Standardization for nanotechnology

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Introduction to standards and standardization

Written, consensual standards, whether formal (national, regional or international) or informal (company, trade association, interest group, etc.) play a critical, though largely invisible role in national economies and in international trade. By providing agreed ways of naming, describing and specifying things, measuring and testing things, managing and reporting things, standards provide vital support for commercialization, markets and market development; they provide a technical basis for procurement, technical support for appropriate legislation/regulation, and can lead to variety and cost reduction through optimization and best practice.

Without written standards, the complex technological world in which we live could not possibly operate. However, though standards are essentially ubiquitous, applying to virtually every aspect of our lives—from the highly innovative, e.g. internet protocols, to the mundane, e.g. shoe sizes, and including aspects that even most people involved in the standardization process do not appreciate, e.g. "Unmanned spacecraft residual propellant mass estimation for disposal manoeuvres", under development by ISO/TC 20/SC14— they are virtually invisible to the general public.

Historically, standards development has followed the commercialization of a particular technology, though more recently standardization has been viewed, by some at least, as an instrument that can provide support for commercialization and market development, particularly in areas that are identified as strategically, economically and/or socially important and technically challenging, and the use of such "anticipatory standards" is now being recognized as an important driver for innovation.

Nanotechnology is clearly all of these and more: it is technically challenging, being dependant on the measurement, manipulation and control of matter at a scale substantially below anything mankind has previously achieved, and well below our conventional ability for visualization; it is viewed as economically important, with a projected market impact of between \$500 and \$3 000 billion[1] per annum by 2015,[2] equivalent to something between 6%

[1] U.S. billions (milliards), i.e. 10^9.
[2] The Economic Development of Nanotechnology—An Indicators-Based Analysis, Angela Hullman, The European Commission, DG Research (http://cordis.europa.eu./nanotechnology).

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and more than 30% of the value of world exports in 2005; it will clearly be strategically important, providing both evolutionary and revolutionary (disruptive) displacement of existing products, processes and materials; the growth in global trade means that the products and processes of nanotechnology will extend across national boundaries and will almost certainly have a global impact; and last, but by no means least, there is increasing public anxiety about the potentially negative health and environmental impacts of certain aspects of nanotechnology. All of these factors mean that early standardization will be important for the successful commercialization, market development and consumer acceptance of many, possibly the vast majority of, the applications of nanotechnology under development or under consideration.

Written standards are developed under the auspices of a number of different bodies and, as such, have a different status depending on the status of the responsible organization. Formal standards are those that are adopted by national, regional or international standardization bodies, for example AFNOR (France), BSI (UK) and DIN (Germany), CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institute), or ISO (International Organization for Standardization), IEC (International Electrotechnical Commission) and ITU (International Telecommunications Union). All formal standards are developed through a process of consensus, meaning that none of the parties involved in their development and approval maintains sustained opposition to their contents (this is not quite the same as unanimity!), and, with very few exceptions, compliance with their requirements is entirely voluntary. Informal standards, whilst also voluntary and based on consensus, are developed by professional standards development organizations (SDOs), business or professional interest groups, companies, etc.

The process of standards development typically follows a well established pattern, which for European and international standardization is detailed in the ISO/IEC Directives.[3] Development is undertaken by a group of experts working together in a Working or Project Group (WG or PG) under the auspices of a Technical Committee (TC) organized to oversee standardization in a particular subject area. Where the need for a specific standard has been identified by a member of the technical committee, or other appropriate organization, a New Work Item Proposal (NWIP) is developed and submitted to the committee for approval. In the case of ISO, this is accomplished when 5 or more “P” (participating) members of the committee agree to work on developing the standard and at least 50% of those voting approve the adoption of the new work item. Once the working or project group has reached consensus on the document’s content, the TC is invited to adopt the standard, and having done so, with or without comment and subsequent revision, the document becomes a Committee Draft. At this stage it is submitted to the full membership of the standardization body for approval, again with or without comments, and once approved, possibly following further revision, it either becomes a formal standard or undergoes one further stage of formal approval prior to its final adoption. Once published, formal standards are subject to regular review to ensure their continued relevance.

In addition to full consensus documents, such as the national, regional or international standards, lower level consensus documents can also be published, depending on the identified

[3] ISO/IEC Directives, Part 1, Procedures for the Technical Work and Part 2, Rules for the Structure and Drafting of International Standards (www.iso.org/directives)

need, the maturity of the subject matter, and the urgency of the development. Documents such as Publicly Available Specifications (PAS), Technical Specifications (TS), Technical Reports (TR) and Workshop Agreements (WA) all have their place in the standardization arena. Indeed, instruments such as these, whilst not "full" standards, can have an important role in providing stakeholders with a draft test method, guideline etc., which they can evaluate and which can be further developed if and when considered necessary. The timescales for publication of such documents is substantially shorter than the 3 year "maximum" for full International Standards, e.g. a PAS might be developed and published in just a few months. As with full standards, such "drafts for development" are subject to a detailed review process, though unlike full standards they have a limited life span and are expected to be converted to full standards or withdrawn within certain defined periods following their publication.

One important point to note is that although the process of standardization and review is facilitated and managed by the relevant standardization body, proposals for and the development and approval of standards is the responsibility of the membership of that body. Hence ISO does not develop or approve International Standards—its members do, and therefore statements such as ISO should develop a standard for xxx are quite meaningless. In the case of ISO, the membership consists of 1 representative body, normally though not exclusively the National Standards Body, from each of about 150 National members, whereas CEN membership comprises the 27 members of the EU together with members of European Free Trade Area.

Similar procedures are normally adopted by developers of informal standards (standards development organizations (SDOs), and other interest groups), and depending on the subject matter, degree of consensus, or standardization need, such standards might eventually be adopted by the national standards body (NSB) as a National Standard. This process is typically used in the development and approval of American National Standards by ANSI, which accredits around 280 SDOs for the preparation of national standards.

Written standards are almost universally voluntary. As a non-governmental organization, ISO has no legal authority to enforce their implementation. A certain percentage of ISO standards—mainly those concerned with health, safety or the environment—has been adopted in some countries as part of their regulatory framework, or is referred to in legislation for which it serves as the technical basis. Such adoptions are sovereign decisions by the regulatory authorities or governments of the countries concerned; ISO itself does not regulate or legislate. However, although ISO standards are voluntary, they may become a market requirement, as has happened in the case of ISO 9000 quality management systems, or the dimensions of freight containers and bank cards.

The needs for standardization for nanotechnology

One of the earliest calls for standardization in the field of nanotechnologies was made at a joint VAMAS-CENSTAR Workshop on Measurement Needs for Nanoscale Materials and Devices, held in June 2002 at the National Physical Laboratory, UK, which concluded that "there is an overarching need for methods, standards, reference materials and guidelines in mechanical property determinations for the characterization of nanoscale materials and devices."[4]

[4] VAMAS BULLETIN NO. 25, November 2002 (www.vamas.org)

This call has been repeated numerous times, notably by a workshop entitled "Mapping out Nano Risks", convened by The Health and Consumer Protection Directorate General of the European Commission in March 2004;[5] by the UK Royal Society and Royal Academy of Engineering, in their report "Nanoscience and Nanotechnologies: Opportunities and Uncertainties", published in July 2004;[6] and by the European Commission in their Communication to the Council, the European Parliament and the Economic and Social Committee "Nanosciences and Nanotechnologies: an Action Plan for Europe 2005-2009", published in July 2005.[7]

One area of high, perhaps the highest visibility for nanotechnology is that of health, safety and environmental effects (HS&E). International concerns about unpredictable health and environmental impacts of nanoparticles and other nanoscale materials has led to calls of varying intensity of demand, from the appropriate application of the precautionary principle to an outright ban or moratorium on all work on nanomaterials and nanotechnologies. A number of international fora have emphasized the need for a responsible approach to the research, development and introduction of nanotechnology, and this is now rapidly becoming a mantra for those with a vested interest in the promotion of nanotechnology. However, in most cases it seems that the notion of responsibility is limited to not doing the "wrong" thing, whilst some, including the author, believe that a more appropriate—and "responsible"—view would also include "doing the right thing". This might, for example, include international cooperation in developing those applications of nanotechnologies that could help address global challenges of sustainability, particularly with respect to energy and water.

This is not to suggest that international action on the issue of health, safety and environmental implications of nanotechnology is absent. Probably the most important development in this respect has been the establishment, by the Chemicals Committee of the Organization for Economic Cooperation and Development (OECD) in the autumn of 2006, of the Working Party on Manufactured Nanomaterials (WPMN) to address health and environmental impacts of these potentially important materials.

Looking at the broader area of risk, and considering the risks of both acting and of failing to act in the adoption of nanotechnology applications, the International Risk Governance Council has completed a project and published a white paper on risk governance for nanotechnology,[8] work which was funded by the US EPA, the Swiss Government and Swiss Re.

Numerous international conferences, congresses and meetings have now been devoted, either wholly or partially, to the issues of HS&E and have done much to identify the areas requiring effort. They have also helped to highlight the complexity of the issues and to emphasize the need for international collaboration in developing protocols and test methods to both evaluate the health and safety impacts of nanomaterials and to provide robust and relevant characterization methods applicable to them.

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[5] Nanotechnologies: a Preliminary Risk Analysis on the Basis of a Workshop Organized in Brussels on 1–2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission (http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm).

[6] Nanoscience and Nanotechnologies: Opportunities and Uncertainties, The Royal Society and Royal Academy of Engineering, July 2004 (http://www.nanotec.org.uk/finalReport.htm).

[7] Nanoscience and Nanotechnologies: an Action Plan for Europe 2005-2009, Commission of the European Communities, COM(2005) 243 final.

[8] See: http://www.irgc.org/spip/IMG/projects/IRGC_white_paper_2_PDF_final_version.pdf

National and international standardization activities

The first country to develop and adopt voluntary standards for nanotechnology was China, which published 7 national standards in December 2004, and implemented them the following April, in accordance with the WTO (World Trade Organization) Technical Barriers to Trade (TBT) regulations. These 7 standards included a terminology for nanotechnology; 4 material specifications—for nanoparticle nickel, titanium dioxide, zinc oxide and calcium carbonate; and two measurement techniques—for the determination of particle size distribution of nanometre-sized powders, and for the determination of the specific surface area of solids by gas adsorption (both the last two are based on existing ISO standards). Since that time China has published and implemented another 5 national standards: three in the area of particle sizing; one providing procedures for dispersing (nano) powders in liquids; and one on nanometre-scale length measurement by scanning electron microscopy (SEM).

China's publication of the first national nanotechnology standards occurred shortly before the UK submitted a proposal to ISO for a new Technical Committee for Nanotechnologies. This was confirmed in April 2005, and the new committee—ISO/TC 229 Nanotechnologies—was established in June 2005 with a UK secretariat and chairman. The committee, which has held four meetings to date—November 2005 in London, June 2006 in Tokyo, December 2006 in Seoul and June 2007 in Berlin—currently has 38 members, 29 "P" and 9 "O".[9] The work of the TC is governed by its scope statement, agreed at the first meeting:

"Standardization in the field of nanotechnologies that includes either or both of the following:

- Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependant phenomena usually enables novel applications;
- Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.

"Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety, and environmental practices."

The scope of the committee's work and other activities are further clarified by the committee's strategy statement, agreed at its first meeting, and its business plan.[9]

Given the "horizontal" nature of its activities, the TC structure consists of 3 Working Groups: Terminology and Nomenclature (WG1, convened by Canada); Measurement and Characterization (WG2, convened by Japan); and Health, Safety and Environment (WG3, convened by the USA). There are currently 10 work items in development: an ISO/TS—terminology and definitions for nanoparticles, which is expected to be published before the end of 2007; an ISO/TR—health and safety practices in occupational settings relevant to nanotechnologies, which should also be published later this year; an ISO/IS (International

[9] For the latest details see: http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeList.TechnicalCommitteeList

Standard) for an endotoxin test on nanomaterial samples applicable to *in vitro* systems, which will be ready for publication in late 2009 or early 2010; and seven recently approved new work items: four in the area of characterization of single walled carbon nanotubes; one on the characterization of multi-walled carbon nanotubes; and two associated with toxicological testing of nanoparticle silver. Three further NWIP—two on additional techniques for the characterization of single walled carbon nanotubes, and one for a terminological framework and core terms for nanotechnologies—are currently out for ballot.

ISO/TC 229 works closely with the CEN TC in the area, via TC 352 "Nanotechnologies" (also chaired by the UK), using the "Vienna agreement" where appropriate, and with IEC/TC 113 "Nanotechnology standardization for electrical and electronic products and systems", chaired by the US, with Germany providing the secretariat. ISO/TC 229 and IEC/TC 113 have established two Joint Working Groups (JWG)—in Terminology and Nomenclature (ISO/TC 229 WG1), and in Measurement and Characterization (TC 229/WG2)—both led by ISO. Close contact will be maintained in the area of HS&E (TC 229/WG3), though it is not currently planned to establish a JWG for this. The two Technical Committees plan to hold joint plenary meetings, starting in December 2007. IEC/TC 113 has also established a third working group, in the area of "performance assessment".

Given the diversity of the subject it is clear that standardization, as with many aspects of nanotechnology, will require collaboration between different disciplines—and for 'disciplines' in the standards arena read 'Technical Committees'. A large number of existing committees already have some activities in the area or will be impacted by nanotechnology and can therefore be expected to have an interest in this field of standardization in the future. Indeed, some of these committees, e.g. TC 24 (Sieves, sieving and other sizing methods), TC 146 (Air quality) and TC 201 (Surface chemical analysis), have already published standards relevant to nanoscale technology and management. Besides these, a number of other bodies have specific interests in standardization for nanotechnology, and in view of these wide interests in the subject, ISO/TC 229 has to date established liaisons with 16 other ISO TCs,[9] with the OECD (Working Party on Manufactured Nanomaterials), with the EC Joint Research Centres (IRMM and Institute for Health and Consumer Protection), with the Asia Nano Forum and with VAMAS. Despite the number of committees already in liaison, it is estimated that eventually some 40 ISO TCs will be directly impacted by developments in nanotechnology and will therefore wish to establish a liaison sometime in the future, if they have not already done so.

In autumn 2006 the TC surveyed members to determine their standardization needs and identified over 100 high priority topics, with 54 being relevant to WG2, 31 relevant to WG3, 5 relevant to a new working group on materials specifications, and 18 relevant to other ISO TCs. The information gathered from the survey is being used to prepare road maps for both the individual working groups and for the TC, the implementation of which will be subject to effective coordination and cooperation between the various stakeholders, both nationally and internationally. Whilst highlighting the necessity for standards development in the area of HS&E, and the need for this to be supported by parallel developments in the areas of terminology and measurement and characterization, the future work of the committee will depend upon the New Work Item Proposals it receives from its members, and could also depend on NWIPs made to other committees with which it works in liaison. The submission and success of these proposals will, in turn, depend upon the resources available to individual member countries, and on specific national and technical committee interests. In support of international cooperation in the area of HS&E, TC 229 is working closely with the OECD WPMN and it is to be hoped that this can help focus national efforts whilst also helping to coordinate and harmonize international efforts in this critical area.

Work in Europe on standardization for nanotechnologies has been ongoing since spring 2004, when a CEN Technical Board Working Group (CEN/TBWG 166) was established to develop a strategy for standardization for Nanotechnologies in Europe. This WG reported in June 2005, with the principal recommendation being that CEN should establish a full Technical Committee in the area, the outcome being CEN/TC 352. This TC was formed in November 2005 and has so far met three times. At its most recent meeting, in Brussels in April 2007, it adopted three NWIPs, for projects to develop a format for reporting the engineered nanomaterials content of products, a guide to nanoparticle measurement methods and their limitations, and a guide to methods for nanotribology measurements.

Whilst international standardization provides the ultimate target for much activity, standardization at a national level has an important role to play, either by providing basis documents for NWIPs for ISO or CEN, or for areas where the subject matter is of largely national, as opposed to international or regional interest. Besides the activities in China referred to earlier, there has been growing activity in a number of other countries. In June 2005 the UK published the Publicly Available Specification (PAS) "Vocabulary for Nanoparticles" (PAS 71), which, in a departure from convention, was made freely available on the world wide web,[10] and has so far been downloaded around 1000 times. This document was used as the basis document for the first NWIP to ISO/TC 229 for a Technical Specification: Terminology and Definitions for Nanoparticles. The UK National Committee, NTI/1, is currently engaged in developing another six sector-specific terminologies—for the bio-nano interface, carbon nanostructures, medical, health and personal care applications of nanotechnologies, nanofabrication, nanomaterials, and nanoscale measurement terms including instrumentation, which it also plans to make available for free download on the web and which will be used as basis documents for further NWIPs to ISO/TC 229. In addition, the UK is working on three other standards—a guide to labelling of manufactured nanoparticles and products containing manufactured nanoparticles, a guide to specifying nanomaterials, and a guide to the handling and disposal of engineered nanoparticles.

In Germany, "Guidance for handling and use of nanomaterials at the workplace" will be published soon. This is intended to assist the safe manufacture and use of nanomaterials and to offer recommendations reflecting the current state of the relevant science and technology.

In Korea, at the end of 2006 there were more than 110 domestic nanomaterial-related standards. This number is expected to increase significantly in the near future, in due consideration of the increasing importance of nanotechnologies to both domestic and the global economies as a future engine for industrial growth.

In the USA, the establishment of the ANSI (American National Standards Institute) Nanotechnology Standards Panel in June 2004 provided a coordination body for the

[10] http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PAS-71/

advancement of nanotechnology standardization. In 2006 the Institute of Electrical and Electronics Engineers published the first measurement standard for the electrical properties of carbon nanotubes (IEEE 1650),[11] and the American Society for Testing Materials International published its Terminology for Nanotechnology.[12] The latter organization is actively involved in developing standards for nanotechnologies, particularly in the area of physical, chemical and toxicological characterization, where it has eight projects under development.

The Russian Technical Committee TC 441 "Nanotechnologies and Nanomaterials" has developed 4 national standards in the field:

- Single-crystal silicon nanometre-range relief measure. Geometrical shapes, linear size and manufacturing material requirements;
- Nanometre-range relief measure with trapezoidal profile of elements. Method for verification;
- Atomic force scanning probe measuring microscopes. Method for verification;
- Scanning electron measuring microscopes. Method for verification.

The diversity of aspects of nanotechnologies that will be impacted by and benefit from standardization in the area were highlighted in a recent issue of ISO Focus (April 2007). Besides reviewing the activities of the three working groups of ISO/TC 229—terminology and nomenclature, measurement and characterization, and health, safety and the environment—the special issue contained articles looking at medical opportunities, food and agriculture, insurance, electronics, sustainability and global challenges, ethical, legal and societal issues, economic aspects, etc.

Conclusions

International collaboration in the development and introduction of standards for nanotechnology, particularly in the areas of terminology and nomenclature, measurement and characterization, and health, safety and the environment, will greatly assist the early commercialization, market development and consumer acceptance of these new and potentially far reaching technologies.[13]

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[11] 1650-2005 IEEE Standard Test Methods for Measurement of Electrical Properties of Carbon Nanotubes, IEEE, 2005.

[12] E2456-06 Standard Terminology Relating to Nanotechnology (http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2456.htm?E+mystore).

[13] Any views expressed in this paper are those of the author and should not be construed as representing general views of the International Organization for Standardization, the ISO Technical Committee for Nanotechnologies, ISO/TC 229, or of any of its members.