



**International Workshop on Documentary Standards
for Measurement and Characterization in Nanotechnologies
NIST, Gaithersburg, Maryland, USA
26 – 28 February 2008,**

1. Summary of main conclusions and recommendations

1.1 In order to enhance the development, efficacy, harmonization and uptake of documentary standards broadly relevant to the field of measurement and characterization for nanotechnologies, there is a **pressing need for**:

- Greater communication and coordination within and between the various standards development organisations and with interested metrology laboratories;
- The development of a centralized, maintained, searchable and freely accessible repository of information on existing standards and standardization projects in the field;
- The development and introduction of a freely accessible, and searchable terminology and definitions database;
- The wider participation of stakeholders in identifying and verifying standards needs;
- Consideration of all available standardization instruments from Workshop Agreements through to full consensus Standards and their equivalents in order to provide stakeholders with relevant documents in a timely manner;
- Urgent and detailed consideration of the instruments needed to address current concerns and challenges in investigating the implications for human health and environmental safety of manufactured nanomaterials.

1.2 Whilst recognising the need for the development of standards related techniques and protocols for characterization at the nanoscale, a clear need was also expressed for good practice /guidance documents covering the suitability and limitations of measurement and characterization techniques for use with nanomaterials.

Such good practice /guidance documents should, inter alia, cover the following topics:

- information needed when handling/using nanoparticles
- suites of measurement techniques that go together and the information the combined data set might provide (what measurement techniques are applicable and what are their limitations);
- sample preparation for measurement, including consideration of dispersion and aggregation/agglomeration;
- sample preparation for human and eco-toxicology testing;
- stability considerations relevant to manufactured nanomaterials;
- application and limitation of surface analysis to nanoparticles;

- the meaning of concentration in the context of nanoparticle dispersions, and how it should it be expressed;
- dose measurement and dosimetry for in-vitro and in-vivo human and ecotoxicology studies

1.3 In the specific area of human health and toxicology, there is a need for greater dissemination, verification and validation of handling and testing protocols and related procedures by the broader community. In particular, there is a pressing need to develop protocols for: pharmacokinetics - ADME (absorption, distribution, metabolism, excretion) and Toxicology screening tests; particle characterization protocols, such as MALDI (matrix-assisted laser desorption/ionization) and SIMS (secondary ion mass spectrometry), that take into account the presence of biological coatings; methods to determine the stability of nanomaterials in biological matrices; and guidance documents for the preparation of suspensions of nanomaterials in various media, particularly biologically relevant fluids.

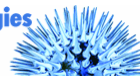
1.4 In the area of nanomaterials characterization, there is a need for clarity in the identification of measurands related to several materials properties, including those corresponding to endpoints addressed by the OECD WPMN's Sponsorship Programme for the Testing of Manufactured Nanomaterials. In this general area there is perhaps a greater need for new measuring instruments and techniques than for new documentary standards, though the former, once developed, will need validation and verification and ultimately the preparation and delivery of standards covering the techniques and principles used. In the specific case of nanoparticles, it is not generally realized that particle size distribution is not a fundamental property of the material being studied, but a temporary state of dynamic equilibrium between dispersion and agglomeration in suspensions or aerosols. This, and numerous other differences between perception and reality, present tremendous challenges in such a high profile subject area.

2. Action items agreed by the workshop participants

2.1 Communication/information sharing

- Development of a discussion forum (continually updated) to align information and developments from the different SDOs (**IEEE agreed to develop and host this on its web site**).
- Development of a centralized, maintained, searchable and freely accessible repository of information on existing standards and standardization projects (NWIs) in the field. A preliminary list of existing standards and current standardization projects on measurement and characterization for nanotechnologies (attached as Annex C) was assembled at the workshop, and will be used as a basis for the development of the database (**NIST agreed to seek support to enable it to develop and host this on the NIST website**).
- Development of a database of existing measurement tools and new tools needed (**volunteer organization will be sought**).
- Development of a searchable database covering definitions (terminology) from all sources. Such an instrument should be freely accessible on the web,¹ and allow for the consolidation of new terms (dustiness, for example) defined by a relevant

¹ Terminology will be freely available, along with a free access layer for search and navigation in the content. This does not preclude the possibility of developing other information layers and added value services, whose access could be restricted.



source, whenever needed. An agreement amongst the various concerned parties maybe needed, to make terminology available from a single source. (**ISO agreed to develop a platform for managing terminology(ies) for nanotechnologies, through the new “ISO Concept Database”**. ISO/TC 229 was proposed² to coordinate terminology with other TCs, with Dr Clive Willis, Convenor of JWG1, assuming the coordination role.)

2.2 Coordination

Potential co-ordination mechanism for ISO and IEC committees

- Use of existing liaison structure
- Current TC229 liaisons with TC24, TC146, TC194, TC201, TC202, TC209, TC213, IEC/TC113 and OECD, and IEC in liaison with IEEE and SEMI
- Participation of many relevant metrology institutes through national participation in TC229.
- It was proposed³ to establish a “Nanotechnologies Liaison Coordination Group”, which will meet at each TC229 plenary week:
 - Proposed membership: open to liaison officers from each relevant ISO and IEC TC and/or SC, liaison from metrology institutes, liaison from OECD WPMN, convenors of TC 229 WGs, 229 chair and secretary, and representatives of other relevant groups.
 - Proposed terms of reference: to coordinate and harmonize the work of relevant TC’s in the field of nanotechnologies and to identify cross cutting gaps and opportunities and ways to resolve these.

3. Evaluation of the workshop and follow-up

The workshop was successful in achieving its objectives of:

- Identifying and exchanging information on existing standards and standardization work programmes
- Identifying short- and medium-term documentary standards needs
- Identifying measurement solutions and other supporting measures, such as pre-normative and co-normative research and certified reference materials, that are necessary to support the development of documentary standards Considering who might contribute and in which specific activities
- Identifying mechanisms for facilitating and enhancing information sharing, cooperation and coordination in the area

The workshop participants took the commitment of strengthening their cooperation (i.a. by implementing the action items highlighted above), with a view to accelerate the development and enhance the efficacy, harmonization and uptake of documentary standards of measurement and characterization for nanotechnologies.

² This proposal should be passed on to ISO TC 229 for approval.

³ This proposal should be passed on to ISO TC 229 and IEC TC 113 for approval.

