Needs for and status of standardization for nanotechnologies

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Introduction

In a formal sense standards fall into one of two categories – measurement standards, providing the base or fundamental units of a measurement system, and written standards, which provide agreed ways of: naming, describing and specifying things; measuring and testing things; managing things e.g. quality and environmental management, e.g. ISO 9001 and ISO 14000; and reporting things, as in e.g. ISO 26000 (Social Responsibility), which is currently under development.

Such written, consensual, standards, whether formal (national, regional or international) or informal (company, trade association, interest group, etc) can support business and other related activities in one or more of the following ways: they can provide a technical, quality, and/or environmental management basis for procurement; they can provide support to specific user groups against what may be seen as unfair competition; they can provide technical support for appropriate legislation/regulation.

It is true to say that 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 commercialisation of a particular technological development, though more recently standardization has been viewed, by some at least, as an instrument that can provide support for commercialisation and market development, particularly in areas that are identified as strategically, economically and/or socially important and technically challenging.

Nanotechnologies are recognised as being all of these and more: they are 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; they are viewed as economically important, with a projected market impact of between $500 billion and $3,000 billion per annum by 2015 (1), equivalent to something between 6% and more than 30% of the value of world exports in 2005; they 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 nanotechnologies will extend across national boundaries and will almost invariably have a global impact; and last, but by no means least, there is increasing public anxiety about the potential negative health and environmental impacts of certain aspects of nanotechnologies. All of these factors mean that early standardization will be important for the successful commercialisation, market development and consumer acceptance of many if not most of the applications of nanotechnologies under development or under consideration.

Standards and standardization

As already indicated, 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 organisation. Formal standards are those standards 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 Organisation 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 those involved in their development and approval maintains sustained opposition to their contents (not quite the same as unanimity!), and, with very few exceptions, compliance with their requirement is entirely voluntary. Informal standards, whilst also voluntary and based on consensus, are developed by business or professional interest groups, companies, etc.

The process of standards development typically follows a well established pattern, which for international standardization is detailed in the ISO/IEC Directives (2). Development is normally 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) organised 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 organisation, 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 WG 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.

In addition to full consensus documents, such as National, Regional or International standards, lower consensus documents can also be published, depending on the identified 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.

One important point to note is that although the process of standardization 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.

Similar procedures are normally adopted by developers of informal standards (Standards Development Organisations – 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 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 of dimensions of freight containers and bank cards.

The need for standardization for nanotechnologies

One of the earliest calls for standardization in the field of nanotechnologies was made at a joint VAMAS – CENSTAR Workshop on Measurement Needs for Nano-scale 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 characterisation of nano-scale materials and devices.' (3).

This call has been reiterated 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 (4); by the UK Royal Society and Royal Academy of Engineering, in their report entitled 'Nanoscience and nanotechnologies: opportunities and uncertainties', published in July 2004 (5); 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 (6).

One area of very high, perhaps the highest visibility for nanotechnologies, 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 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 nanotechnologies, and this is now rapidly becoming a mantra for those with a vested interest in their adoption. 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 include international cooperation in developing those applications of nanotechnologies that could help address the global challenges of sustainability, particularly for energy and water.

This is not to suggest that international action on the issue of health, safety and environmental implications of nanotechnologies is absent. As mentioned above, the Health and Consumer Protection Directorate General of the European Commission convened a workshop in March 2004 entitled 'Mapping out Nano Risks', which gave rise to twelve recommendations from the experts, including the following, which are all strongly related to standardization: 'developing a nomenclature for NPs, developing instruments, developing risk assessment methods, promoting good practices, developing guidelines and standards, and eliminating whenever possible and otherwise minimizing the production and unintentional release of waste nanosized particles'. In the autumn of 2006, and after significant deliberation, the Chemicals Committee of the Organisation for Economic Cooperation and Development (OECD) established a Working Party on Manufactured Nanomaterials (WPMN) to address health and environmental impacts of these potentially important materials. The Working Party has now developed a detailed programme of work divided into six separate projects:

1. Development of an OECD (Nanosafety) Database on Human Health and Environmental Safety (EHS) research
2. EHS Research Strategies on Manufactured Nanomaterials
3. Safety Testing of a Representative Set of Manufactured Nanomaterials
4. Manufactured Nanomaterials and Test Guidelines
5. Co-operation on Voluntary Schemes and Regulatory Programmes
6. Co-operation on Risk Assessments and Exposure Measurements

With a remit to look 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 (7), 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.

National and international standardization for nanotechnologies

The first country to develop and adopt voluntary standards for nanotechnologies was China, which published 7 national standards in December 2004, and implemented them the following April, in accordance with the WTO (World Trade Organisation) 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 nanometer powders, and for the determination of the specific surface area of solids by gas adsorption (both these latter 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 nanometer-scale length measurement by Scanning Electron Microscopy (SEM).

The publication by China of the first national nanotechnology standards occurred shortly before the UK submitted a proposal for a new ISO Technical Committee for Nanotechnologies. This proposal was confirm in April 2005, and the new committee – ISO/TC 229 – Nanotechnologies – was formally established in June 2005 with a UK secretariat and chairman. To date the committee has held four meetings - November 05 in London, June 06 in Tokyo, December 06 in Seoul and June 07 in Berlin. The next meeting will be in Singapore in December. The committee currently has 37 members - 29 'P' and 8 'O' – see (8) for details. 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-dependent 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 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 3 work items in development: an ISO/TS - terminology and definitions for nanoparticles, which is subject to a ballot as a Committee Draft; an ISO/TR - health and safety practices in occupational settings relevant to nanotechnologies, which should be published later this year; and an ISO/IS (International Standard) - endotoxin test on nanomaterial samples for in vitro systems, which will be ready for publication in late 2009 or early 2010. The committee has recently approved 6 new work items – four in the area of characterization of single walled carbon nanotubes and two associated with toxicological testing of nanoparticle silver, and work will start on these shortly. Three further NWIP – one on characterization of multi-walled carbon nanotubes, one on a further technique 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 (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.

Given the diversity of the subject it is clear that standardization, as with many aspects of nanotechnologies, will require collaboration between different disciplines – and for disciplines in the standards arena read Technical Committees. A large number of existing committees already work in the area or will be impacted by nanotechnology and can therefore be expected to have an interest in this field of standardization. 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 a specific interest in standardization for nanotechnologies, and in view of these wide interests in the subject, ISO/TC 229 has to date established liaisons with

15 other ISO TC's (8), with the OECD (Working Party on Manufactured Nanomaterials), with the EC Joint Research Centres (IRMM and Institute for Health and Consumer Protection, Ispra), with the Asia Nano Forum and with VAMAS. Despite the elatively high number of existing committees in liaison, it is estimated that some 40 ISO Technical Committees will be directly impacted by nanotechnologies and will therefore wish to establish a liaison sometime in the future, if they have not already done so.

In autumn 2006 the TC undertook a survey of the standardization needs of members, which 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, though the implementation of these will be subject to effective coordination and cooperation between the various stakeholders, both nationally and internationally. Whilst highlighting the need for standards development in the area of HS&E, and for this work to be supported by parallel developments in the areas of terminology and measurement and characterization, the actual future work of the committee will depend upon the NWIPs it receives from its members, and might also depend on NWIPs made to other, liaison committees. 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, particularly within project 3 and 4, 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/BTWG 166) was established to develop a strategy for standardization for Nanotechnologies in Europe. This WG reported in June 2005 with the principal recommendation 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 on:

- Format for reporting the engineered nanomaterials content of products (to be published as a CEN/TS);
- Guide to nanoparticle measurement methods and their limitations (CEN/TR)
- Guide to methods for nanotribology measurements (CEN/TR).

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 for areas where the subject matter is of largely national, as opposed to international interest. Besides the activities in China, referred to earlier, there has been significant activity in a number of other countries. In June 2005 the UK published a Publicly Available Specification (PAS) 'Vocabulary for Nanoparticles' (PAS 71), which was made freely available on the www (9) 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. It is understood that the UK National Committee, NTI/1, is currently engaged in developing another 6 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 www and will use as basis documents for further NWIPs to ISO/TC 229. In addition it is understood that the UK is working on three other standards – a guide to labelling of engineered nanoparticles and products containing engineered nanoparticles, a guide to specifying nanomaterials, and a guide to handling and disposal of engineered nanoparticles.

In Germany, a guideline 'Guidance for handling and use of nanomaterials at the working place' 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 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 considering the increasing importance of nanotechnologies to both the 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 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) (10) and the American Society for Testing Materials International published its Terminology for Nanotechnology (11). The latter organisation is actively involved in developing standards for nanotechnologies, particularly in the area of physical, chemical and toxicological characterization, where it has 8 projects under development.

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

- Single-crystal silicon nanometer range relief measure. Geometrical shapes, linear size and manufacturing material requirements;
- Nanometer 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 nanotechnologies, particularly in the areas of terminology and nomenclature, measurement and characterization, and health, safety and the environment, will greatly assist the early commercialisation, market development and consumer acceptance of these new and potentially far reaching technologies.

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

References

(1) The Economic Development of Nanotechnology – An Indicators Based Analysis, Dr Angela Hullman, The European Commission, DG Research, downloadable from http://cordis.europa.eu./nanotechnology

(2) ISO/IEC Directives, Part 1, Procedures for the technical work and Part 2, Rules for the structure and drafting of International Standards, see www.iso.org/directives

(3) VAMAS BULLETIN NO. 25, November 2002: www.vamas.org

(4) 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.)

(5) Nanoscience and nanotechnologies: opportunities and uncertainties, The Royal Society and Royal Academy of Engineering, July 2004 - http://www.nanotec.org.uk/finalReport.htm

(6) Nanoscience and nanotechnologies: An action plan for Europe 2005-2009, Commission of the European Communities, COM(2005) 243 final

(7) See: http://www.irgc.org/spip/IMG/projects/IRGC_white_paper_2_PDF_final_version.pdf

(8) See: http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeList.TechnicalCommitteeList

(9) See: http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PAS-71/

(10) 1650-2005 IEEE Standard Test Methods for Measurement of Electrical Properties of Carbon Nanotubes, IEEE, 2005

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