials during their product life cycle.

Germany's Bundesanstalt für Materialforschung und -prüfung ((BAM) Federal Institute for Materials Research and Testing) has created a range of “nano-scaled reference materials” available as certified reference materials, quality control materials, and reference materials to support reliable characterization of materials and material properties in the nanoscale. The attributes covered by these materials include flatness, film thickness, step heights, lateral dimensions, critical dimensions (e.g., pitch, surface topography, etc.), pore depth, particle size (including standards to characterize contaminants on surfaces), crystal size, and other attributes.<sup>31)</sup>

The development of these materials takes significant lead time and effort. While these materials might be issued by one organization, the development of these materials, including sourcing of the raw materials and validation of testing methods, requires collaborations with many other organizations. Significant effort is spent in developing a suitable sampling scheme to ensure all samples of the material are statistically similar to each other and the values assigned to the material would apply to any sample, within the limits of the associated uncertainty.

## 1.4 Challenges

There are several challenges confronting nanotechnology standards development, despite the robust network of organizations that are helping develop nanotechnology standards and a healthy body of standards-related activities. While many of these challenges are similar to those encountered in the early stages of standardization of any technology, there are other challenges that are unique to nanotechnology standardization and are also magnified due to the broad interest in nanotechnology, due to the large resource investment in these technologies by both governments and private sector, and due to the initial excitement about the benefits of nanotechnology.

### 1.4.1 Data and Information Gaps

Technology standardization inherently depends on robust data and knowledge that often represents, and is derived from, the state of science within that technology. In well-established technology areas, there is an existing body of work and commonly agreed-upon scientific practices and processes that help generate data which in turn forms the basis for standardization work. Consequently, the

31) <http://www.nano-refmat.bam.de/en/>.

standards enable further uniformity in generating new data. This virtuous cycle enables technology development and innovation in a somewhat incremental manner.

One of the biggest hurdles confronting experts developing nanotechnology standards is that much of the data and information needed for standards development such as for physical and chemical characterization, or for evaluating toxicological effects, are still being developed. Further confounding the issue is that there are a large number of material systems that are of both academic and commercial interests. While some material systems display similarities in properties and lend themselves to classification, other material systems are remarkably different and have to be dealt with separately. While teams around the world are actively generating and contributing data, the validation of the data and confidence in the techniques used to generate this data form a critical step before the data can be used for standardization.

The interplay between material systems and techniques is particularly vexing as measurement characterization techniques that have traditionally been used at the macroscale often do not readily lend themselves for use with nanomaterials and so may have to be modified. At present, new and derivative techniques specific for use in the nanoscale are being developed. The validation of these techniques through interlaboratory comparisons, application across different material types and systems, and so on takes time, but it provides the needed confidence in their use and in the data generated through these techniques.

To counter the time lag issue, practitioners have also adopted the approach of developing measurement protocols<sup>32)</sup> that are then put to use. Data and experience generated over time from using these protocols help refine the protocols in an iterative manner. These protocols can in turn be used to inform formal standards development. A successful example of this approach is the set of measurement protocols developed by the National Institute of Health's National Cancer Institute Nanotechnology Characterization Lab.<sup>33)</sup> Recognizing the need to balance timeliness in the development of standardized techniques with the need for greater confidence in data and the measurement techniques, experts in ISO TC229 have chosen to develop technical specifications and technique reports as the first step toward developing international standards. This approach enables experts to review the specifications in approximately 2–3 years and determine aspects of the specifications that need to be updated, changed, eliminated, or formalized. When formalized as international standards, these documents have regular review cycles of 5 years, though they can be reviewed and updated by experts sooner.

32) <http://www.nist.gov/mml/nanoehs-protocols.cfm>.

33) Assay Cascade Protocols, Frederick National Lab, Nanotechnology Characterization Laboratory, National Cancer Institute, [ncl.cancer.gov/working\\_assay-cascade.asp](http://ncl.cancer.gov/working_assay-cascade.asp)

### 1.4.2

#### Competing Priorities

The promise of nanotechnology has raised significant expectations about the benefits and also raised many questions about safety and conditions under which exposure to nanomaterials might be hazardous. Nanomaterials and nanotechnology are increasingly finding their way into commercially available products. While efforts to quantify the use of nanotechnology and nanomaterials in commerce, such as the Woodrow Wilson Center's Nanotechnology Consumer Product Inventory (which identifies over 1800 commercial products),<sup>34)</sup> indicate varying numbers of consumer products that are nanoenabled or nanoenhanced, depending upon the scope of the inventory and the methodology, there is no doubt that nanoenabled and nanoenhanced products are being used widely. This growth and associated questions of increased product performance or efficacy due to the "nano" inside, or questions about the safety of these products, are adding pressure to develop more standards to address these questions. As there are only a very limited number of organizations developing nanotechnology-related standards, this demand is competing with standards for other purposes such as property measurement or for definitions. The limited availability of expertise to work on these diverse set of issues, particularly when these issues are in play in either regulatory contexts or in litigation (or the potential for litigation), has set the stage for competing priorities for nanotechnology standards development.

Some interesting challenges also arise due to the crosscutting nature of this field, which is attracting experts not just from the traditional fields of science, engineering and technology. Nanotechnology standards development efforts are also benefiting from the expertise of practitioners in social sciences, economics, law, international trade, and other nontechnical fields. This interplay of expertise is creating a dynamic in which participants have different priorities for standards development, envision the use of standards for sometimes very different purposes, and use different terms and lexicon to define similar concepts – or use the same terms to mean very different things. Bridging these differences and creating a cohesive group that can rapidly develop the needed standards and specifications requires a tremendous amount of time, effort, and resources, which are often limited as most participants in consensus standards development are volunteering their time and expertise.

### 1.4.3

#### Knowledge of Standards Availability and Their Use

While the work underway in standards developing organizations has resulted in a robust portfolio of important nanotechnology-related fundamental standards and specifications, widespread knowledge about these standards, their scope,

34) Also see M. E. Vance, *et al.*, "Nanotechnology in the real world: redeveloping the nanomaterial consumer product inventory," *Beilstein J. Nanotechnol.*, 6 (2015): 1769–1780.

and their applicability is limited, thereby limiting the impact of the standardization efforts. Though the organizations that develop these standards and the national standards bodies in many countries have in place a range of tools to raise awareness on the standards, these tools often do not reach target audiences such as students, faculty, or other practitioners working in nanotechnology-related fields. Databases that enable discovery of relevant standards, regulations, guidelines, and so on, such as the American National Standards Institute's Nanotechnology Standards Panel Database<sup>35)</sup>, help fill these knowledge gaps. This database was established to enable standards developers or anyone with knowledge of standards or associated relevant documents to enter information into the database. Potential users of these standards and guidelines may in some instances identify the cost of the standards as a barrier to access and use of these standards. To address this issue, standards organizations have tried a range of approaches to provide easier access to standards. The ISO Online Browsing Platform enables users to search for standards, terms, definitions, using a range of search attributes, and then view parts of the document in question without having to necessarily purchase the entire standard. Organizations like ASTM International have subscription models that enable faculty and students to access standards at greatly reduced prices, compared to regular purchasing models.

In discussions about increased utilization of nanotechnology standards, the use of these standards by government to support regulation or procurement activities is often cited as a possible driver for greater use of standards. While their use for these activities will certainly generate greater awareness and interest in nanotechnology standards, the use in support of regulations or procurements is often limited because of the need to have a good match between the standards or specification in question and the government's needs. Existing international agreements, such as the World Trade Organization's Agreement on Technical Barriers to Trade, and government policies in various nations, such as the National Technology Transfer and Advancement Act in the United States and the associated Office of Management and Budget (OMB) Circular A-119,<sup>36)</sup> already require agencies to consider the use of international standards or other consensus standards in view of government unique requirements.

## 1.5

### Opportunities

As a field of standardization in technological areas that are cross-disciplinary, have wide applicability, and are in their early stages, nanotechnology standards and standardization offer many opportunities despite various challenges. These challenges can be thought of as "growing pains." As discussed in the previous

35) [nanostandards.ansi.org/tiki-index.php](http://nanostandards.ansi.org/tiki-index.php).

36) [https://www.whitehouse.gov/sites/default/files/omb/inforeg/revISED\\_circular\\_a-119\\_as\\_of\\_1\\_22.pdf](https://www.whitehouse.gov/sites/default/files/omb/inforeg/revISED_circular_a-119_as_of_1_22.pdf).

section, some of these challenges are not unique to nanotechnology and are inherent to any new efforts in standardization. The investment of tremendous resources from both public and private sectors in nanotechnology is supporting a very diverse effort in nanotechnology research and development. This is generating new data, insights, and applications for new materials and systems that are already transforming our lives and finding applications in fields as diverse as agriculture and telecommunications. The availability of relevant standards can greatly accelerate further technology applications and development and also has the potential for catalyzing other applications that are not even on the horizon.

Because of its cross-disciplinary and enabling nature, nanotechnology is already drawing experts from both traditional scientific areas and other non-scientific areas. This collection of broad expertise provides a really unique resource that can be leveraged to explore issues that extend beyond the purview of any one discipline. As convergence of technologies and public policy-related aspects become more of a norm than an exception, means to address differences of opinions and the prioritization between the technical issues and the societal implication issues are being tested in the current efforts and this will likely inform similar questions in standardization efforts for other technologies. There is also much opportunity to explore how technical standardization activities can be informed by nontechnical implications and questions. Likewise, technology experts and technical standards can also help address nontechnical questions, providing input on whether solutions being considered are technologically feasible and cost-effective or may have other intended or unintended consequences.

## 1.6 Summary

Though still in relatively early stages of development, nanotechnology standardization is off to a promising start. It is beginning to provide much needed solutions and tools to help address key considerations that will dictate further development and deployment of nanotechnology and nanotechnology-/nanomaterials-enabled applications. Significant resources will be needed to continue the current efforts and the resource availability is also inherently tied to the quality of nanotechnology standards being developed, their relevance in the marketplace and their uptake and use by the broader community. Meeting these needs requires a concerted effort by the community at large to pitch in and contribute to the development of nanotechnology standards – through direct participation in the development of standards, by generating data/results that in turn inform the development of standards, or by using the standards and providing feedback to those involved in the development of standards about what works and what does not work.

Nanotechnology standards are already playing an important role in numerous ways: bringing clarity in the usage of nanotechnology-related terms through agreed-upon definitions; enabling consistency in characterization of materials

and systems through metrology- and measurement-related standards; addressing important EHS-related questions through standards that help understand, characterize, and articulate interactions between nanomaterials and other systems; and improving workplace and worker safety. Finally, standards facilitate trade and commerce by streamlining and minimizing ambiguity in business-to-business communications. As commercialization of nanotechnology-related products grows, future standards will also address many other aspects of nanomaterials and nanotechnology specifications and applications.