**ISO, IEC, NIST and OECD International workshop on documentary standards for measurement and characterization for 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 organizations and with interested metrology institutes;
- 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;
- 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 recognizing the need for the development of standards-related techniques and protocols for characterization at the nanoscale, a clear need was also identified 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 be expressed;
- Dose measurement and dosimetry for *in vitro* and *in vivo* human and eco-toxicology 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 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 Working Party on Manufactured Nanomaterials' (WPMN) 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 standards developing organizations (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 develop and host this on the NIST Web site**.
- 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 source, whenever needed. An agreement amongst the various concerned parties may be 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 proposed[2] to coordinate terminology with other TCs, with Dr Clive Willis, Convenor of JWG 1, assuming the coordination role.

### 2.2 Potential coordination mechanism for ISO and IEC committees

- Use of existing liaison structure.

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

- Current ISO/TC 229 liaisons with ISO/TC 24, ISO/TC 146, ISO/TC 194, ISO/TC 201, ISO/TC 202, ISO/TC 209, ISO/TC 213, ISO/REMCO, IEC/TC 113 and OECD, and IEC in liaison with IEEE and SEMI.
- Participation of many relevant metrology institutes through national participation in ISO/TC 229.
- It was proposed[3] to establish a "nanotechnologies liaison coordination group", which will meet at each ISO/TC 229 plenary week.
  - Proposed membership: open to liaison officers from each relevant ISO and IEC TC and/or SC, liaison with metrology institutes, liaison with OECD WPMN, convenors of ISO/TC 229 WGs, ISO/TC 229 chair and secretary, and representatives of other relevant groups.
  - Proposed terms of reference: to coordinate and harmonize the work of relevant TCs in the field of nanotechnologies and to identify cross-cutting gaps and opportunities and ways to address 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 committed to 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.

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

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## 1. INTRODUCTION

The high global interest in the field of nanotechnologies has increased pressure on standards makers to develop deliverables to support commercial and regulatory needs. Standardization activities in the field are taking place at the international level and in many countries, involving a broad range of interests and organizations.

The area of measurement and characterization has a fundamental supporting role in nanotechnology development, thus requiring special and early attention. In particular, there is a pressing need for the development, validation and approval of standardized methods for physico-chemical characterization of manufactured nanomaterials to support human and eco-toxicology testing.

Given the large number and diversity of standards developers and stakeholders actively participating in the field, it is clear that exchange of information and cooperation among the key players in nanotechnologies standardization need to be intensified and promoted, with a view to supporting the emergence of high quality, globally relevant international standards covering both horizontal and sector-specific needs. The workshop was designed to promote such a dialogue among the key players and to capture input and recommendations on relevant matters, including prioritized measurement needs which could be channelled for consideration to the existing technical bodies.

The workshop was jointly sponsored by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the U.S. National Institute of Standards and Technology (NIST) and the Organisation for Economic Co-operation and Development's Working Party on Manufactured Nanomaterials (OECD WPMN), and was generously hosted by NIST at their Gaithersburg, Maryland, facility.

## 2. OBJECTIVES

The workshop was designed to encompass the broad domain of measurement and characterization for nanotechnologies, with a view to:

- 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.

## 3. PARTICIPATION

Participation, which was by invitation, was on the basis of an established track record in standards development at committee/subcommittee chair or convenor level, or equivalent, or particular competence in an area of special relevance.

Annex A contains a list of the organizations represented at the workshop.

## 4. PROGRAMME

All participating groups were asked to present their existing standards portfolios and current and planned activities relevant to nanotechnologies, and any needs they could identify that are not, to their knowledge, being met. These “scene-setting” presentations occupied much of the first day and, together with a moderated discussion on metrology needs and gaps, helped to provide a common baseline for the remainder of the workshop.

The next half day was devoted to four parallel breakout sessions on the theme of documentary and measurement standards needs for fundamental material property characterization. This was followed in the afternoon by four focused breakout meetings on needs for human health and medicine, the environment, electronics, and materials applications.

The final day commenced with a report by the facilitators of the previous afternoon’s breakout meetings, and was followed by the final session, which brought together all participants to consider how future cooperation and coordination could be achieved to ensure stakeholder needs are met, particularly, though by no means exclusively, in the areas of human and eco-toxicology and risk assessment.

The full programme is given in Annex B.

## 5. SCENE SETTING

The scene-setting presentations identified significant numbers of existing documentary standards that are either relevant to or might have relevance for nanoscale measurement or observation. These are listed in Annex C. They also identified several projects and/or areas on which work is planned, about to commence or needed, and these are listed in Annex D.

In summary, the scene-setting sessions highlighted that:

- Much work in the area is already underway in multiple venues:
    - industry, standardization organizations and governments are active, but there is less activity/understanding by end users;
- Industry venues with active work programmes include ASTM International, IEEE-SA and SEMI, amongst others;
- Standards developing venues include ASTM International, IEC, IEEE-SA, ISO and SEMI, amongst others;
- Accessing and recruiting expertise for standards development present a challenge for all committees;
- Inter-governmental activities are largely being coordinated through the OECD;
- Measurement research is being undertaken within the metrology institutes and in the context of VAMAS;

- There is a pressing need for the development of guides and protocols, particularly in the areas of surface analysis and particle sizing – dispersion of nanoparticles poses a particular challenge;
- For many areas of measurement and characterization, there is a need for better understanding of the relevance of measurement results and better definition of the measurand to be evaluated;
- There is a need for improved coordination between the activities of the various committees involved;
- There is a need for pre- and co-normative research in many areas;
- There is a need for reference materials, particularly polydisperse nanoparticles.

Highlights from the presentations in the different areas of measurement and characterization are given in Annex E.

**NMI discussion**

The current status, gaps and needs in the area of metrology identified in the discussions are given in the table below.

| | **Current status** | **Metrology gaps and needs** |
|---|---|---|
| **Dimensional metrology** | - Well-established capability for dimensional nanometrology – excellent international coordination.<br>- GPS (geometrical product specification) key documentary standards used by NMIs for surface texture – wider uptake needed. | - Dimensional measurement of nanoparticles.<br>- Accuracy at sub-nm level over 3D space with mm dimensions and over several 100 mm on 2D substrates.<br>- Probe-sample interaction modeling |
| **Nanomechanical metrology** | - AFM key tool. Pre-normative (VAMAS TWA 22, TWA 29, - - TWA 2) and documentary standards underway (ISO/TC 164, ISO/TC 201) – much to do. Underpinning metrology for contact mechanics being developed. | - Force measurement – AFM spring constant calibration – normal and lateral.<br>- Indentation of complex materials (nanolayers, nanodomains, nanoparticle composites).<br>- Friction at the nanoscale – JKR, Amonton's, environment (water, etc). |
| **Nanostructured materials metrology** | - Many established measurement techniques – strong pre-normative (VAMAS) and ISO documentary standards.<br>- Multiple techniques are required, TEM, SPM, NEXAFS, XRR, XRD, NR, SANS, RBS, Atom Probe, He+ ion microprobe. | - Nanoparticle and nanomaterial reference materials.<br>- Nanoparticle characterization in liquid, composite matrix, dry form.<br>- A coherent strategy is required to apply techniques to understand structure.<br>- SPM methods such as MFM, SCM, KPM. |
| **Nanochemical metrology** | - Strong metrology base.<br>- Significant activity through pre-normative (VAMAS TWA 2) and > 50 standards and technical reports published.<br>- AES, XPS, SIMS, SPM, TXRF, | - SPM (SNOM, AFM) calibration, reference materials, effects of environment, description of probes, cantilever calibration.<br>- Surface analysis of nanostructured materials. |

| | | |
|---|---|---|
| | GDOES. | - Organic and biological materials.<br>- Nanoparticle characterization (surface to core).<br>- New techniques < 50 nm chemical analysis (TERS, etc). |
| **Nanobio metrology** | - NMIs establishing metrology.<br>- BIPM CCQM and JCTM (Joint Committee on Traceability in Laboratory Medicine) are a key focus of metrology for biotechnology – roadmaps.<br>- Single molecule metrology. | - Nanomedicine (European Technology Platform) major area for innovation and new therapeutics.<br>-Quantity, structure, function and activity.<br>- Biochemical techniques that operate *ex situ* or *in vivo*.<br>- Bioactivity of nanoparticles.<br>- Process analytical technologies driving physico-chemical measurement.<br>- Metrology to support IVD Directives. |
| **Nanoelectrical metrology** | - Metrology and characterization methods for Si-based extended CMOS devices – strained Si, high-k materials.<br>- Metrology for novel systems, i.e. (CNTquantized electrical and thermal conductance). IEEE standards for CNTs in development.<br>- Single electron transport measurement. | - Quantum standards based on *c*, *e* and *h* using so-called Quantum Metrological Triangle V, I, f.<br>- Beyond CMOS – metrology for molecular electronics; molecules, CNTs, graphene and nanorods.<br>- Quantum detection and sensors. |

The most important messages from this wide-ranging discussion were the following.

- A measurement result depends on the physical basis of the measurement method used.
- It is necessary to agree on the measurand (referring to the characterization of manufactured nanomaterials prior to toxicity testing).
- Traceability is a prerequisite of a measurement method.
- Customers (generally) want to measure something that predicts performance.
- Standards provide confidence (in the measurement).
- How much measurement is enough – sensitivity analysis is needed (referring to the characterization of manufactured nanomaterials prior to toxicity testing).

## 6. OUTCOMES OF FIRST BREAKOUT SESSION

The first breakout session consisted of four groups, each considering the issue of identifying documentary standards and other needs for fundamental property characterization at the nanoscale.

Whilst the development of standardized techniques and protocols for some material properties was deemed important, a clear need was identified for the development of guidance documents covering both the application and limitations of certain techniques to nanomaterials and related issues, such as sample preparation for characterization and toxicology testing.

The following was highlighted.

a) Measurands are not always clearly defined regarding properties, and clarity is needed in this area.

b) Documentary needs were identified for guides/guidance documents (to include EHS consideration) on:

- Information needed when handling/using nanoparticles;
- Suite of measurement techniques and the information the combined data set might provide (which measurement techniques are applicable and what are their limitations);
- Sample preparation for characterization, including consideration of dispersion and aggregation/agglomeration;
- Sample preparation for toxicology testing;
- Stability considerations relevant to manufactured nanomaterials;
- Application and limitation of surface analysis to nanoparticles;
- Expression of concentration and dosimetry.

c) Documentary needs were identified for specification of nanomaterials:

- For raw materials;
- For process control/quality;
- Performance measures;
- Means to classify or “grade” nanomaterials so users can make informed decisions about what they are purchasing ("fit for purpose", good enough);
- Specification of materials for specific applications:
    - Properties and definitions thereof.

d) Measurement needs were identified for:

- *In situ* measurement tools;
- Standardized measurement methods:
    - measurements that are proven to be appropriate and “fit for purpose”,
    - for mixed production processes, key characteristics of needed NM properties should be specified,
    - identified priorities – which methods should be concentrated on first,
    - determination of “quality” needed – how much is enough;
- Measurements for toxicity testing.

e) Reference material needs:

- Polydisperse reference materials for instrument/measurement performance.

f) Communication mechanisms:

- Combined resources of different committees and organizations to address cross-cutting issues;
- Permanently updated discussion forum to align information and developments from the different SDOs:
    - should include existing standards and NWIs;
- Database of existing measurement tools and new tools needed;
- Definitions (terminology) from all sources in a searchable database, freely accessible:
    - may need to define new terms (dustiness, for example),
    - may need an agreement amongst the various parties to make terminology available in one document.

g) NMI activities:

- Fundamental principles and knowledge of metrology and measurement technologies to inform the standards development activities;

- Prioritize measurement needs;
- NMIs need 2- to 5-year lead time to develop reliable measurement solutions.

## 7. OUTCOMES OF SECOND BREAKOUT SESSION

The second breakout session consisted of four parallel meetings, each considering standardization needs in one of the following sectors: human health and medicine; environment; electronics; and materials applications.

### a) Human health and medicine

*Standards needs – short term (less than 2 years)*

- Protocols for pharmacokinetics – ADME Tox (absorption, distribution, metabolism, excretion) – high priority in OECD;
- Definiton of a minimum set of measurements – size, zeta potential (surface charge), solubility – predictor of toxicity?
- Particle characterization protocols for nanohealth – ones that take into account the biological coating (MALDI, SIMS):
  - Methods for analysis of surface conjugated layers;
- Toxicology screening tests – good or bad for human health;
- Methods to determine NM stability in biological matrices;
- Standards for delivery for NMs – route of exposure:
  - Most should be publicly available specification or technical reports in short term to support community with best practices.

*Measurement needs*

Existing methods/tools:

- Many disparate efforts, NCI-NCL laboratory specifically for nanohealth applications (from characterization through *in vivo*).

New methods/tools needed for:

- Surface stoichiometry (ratio of proteins adsorbed);
- Surface biofunctionality (bioactivity);
- Epitope map (mapping small units of peptides with bio activity);
- *In vivo* imaging of NMs;
- *In vivo* measurements of distribution;
- Cross imaging modalities (modeling).

New tools needed in:

- Separation science;
- Computer simulation and modeling;
- Imaging (CARS, Neutron imaging, attosecond science for tomography at nm scale).

### b) Environment

*Standards needs – top 4 needs for environmental health and safety standardization, voted by the breakout session members*

- Identification of MNP characterization measurands, including those corresponding to OECD endpoints (see presentation from OECD WPMN SG3);
- Standard method to disperse solid nanomaterials in aqueous solutions – protocol for use of surfactant for liquid dispersion;
- Standardized method for sample preparation for *in vitro* and *in vivo* toxicity testing, including use and application of surfactants;
- Checking of applicability of standard P-chem analytical methods for MNP.

### c) Electronics

*Standards needs – short term (less than 2 years; beyond 2 years picture is not clear)*

- Taking IEEE NESR to the next level;
- Decision on what to do with existing nano-enabled products on or entering the market (e.g. nano-enabled batteries);
- IEC/TC 113 Framework Survey;
- Coordination of SDOs involved in nanoelectronics standardization.

### d) Materials applications

*Factors driving standards*

- Life cycle concerns: from concept to end of life. How will nano-enhanced electronics be disposed of (*also discussed in the electronics application session*)?
- What should be specified? What should be measured?
- Understanding nanoscale-driven failure/success modes.
- Multi-committee sponsorship.
- Education/communication readily accessible.
- Need for more source information that is driving nano-enabled products.
- Non-tariff technical barriers to trade (e.g. WTO).

*Measurement needs*

- New tools/techniques needed for:
  - Contactless measurements;
  - Non-destructive techniques;
  - Framework for validation of embedded nano-enabled product claims.

*Physical/chemical parameters to be measured*

| | Size | Shape | Thickness | Surface/Interface comp. | Comp. Purity | Solubility | Adhesion |
|---|---|---|---|---|---|---|---|
| Photovoltaic | x | x | x | xx | x | | x |
| Energy/Batteries | x | x | x | x | x | | |
| Emulsion/Surfactant | x | | | x | x | x | |
| Catalysis | x | x | | xx | x | | |
| Corrosion inhibitors | | | x | x | | x | x |
| Quantum dots | xx | x | | x | x | | x |
| Filters | x | | | | | | x |
| Films Coating | | | x | x | x | | xx |
| Fillers | | x | | x | x | x | x |
| Paints/Coatings | x | | x | x | x | x | xx |
| Composites | x | x | x | x | x | | x |
| Sensors | | | x | x | | | |
| Cosmetics | x | x | | x | x | | |
| MEMS/NEMS | | | x | x | | | x |
| Concrete | x | x | | | x | | |
| | ISO/TC24/TC201, ASTM/E29 | ISO/TC24, TC201, ASTM E29 | ISO/TC202 | ISO/TC201, ASTM/E42 | | | ISO/TC206 |

Red box: critical need
xx: Important measurement need
x: measurement need

## 8. PRIORITIES AND ACTIONS

Key recurring themes expressed throughout the workshop were:
- Existing relevant information;
- Prioritization of measurement needs;
- Terminology;
- Who does what;
- Progress and feedback;
- Communication;
- Coordination.

### a) Priorities

- Greater communication and coordination:
  - Amongst ISO TCs,
  - Between ISO and IEC,
  - Between SDOs;
- Centralized, maintained and freely accessible repository of pertinent information;
- Wider participation of stakeholders in identifying and verifying standards needs;
- Delivery of toxicology testing protocols to the community for refinement and validation;
- Mechanisms, such as PAS, as a rapid means for information dissemination and evaluation;
- OECD endpoints and the list of representative nanomaterials (see presentation from OECD WPMN SG3).

### b) Immediate documentary needs

Practice guides/guidance documents (to include EHS issue consideration) on:
- What information is needed when handling/using nanoparticles;
- Suite of measurement techniques that go together and the information the combined data set might provide (which measurement techniques are applicable and what are their limitations);
- Sample preparation for characterization, including consideration of dispersion and aggregation/agglomeration;
- Sample preparation for toxicology testing;
- Stability considerations relevant to manufactured nanomaterials;
- Application and limitation of surface analysis to nanoparticles;
- Expression of concentration and dosimetry.

### c) Communication needs

- Combination of resources of different committees and organizations to address cross-cutting issues – IEEE agreed to host this on their Web site.
- Permanently updated discussion forum to align information and developments from the different SDOs:
  - should include existing standards and new work items (NWIs).
- NIST agreed to seek support to enable it to host this on the NIST Web site.
- Database of existing measurement tools and new tools needed.
- Definitions (terminology) from all sources in a searchable database, freely available:
  - might need to define new terms (dustiness, for example),
  - might need an agreement amongst the various parties to make terminology available in one document.

- ISO agreed to make the terminology(ies) for nanotechnologies freely accessible on the Web through the new “concept database”. The ISO/TC 229 chair agreed to seek approval from the committee to coordinate terminology with other TCs, with Dr Clive Willis, Convenor of JWG 1, assuming the coordination role.

**d) Coordination**

Potential coordination mechanism for ISO and IEC committees:

- Use of existing liaison structure;
- Current ISO/TC 229 liaisons with ISO/TC 24, ISO/TC 146, ISO/TC 194, ISO/TC 201, ISO/TC 202, ISO/TC 209, ISO/TC 213, ISO REMCO, IEC/TC 113 and OECD, and IEC in liaison with IEEE and SEMI;
- Participation of many relevant NMIs through national participation in ISO/TC 229;
- It was agreed to establish a “nanotechnologies liaison coordination group”, which will meet formally at each ISO/TC 229 plenary week:
    - Proposed membership: liaison officers from each TC and/or relevant SC, liaison with NMIs, liaison with OECD WPMN, convenors of ISO/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 TCs in the field of nanotechnologies and to identify cross-cutting gaps and opportunities and ways to address these.

## 9. CONCLUSIONS

The workshop successfully achieved its objectives of:

- Identifying and exchanging information on existing standards and standardization work programmes;
- Identifying short- and medium-term documentary standards needs;
- Identifying some 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, and considering who might contribute and in which specific activities;
- Identifying tentative mechanisms for facilitating and enhancing information sharing, cooperation and coordination in the area.

The principal outcomes were:

- Lists of existing standards and current standardization projects on measurement and characterization for nanotechnologies, which can be used to establish a database for the area, are to be maintained by NIST and made available through its Web site;
- A list of proposed short-term standardization activities in the area was prepared;
- It was agreed that a Web page of other relevant information in support of communication and coordination in the area would be hosted by IEEE’s Nanoelectronic Standards Roadmap team;
- It was agreed that ISO would make its terminology for nanotechnologies freely accessible though its new “concept database”;
- It was agreed to establish a coordination mechanism for the relevant committees in ISO and IEC in order to facilitate harmonization and to identify cross-cutting gaps and opportunities and ways to address these.

# Annex A

## List of participating organizations

ASTM E42: Surface Analysis

ASTM E56: Nanotechnology

IEC/TC 113: Nanotechnology standardization for electrical and electronic products and systems

ISO/TC 24/SC 4: Sizing by methods other than sieving

ISO/TC 146: Air quality

ISO/TC 201: Surface chemical analysis

ISO/TC 209: Cleanrooms and associated controlled environments

ISO/TC 213: Dimensional and geometrical product specifications and verification

ISO/TC 229: Nanotechnologies

ISO REMCO: Committee for Reference Materials

OECD WPMN SG 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

OECD WPMN SG 4: Manufactured Nanomaterials and Test Guidelines

OECD WPMN SG 7: The Role of Alternative Methods in Nano Toxicology

OECD WPMN SG 8: Exposure Measurement and Exposure Mitigation

SEMI, IEEE-SA

**Participating metrology laboratories**

Canada: National Research Council of Canada (NRCC)

France: Laboratoire National de Metrologie et D'Essais (LNE)

Germany: Physikalisch-Technische Bundesanstalt (PTB)

India: National Physical Laboratory (NPL)

Japan: Advanced Institute of Standards and Technology (AIST)

Korea: Korea Research Institute of Standards and Science (KRISS)

South Africa: National Metrology Institute (NMISA)

Taiwan: Industrial Technology Research Institute (ITRI)

UK: National Physical Laboratory (NPL)

USA: National Institute of Standards and Technology

## Annex B

## International workshop on documentary standards for measurement and characterization in nanotechnologies

### Workshop programme

| Tuesday, 26 February 2008 | |
|---|---|
| 9:00 | **Registration starts** |
| 10:00 am | **Welcome and introduction to NIST**<br>Mary Saunders (NIST) – Workshop Chair |
| 10:10 am | **Participant introductions**<br>All |
| 10:30 am | **Workshop expectations and partners' motivation**<br>Tom Chapin (IEC)<br>Peter Hatto (ISO)<br>Rich Kayser (NIST)<br>Jim Willis (OECD) |
| 11:00 am | **Setting the scene**<br>*Facilitator: Mary Saunders*<br>Presentations from:<br>ASTM: E42, E56<br>IEC/TC:113<br>IEEE-Nanoelectronic Standards Roadmap (NESR)<br>SEMI |
| 12:30 pm | Lunch |
| 1:30 pm | **Setting the scene presentations (cont'd)**<br>ISO TCs: 24/SC 4, 146, 194, 201, 209, 213, 229, ISO REMCO, OECD-Working Party on Manufactured Nanomaterials (WPMN) – SG 3, SG 4, SG 7 and SG 8 |
| 3:15 pm | Break |
| 3.30 pm | **Moderated discussion:** *The development of documentary standards for the measurement and characterization of nanotechnologies – Metrology needs and gaps: perspectives from metrology institutes*<br>*Facilitator: Alan Steele (NRCC, Canada)* |
| 5.00 pm | **Review of information from scene-setting presentations** |
| 5:30 pm | Adjourn |

| Wednesday, 27 February 2008 | |
|---|---|
| 9:00 am | **Day 1 recap**<br>Mary Saunders |

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|---|---|
| 9:05 am | **Instructions for breakout session 1** |
| 9:10 am | **Breakout session 1:**<br>Identifying documentary standards needs: Fundamental property characterization (e.g. physical, chemical and structural)<br>*Four smaller groups addressing the same issue*<br>*(Group members will be pre-selected to ensure a mix of participants in each group)*<br>*Facilitators:*<br>*Kamal Hossain (NPL, UK)*<br>*Harald Bosse ( PTB, Germany)*<br>*Alan Rawle (ASTM E56)*<br>*Peter Hatto (ISO/TC 229)* |
| 10:30 am | Break |
| 10:45 am | **Breakout session 1 (cont'd)** |
| 12:00 pm | Lunch |
| 1:00 pm | **Outcomes from breakout session 1**<br>Brief (5-7 minute) presentations from facilitators highlighting needs identified by breakout groups<br>*Facilitator: Mary Saunders* |
| 1:30 pm | **Breakout sessions 2 to 5:**<br>Identifying documentary standards needs: Nanomaterials in:<br>2. Human health and medicine: *Scott McNeil (ASTM E56 and NIH, USA ) and Laurie Locascio (NIST, USA)*<br>*3.* Environment: *Tero Eklin (OECD WPMN)*<br>4. Electronics IEEE/SEMI: *Jonathan Tucker (IEEE ) and Evelyn Hirt (IEEE ); Robert Scace (SEMI)*<br>*5.* Materials applications: *Steve Freiman (VAMAS ) and Shingo Ichimura (ISO/TC 229)*<br>Breakout sessions will be structured based on how participants prioritize interests in these sessions |
| 3:30 pm | Break |
| 3:45 pm | **Breakout sessions 2 to 5 (cont'd)** |
| 5:00 pm | Adjourn |

Thursday, 28 February 2008

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| 9:00 am | **Reports from facilitators of breakout sessions 2-5**<br>(10 minute presentation + 10 minute discussions for each)<br>*Facilitator: Mary Saunders* |
| 10:15 am | Break |
| 10:30 am | **Prioritization of identified needs and means to achieve these**<br>*Facilitators: Peter Hatto and Ajit Jilla (NIST)* |
| 12:00 pm | Lunch |
| 1:00 pm | **Identifying mechanisms for cooperation and coordination**<br>*Facilitator: Mary Saunders* |
| 2.00 pm | **Summary, action items and next steps**<br>Mary Saunders |
| 2:30 pm | Adjourn |

## Annex C

### Existing standards and standards under development relevant to or which might have relevance for nanoscale measurement or observation (not a comprehensive list)

| **Reference/No.** | **Title** | **Responsible committee** |
|---|---|---|
| **AES, XPS and SIMS** | | |
| E1078-02 | Standard Guide for Specimen Preparation and Mounting in Surface Analysis | ASTM E42 |
| E827-02 | Standard Practice for Indentifying Elements by the Peaks in Auger Electron Spectroscopy | ASTM E42 |
| E902-05 | Standard Practice for Checking the Operating Characteristics of X-Ray Photoelectron Spectrometers | ASTM E42 |
| E983-05 | Standard Guide for Minimizing Unwanted Electron Beam Effects in Auger Electron Spectroscopy | ASTM E42 |
| E995-04 | Standard Guide for Background Subtraction Techniques in Auger Electron Spectroscopy and X-ray Photoelectron Spectroscopy | ASTM E42 |
| ISO 14237:2000 | Surface chemical analysis – Secondary-ion mass spectrometry – Determination of boron atomic concentration in silicon using uniformly doped materials | ISO/TC 201 |
| ISO 15470:2004 | Surface chemical analysis – X-ray photoelectron spectroscopy – Description of selected instrumental performance parameters | ISO/TC 201 |
| ISO 15471:2004 | Surface chemical analysis – Auger electron spectroscopy – Description of selected instrumental performance parameters | ISO/TC 201 |
| ISO 15472:2001 | Surface chemical analysis – X-ray photoelectron spectrometers – Calibration of energy scales | ISO/TC 201 |
| ISO 17560:2002 | Surface chemical analysis – Secondary-ion mass spectrometry – Method for depth profiling of boron in silicon | ISO/TC 201 |
| ISO 17973:2002 | Surface chemical analysis – Medium-resolution Auger electron spectrometers – Calibration of energy scales for elemental analysis | ISO/TC 201 |
| ISO 17974:2002 | Surface chemical analysis – High-resolution Auger electron spectrometers – Calibration of energy scales for elemental and chemical-state analysis | ISO/TC 201 |
| ISO 18114:2003 | Surface chemical analysis – Secondary-ion mass spectrometry – Determination of relative sensitivity factors from ion-implanted reference materials | ISO/TC 201 |
| ISO 18118:2004 | Surface chemical analysis – Auger electron spectroscopy and X-ray photoelectron spectroscopy – Guide to the use of experimentally determined relative sensitivity factors for the quantitative analysis of homogeneous materials | ISO/TC 201 |
| ISO 18516:2006 | Surface chemical analysis – Auger electron spectroscopy and X-ray photoelectron spectroscopy – Determination of lateral resolution | ISO/TC 201 |
| ISO 19318:2004 | Surface chemical analysis – X-ray photoelectron spectroscopy – Reporting of methods used for charge control and charge correction | ISO/TC 201 |
| ISO 20341:2003 | Surface chemical analysis – Secondary-ion mass spectrometry – Method for estimating depth resolution parameters with multiple delta-layer reference materials | ISO/TC 201 |
| ISO 20903:2006 | Surface chemical analysis – Auger electron spectroscopy and X-ray photoelectron spectroscopy – Methods used to determine peak intensities and information required when reporting results | ISO/TC 201 |
| ISO 21270:2004 | Surface chemical analysis – X-ray photoelectron and Auger electron spectrometers – Linearity of intensity scale | ISO/TC 201 |

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| ISO 24236:2005 | Surface chemical analysis – Auger electron spectroscopy – Repeatability and constancy of intensity scale | ISO/TC 201 |
| ISO 24237:2005 | Surface chemical analysis – X-ray photoelectron spectroscopy – Repeatability and constancy of intensity scale | ISO/TC 201 |
| ISO 5472:2001/CD Amd 1 | Surface chemical analysis – X-ray photoelectron spectrometers – Calibration of energy scales/CD Amd 1 | ISO/TC 201 |
| ISO/AWI 29081 | Surface chemical analysis – Auger electron spectroscopy – Reporting of methods used for charge control and charge correction | ISO/TC 201 |
| ISO/DIS 23812 | Surface chemical analysis – Secondary-ion mass spectrometry – Method for depth calibration for silicon using multiple delta-layer reference materials | ISO/TC 201 |
| ISO/DIS 23830 | Surface chemical analysis – Secondary-ion mass spectrometry – Repeatability and constancy of the relative-intensity scale in static secondary-ion mass spectrometry | ISO/TC 201 |
| ISO/TR 18392:2005 | Surface chemical analysis – X-ray photoelectron spectroscopy – Procedures for determining backgrounds | ISO/TC 201 |
| ISO/TR 18394:2006 | Surface chemical analysis – Auger electron spectroscopy – Derivation of chemical information | ISO/TC 201 |
| ISO/TR 19319:2003 | Surface chemical analysis – Auger electron spectroscopy and X-ray photoelectron spectroscopy – Determination of lateral resolution, analysis area, and sample area viewed by the analyser | ISO/TC 201 |
| ISO/WD 10810 | Surface chemical analysis – X-ray photoelectron spectroscopy – Guide to analysis | ISO/TC 201 |
| ISO/AWI 11939 | Standards on the measurement of angle between an AFM tip and surface and its certified reference material | ISO/TC 201 |
| ISO/WD 11775 | Surface chemical analysis -- Scanningprobe microscopy -- Determination of cantilever normal springconstants | ISO/TC 201 |
| ISO/WD 11952 | Guideline for the determination of geometrical quantities using Scanning Probe Microscopes -- Calibration of measuring systems | ISO/TC 201 |
| **STM/AFM** | | |
| E1813-96(2007) | Standard Practice for Measuring and Reporting Probe Tip Shape in Scanning Probe Microscopy | ASTM E42 |
| E2382-04 | Guide to Scanner and Tip Related Artifacts in Scanning Tunneling Microscopy and Atomic Force Microscopy | ASTM E42 |
| E2530-06 | Standard Practice for Calibrating the Z-Magnification of an Atomic Force Microscope at Subnanometer Displacement Levels Using Si(111) Monatomic | ASTM E42 |
| ISO/NP 11039 | Standards on the definition and measurement methods of drift rates of SPMs | ISO/TC 201 |
| ISO/WD 27911 | Surface chemical analysis - Scanning Probe Microscopy-Definition and calibration of lateral resolution of a Near-field optical microscope | ISO/TC 201 |
| ISO 14887 | Sample preparation – Dispersing procedures for powders in liquids | ISO/TC 24/SC4 |
| **Microbeam Analysis** | | |
| ISO 14594:2003 | Microbeam analysis – Electron probe microanalysis – Guidelines for the determination of experimental parameters for wavelength dispersive spectroscopy | ISO/TC 202 |
| ISO 14595:2003 | Microbeam analysis – Electron probe microanalysis – Guidelines for the specification of certified reference materials (CRMs) | ISO/TC 202 |
| ISO 14595:2003/Cor 1:2005 | | ISO/TC 202 |
| ISO 15632:2002 | Microbeam analysis – Instrumental specification for energy dispersive X-ray spectrometers with semiconductor | ISO/TC 202 |

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| | detectors | |
| ISO 16592:2006 | Microbeam analysis – Electron probe microanalysis – Guidelines for determining the carbon content of steels using a calibration curve method | ISO/TC 202 |
| ISO 16700:2004 | Microbeam analysis – Scanning electron microscopy – Guidelines for calibrating image magnification | ISO/TC 202 |
| ISO 17470:2004 | Microbeam analysis – Electron probe microanalysis – Guidelines for qualitative point analysis by wavelength dispersive X-ray spectrometry | ISO/TC 202 |
| ISO 22029:2003 | Standard file format for spectral data exchange | ISO/TC 202 |
| ISO 22309:2006 | Microbeam analysis – Quantitative analysis using energy-dispersive spectrometry (EDS) | ISO/TC 202 |
| ISO 22489:2006 | Microbeam analysis – Electron probe microanalysis – Quantitative point analysis for bulk specimens using wavelength-dispersive X-ray spectroscopy | ISO/TC 202 |
| ISO/FDIS 22493 | Microbeam analysis - Scanning electron microscopy - Vocabulary | ISO/TC 202 |
| ISO/CD 24173 | Microbeam analysis - Guidelines for orientation measurement using electron backscatter diffraction | ISO/TC 202 |
| ISO/CD 25498 | Method of selected area electron diffraction for transmission electron microscopy | ISO/TC 202 |
| ISO/CD 29301 | Microbeam analysis - Analytical transmission electron microscopy - Methods for calibrating image magnification by using periodic pattern in layered structure | ISO/TC 202 |
| ISO/WD 29222 | Standards for thickness measurement of thin films by TEM-EELS and STEM-EDS analytical electron microscopy at the nanometer and subnanometer level | ISO/TC 202 |
| ISO/CD 24597 | Microbeam analysis - Scanning electron microscopy – Measurement methods of image sharpness | ISO/TC 202 |
| **Characterization** | | |
| E56 WK10417 | Standard Practice for the Preparation of Nanomaterial Samples for Characterization | ASTM E56 |
| ISO 10993-19 | Part 19: Physico-chemical, Morphological and Topographical Characterization of Materials (TS, 2006) | ISO/TC 194 |
| ISO WD 30011 | Workplace air – Determination of metals and metalloids in airborne particulate matter by inductively coupled plasma mass spectrometry | ISO/TC 146 |
| ISO/AWI TR 11808 | Nanotechnologies – Guide to nanoparticle measurement methods and their limitations | ISO/TC 229 |
| ISO/AWI TR 11811 | Nanotechnologies – Guide to methods for nanotribology measurements | ISO/TC 229 |
| ISO/AWI TS 10797 | Nanotubes – Use of Transmission Electron Microscopy (TEM) in the Characterization of Single Walled Carbon Nanotubes (SWCNTs) | ISO/TC 229 |
| ISO/AWI TS 10798 | Nanotubes – Scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the characterization of single walled carbon nanotubes (SWCNTs) | ISO/TC 229 |
| ISO/AWI TS 10929 | Measurement methods for the characterization of multi-walled carbon nanotubes (MWCNTs) | ISO/TC 229 |
| ISO/AWI TS 11251 | Nanotechnologies – Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-walled carbon nanotubes (SWCNTs) | ISO/TC 229 |
| ISO/AWI TS 11308 | Nanotechnologies – Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-walled carbon nanotubes (SWCNT) | ISO/TC 229 |
| ISO/FDIS 14488 | Particulate materials – Sampling and sample splitting for the determination of particulate properties | ISO/TC 24/SC4 |
| ISO/NP TS 10812 | Nanotechnologies – Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes | ISO/TC 229 |

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| | (SWCNTs) | |
| ISO/NP TS 10867 | Nanotubes – Use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs) | ISO/TC 229 |
| ISO/NP TS 10868 | Nanotubes - Use of UV-Vis-NIR absorption spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs) | ISO/TC 209 |
| ISO/NP TS 11888 | Determination of mesoscopic shape factors of multiwalled carbon nanotubes (MWCNTs) | ISO/TC 229 |
| ISO/PWI 20998-2 | Measurement and characterization of particles by acoustic methods – Part 2: Guidelines for linear theory | ISO/TC 24/SC 4 |
| ISO/PWI 20998-3 | Measurement and characterization of particles by acoustic methods – Part 3: Guidelines for non-linear theory | ISO/TC 24/SC 4 |
| **Particle size/size distribution** | | |
| ISO CD 28439 | Workplace atmospheres – Sampling of ultrafine aerosols/nanoaerosols – Determining the size distribution and number concentration using mobility particle sizers/differential mobility analysers | ISO/TC 146 |
| E2578-07 | Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions | ASTM E56 |
| E56 WK8705 | Standard guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (PCS) | ASTM E56 |
| ISO 13318-1 | Determination of particle size distribution by centrifugal liquid sedimentation methods – Part 1: General principles and guidelines | ISO/TC 24/SC 4 |
| ISO 13318-2 | Determination of particle size distribution by centrifugal liquid sedimentation methods– Part 2: Photocentrifuge method | ISO/TC 24/SC 4 |
| ISO 13318-3 | Determination of particle size distribution by centrifugal liquid sedimentation methods – Part 3: Centrifugal X-ray method | ISO/TC 24/SC 4 |
| ISO 13320-1 | Particle size analysis – Laser diffraction methods – Part 1: General principles | ISO/TC 24/SC 4 |
| ISO 13321 | Particle size analysis – Photon correlation spectroscopy | ISO/TC 24/SC 4 |
| ISO 13322-1 | Particle size analysis – Image analysis methods – Part 1: Static image analysis methods | ISO/TC 24/SC 4 |
| ISO 13322-2 | Particle size analysis – Image analysis methods – Part 2: Dynamic image analysis methods | ISO/TC 24/SC 4 |
| ISO 13323-1 | Determination of particle size distribution – Single-particle light interaction methods – Part 1: Light interaction considerations | ISO/TC 24/SC 4 |
| ISO 20998-1 | Measurement and characterization of particles by acoustic methods – Part 1: Concepts and procedures in ultrasonic attenuation spectroscopy | ISO/TC 24/SC 4 |
| ISO/CD 21501-1 | Determination of particle size distribution – Single particle light interaction methods – Part 1: Light scattering aerosol spectrometer | ISO/TC 24/SC 4 |
| ISO 21501-2 | Determination of particle size distribution – Single particle light interaction methods – Part 2: Light scattering liquid-borne particle counter | ISO/TC 24/SC 4 |
| ISO 21501-3 | Determination of particle size distribution – Single particle light interaction methods – Part 3: Light extinction liquid-borne particle counter | ISO/TC 24/SC 4 |
| ISO 21501-4 | Determination of particle size distribution – Single particle light interaction methods – Part 4: Light scattering airborne particle | ISO/TC 24/SC 4 |
| ISO 9276-1 | Representation of results of particle size analysis – Part 1: Graphical representation, ISO 9276-1:1998/Cor 1:2004 | ISO/TC 24/SC 4 |
| ISO 9276-2 | Representation of results of particle size analysis - Part 2: Calculation of average particle sizes/diameters and moments from particle size distributions | ISO/TC 24/SC 4 |

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| ISO 9276-4 | Representation of results of particle size analysis - Part 4: Characterization of a classification process | ISO/TC 24/SC 4 |
| ISO 9276-5 | Representation of results of particle size analysis - Part 5: Methods of calculation relating to particle size analyses using logarithmic normal probability distribution | ISO/TC 24/SC 4 |
| ISO 9277 | Determination of the specific surface area of solids by gas adsorption using the BET method | ISO/TC 24/SC 4 |
| ISO DIS 15767 | Workplace atmospheres – Controlling and characterizing errors in weighing collected aerosols | ISO/TC 146 |
| ISO/DIS 15900 | Determination of particle size distribution – Differential electrical mobility analysis for aerosol particles | ISO/TC 24/SC 4 |
| ISO/DIS 9276-3 | Representation of results of particle size analysis – Part 3: Adjustment of an experimental curve to a reference model | ISO/TC 24/SC 4 |
| ISO/DIS 9276-6 | Representation of results of particle size analysis – Part 6: Descriptive and quantitative representation of particle shape and morphology | ISO/TC 24/SC 4 |
| ISO/DIS13320 | Particle size analysis – Laser diffraction methods 40.20 2009 | ISO/TC 24/SC 4 |
| ISO/FDIS 22412 | Particle size analysis – Dynamic light scattering (DLS) | ISO/TC 24/SC 4 |
| ISO/TS 13762 | Particle size analysis – Small angle X-ray scattering method | ISO/TC 24/SC 4 |
| ISO/PWI 27891 | Validation and calibration of aerosol particle number counters | ISO/TC 24/SC 4 |
| PWI | Dispersed Stability Characterisation in Liquids | ISO/TC 24/SC 4 |
| **Pore size** | | |
| ISO 15901-1 | Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption – Part 1: Mercury porosimetry | ISO/TC 24/SC 4 |
| ISO 15901-2 | Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption – Part 2: Analysis of mesopores and macropores by gas adsorption | ISO/TC 24/SC 4 |
| ISO 15901-3 | Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption – Part 3: Analysis of micropores by gas adsorption | ISO/TC 24/SC 4 |
| **Nanomaterial specifications** | | |
| ISO/AWI TS 11803 | Nanotechnologies – Format for reporting the engineered nanomaterials content of products | ISO/TC 209 |
| ISO/NP 11931 | Nanotechnologies – Nano-calcium carbonate | ISO/TC 209 |
| ISO/NP 11937 | Nanotechnologies – Nano-titanium dioxide | ISO/TC 229 |
| ISO/NP 12025 | Nanomaterials – General framework for determining nanoparticle content in nanomaterials by generation of aerosols | ISO/TC 229 |
| **Electrical characterization** | | |
| 1650™-2005 | Standard Test Methods for Measurement of Electrical Properties of Carbon Nanotubes | IEEE |
| P1620.2™ | Standard Methods for the Characterization of Printed and Organic Diode Bridges Structures for RF Devices | IEEE |
| P1690™ | Standard Methods for the Characterization of Carbon Nanotubes Used as Additives in Bulk Materials | IEEE |
| **Cleanrooms** | | |
| ISO 14644-1:1999 | Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness | ISO/TC 209 |
| ISO 14644-2:2000 | Cleanrooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 | ISO/TC 209 |
| ISO 14644-3:2005 | Cleanrooms and associated controlled environments – Part 3: Test methods | ISO/TC 209 |
| ISO 14644-4:2001 | Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up | ISO/TC 209 |
| ISO 14644-5:2004 | Cleanrooms and associated controlled environments – Part 5: Operations | ISO/TC 209 |
| ISO 14644- | Cleanrooms and associated controlled environments – Part | ISO/TC 209 |

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| 6:2007 | 6: Vocabulary | |
| ISO 14644-7:2004 | Cleanrooms and associated controlled environments – Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments) | ISO/TC 209 |
| ISO 14644-8:2006 | Cleanrooms and associated controlled environments – Part 8: Classification of airborne molecular contamination | ISO/TC 209 |
| ISO 14698-1:2003 | Cleanrooms and associated controlled environments – Biocontamination control – Part 1: General principles and methods | ISO/TC 209 |
| ISO 14698-2:2003 | Cleanrooms and associated controlled environments – Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data | ISO/TC 209 |
| ISO 14698-2:2003/Cor 1:2004 | Cleanrooms and associated controlled environments – Biocontamination control – Part 2: Evaluation and interpretation of biocontamination data/Cor 1 | ISO/TC 209 |
| ISO/CD 14644-9 | Cleanrooms and associated controlled environments – Part 9: Classification of surface particle cleanliness | ISO/TC 209 |
| **Health and medical** | | |
| E2524-08 | Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles | ASTM E56 |
| E2525-08 | Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies | ASTM E56 |
| E2526-08 | Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells | ASTM E56 |
| ISO 10993-1 | Biological evaluation of medical devices – Part 1: Evaluation and testing | ISO/TC 194 |
| ISO 10993-2 | Biological evaluation of medical devices – Part 2: Animal welfare requirements | ISO/TC 194 |
| ISO 10993-3 | Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity | ISO/TC 194 |
| ISO 10993-4 | Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood | ISO/TC 194 |
| ISO 10993-5 | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity | ISO/TC 194 |
| ISO 10993-6 | Biological evaluation of medical devices – Part 6: Tests for local effects after implantation | ISO/TC 194 |
| ISO 10993-9 | Biological evaluation of medical devices – Part 9: Framework for the identification and quantification of potential degradation products | ISO/TC 194 |
| ISO 10993-10 | Biological evaluation of medical devices – Part 10: Tests for Irritation and delayed-type hypersensitivity | ISO/TC 194 |
| ISO 10993-11 | Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (2006, NWIP) | ISO/TC 194 |
| ISO 10993-12 | Biological evaluation of medical devices – Part 12: Sample preparation and reference materials | ISO/TC 194 |
| ISO 10993-13 | Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices | ISO/TC 194 |
| ISO 10993-14 | Biological evaluation of medical devices – Part 14: Identification and quantification of degradation products from ceramics | ISO/TC 194 |
| ISO 10993-15 | Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys | ISO/TC 194 |
| ISO 10993-16 | Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables | ISO/TC 194 |
| ISO 10993-17 | Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances | ISO/TC 194 |

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| ISO 10993-18 | Biological evaluation of medical devices – Part 18: Chemical characterization of materials | ISO/TC 194 |
| ISO 10993-20 | Biological evaluation of medical devices – Part 20: Principles and methods for immunotoxicology testing of medical devices | ISO/TC 194 |
| ISO/AWI 10801 | Nanotechnologies – Generation of silver nanoparticles for inhalation toxicity testing | ISO/TC 209 |
| ISO/AWI 10808 | Nanotechnologies – Monitoring silver nanoparticles in inhalation exposure chambers for inhalation toxicity testing | ISO/TC 229 |
| ISO/NP 29701 | Nanotechnologies – Endotoxin test on nanomaterial samples for in vitro systems | ISO/TC 229 |
| **Occupational health** | | |
| E2535-07 | Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings | ASTM E56 |
| ISO 7708 | Air quality – Particle size fraction definitions for health-related sampling (1995) | ISO/TC 146 |
| ISO TR 27628 | Workplace atmospheres – Ultrafine, nanoparticle and nano-structured aerosols – Inhalation exposure characterization and assessment (2006). | ISO/TC 146 |
| **Risk** | | |
| ISO/TS 20993:2006 | Biological evaluation of medical devices – Guidance on a risk-management process http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E983.htm?L+mystore+axhd3469+1192075174 | ISO/TC 194 |
| **Terminology** | | |
| E2456-06 | Standard Terminology Relating to Nanotechnology | ASTM E56 |
| ISO 18115:2001 | Surface chemical analysis – Vocabulary | ISO/TC 201 |
| ISO 18115:2001 /Amd 1:2006 | Surface chemical analysis – Vocabulary Amd 1 | ISO/TC 201 |
| ISO 18115:2001 /Amd 2:2007 | Surface chemical analysis – Vocabulary Amd 2 | ISO/TC 201 |
| ISO 23833:2006 | Microbeam analysis – Electron probe microanalysis (EPMA) – Vocabulary | ISO/TC 202 |
| ISO/AWI TR 11360 | Nanotechnologies – Outline of nanomaterials classification (Nano tree) | ISO/TC 209 |
| ISO/AWI TS 11751 | Terminology and definitions for carbon nanomaterials | ISO/TC 229 |
| ISO/NP 26824 | Particle characterization of particulate systems – Vocabulary | ISO/TC 24/SC 4 |
| ISO/PRF TS 27687 | Nanotechnologies - Terminology and definitions for nanoparticles | ISO/TC 229 |

## Annex D

## New standards needed/planned developments

| Subject | Needed (N) Planned (P) Being developed (D) | Responsible committee |
|---|---|---|
| Oxide sputter rates | N | ASTM E42 |
| Film thickness guide | N | ASTM E42 |
| Film thickness dielectrics | N | ASTM E42 |
| Common material sputter rates | N | ASTM E42 |
| Layered material guide | N | ASTM E42 |
| Thin film/corrosion layer analysis protocol | D | ASTM E42 |
| Preferential Sputtering | N | ASTM E42 |
| Sputter rates compound semiconductors and electronic materials | N | ASTM E42 |
| Protocol/guide on analysis/characterization of self assemble monolayers | P | ASTM E42 |
| Measurement of zeta potential | N | ISO/TC 24/SC 4 |
| Electrostatic stabilization | N | ISO/TC 24/SC 4 |
| Seric stabilization | N | ISO/TC 24/SC 4 |
| Chemically aided dispersion | N | ISO/TC 24/SC 4 |
| Mechanically aided dispersion | N | ISO/TC 24/SC 4 |
| Dispersion index (indices) | N | ISO/TC 24/SC 4 |
| Ultra-thin film analysis with AES | P | ISO/TC 201 |
| Surface analysis of nanostructured materials with AES | P | ISO/TC 201 |
| Multivariate analysis for SIMS | P | ISO/TC 201 |
| Linearity intensity scale for SIMS | P | ISO/TC 201 |
| Organic damage through the use of SIMS | P | ISO/TC 201 |
| SIMS quantification | P | ISO/TC 201 |
| SIMS depth profiling of organic layers | P | ISO/TC 201 |
| Day-to-day performance of XPS | P | ISO/TC 201 |
| Determination of surface normal in XPS analysis | P | ISO/TC 201 |
| Thickness ultra-thin SiO2 by the use of XPS | P | ISO/TC 201 |
| Guide to XPS analysis | P | ISO/TC 201 |
| SPM – drift rate | P | ISO/TC 201 |
| Reference materials and calibration methods for use with SPM | P | ISO/TC 201 |
| AFM tip-surface angle | P | ISO/TC 201 |
| AFM environment effects | P | ISO/TC 201 |
| AFM probe characterization | P | ISO/TC 201 |
| Cantilever normal spring constant | P | ISO/TC 201 |
| Terminology for nanoscale measurement applications | P | ISO/TC 229 |
| Terminology for bio-nano interface applications | P | ISO/TC 229 |
| Terminology for nanofabrication applications | P | ISO/TC 229 |
| Terminology for medical, health, and personal care applications | P | ISO/TC 229 |
| Terminology for nanomaterials applications | P | ISO/TC 229 |
| Measurement and characterization of carbon nanotubes and related structures | P | ISO/TC 229 |
| Measurement and characterization of engineered | P | ISO/TC 229 |

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| nanoparticles | | |
| Measurement and characterization of coatings | P | ISO/TC 229 |
| Nanostructured materials (composite and porous structures) | P | ISO/TC 229 |
| Basic metrology at the nanoscale | P | ISO/TC 229 |
| Guidance for the characterization, specification and production of reference materials | P | ISO/TC 229 |
| Determining relative toxicity/hazard potential of nanomaterials | P | ISO/TC 229 |
| Nanoparticle toxicity testing | P | ISO/TC 229 |
| Nanoparticle inhalation testing | P | ISO/TC 229 |
| Toxicological screening of nanomaterials:<br>In vitro toxicology test<br>In vivo toxicology test | P | ISO/TC 229 |
| Life cycle assessment of nanomaterials | P | ISO/TC 229 |
| (WK8705) Guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (pcs) | D | ASTM E56 |
| WK8051 Standard terminology for nanotechnology – continuous update and revision | D | ASTM E56 |
| Mobility/zeta potential | P | ASTM E56 |
| Nanotechnology ontology | P | ASTM E56 |
| Interlaboratory studies to generate data necessary to develop precision and bias statements for:<br>• E56 WK8705: Standard guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (PCS)<br>• E2524-08: Standard practice for analysis of hemolytic properties of nanoparticles<br>• E2526-08: Standard practice for evaluation of cytotoxicity of nanoparticulate materials on porcine kidney cells and human hepatocarcinoma cells | P | ASTM E56 |
| Generate ancillary data to support E56 WK8705 bias statement using<br>• Atomic force microscopy (AFM)<br>• Transmission electron microscopy (TEM) | P | ASTM E56 |
| Test sample preparation methods for E56 WK10417: Standard practice for the preparation of nanomaterial samples for characterization<br>test materials:<br>• RM 8011, nominal 10 nm diameter gold nanoparticles<br>• RM 8012, nominal 30 nm diameter gold nanoparticles<br>• RM 8013, nominal 60 nm diameter gold nanoparticles<br>• Amine terminated G6 PAMAM dendrimers<br>• Hydroxy terminated G6 PAMAM dendrimers | P | ASTM E56 |

## Annex E – Highlights from scene setting presentations

### 1. Analysis – ASTM E42 and ISO/TC 201

Surface chemical analytical techniques are key for many studies in nanotechnology, nanobiotechnology and nanomedicine.

a) Technological and educational challenges

- Extracting information needed about complex and nanostructured materials:
    - Consider topology and structure in analysis,
    - Complementary information from many techniques,
    - Increased environmental and probe sensitivity.
- Passing along expert knowledge about application approaches to users who need to use an increasing number of methods in complex ways:
    - The USA National Academies Study of Advanced Research Instrumentation observed that:
        - Instrumentation is increasingly advanced, pushing the boundaries of our science and engineering knowledge and our technologic capabilities…
        - The need for particular types of instruments and facilities has broadened, crossing scientific, engineering, and medical disciplines.
        - Instruments that were once of interest only to specialists are required by a wide array of scientists to solve critical research problems. (The National Academies Press, 2006)

b) Pressing needs

- Protocol or Guide on how experts in specific areas would approach a technical or analysis problem using a surface analysis method. For example, researchers who study corrosion ask specific questions from XPS spectra. They collect the spectra in some relatively standard ways to answer those questions and process the data to meet the analysis needs.
- Having a “consensus” protocol provides guidance and direction to dealing with complex analysis issues and passes on the knowledge of experts.

c) Making progress

- Develop protocol guides for characterization of nanomaterials, nanostructures and nanoparticles.
- Establish joint working groups between ISO/TC 229, ISO/TC 201 (and others) on specific problems/materials.
- ISO/TC 201 will prepare more general document(s) on the application of surface analysis to nanomaterials in coordination with ISO/TC 229.
- Future key areas for liaison are measurements of nanoparticles, applications to nanotechnology and SPM based methods.

### 2. Particle sizing and characterization – ISO/TC 24/SC 4

Principal challenge: Particle size distribution is not a material property, but a *temporary state* of a dynamic equilibrium between dispersing and agglomerating effects *in suspensions or aerosols.*

a) Areas of standardization in nanotech related areas

- Representation of results of particle size analysis,
- Particle characterization methods,

- Sampling, accuracy, calibration, reference material needs.

b) Program drivers, customers/stakeholders
- Measurement instrument producers,
- Chemical, pharmaceutical and food industries,
- Microelectronic and other clean room industries,
- Environmental protection agencies:
  - Outdoor environmental air pollution and climate change monitoring,
  - Engine exhaust regulatory certifications,
  - Traffic-related aerosol pollution surveys,
- Workplace environmental health and industrial hygiene surveys,
- Mining occupational health regulations,
- Filter performance testing and certification,
- Aerosol research.

c) Prioritization challenges
- Nomenclature,
- Reference materials,
- Guidance on dispersion issues,
- Fundamental knowledge issues:
  - Interparticle forces.

d) Measurement and characterization needs
- Measurement of polydispersity at the nanoscale,
- Standards for particle handling scenarios, e.g.
  - ISO/TC 229 N 290 NWIP General framework for determining nanoparticle content in nanomaterials by generation of aerosols,
- Supporting reference materials:
  - Specific needs for different characterization methods – in particular a need for Polydisperse reference materials for instrument calibration/measurement performance.

e) Pre- and co-normative research needs
- Certification methods for reference materials.

f) Market need/demand
- Online methods with link to the lab methods,
- Do people really use our standards?

g) Technical or policy issues
- Sampling and dispersion:
  - Correct choice of measurement technique,
  - What degree of accuracy/precision can be expected?
  - Work item coordination between TCs within ISO.

h) Major Current issues include
- Reference materials for particle sizing,
- Dispersion,
- Dissemination of standards.

### 3. Contamination control with clean rooms ISO/TC 209

Prioritization challenges: Facility requirements for safety and contamination control will be driven by problems encountered as new products are commercialized – difficult “to get ahead of the curve” because of time to develop standards.

a) Fundamental knowledge issues
   - Controlled environment requirements for vibration, EM, T, RH and contaminates are unknown for emerging concepts,
   - Contemporary techniques have not been tested for nanomaterials,
   - Nanobio requirements with respect to regulated industries.

b) Measurement and characterization needs
   - Low concentration quantification in all media and surfaces. (Air is the most advanced with condensation nuclei counters.)

c) Supporting reference materials needs
   - nanoparticles, well characterized surfaces.

d) Pre- and co-normative research needs
   - Where contamination limits manufacturing in nanoscale dimensions, new technologies might be needed for isolation, cleaning and inspection.

e) Market need/demand
   - The need for standardization with respect to facilities will build as nanotech industry advances.

f) Technical or policy issues
   - The anticipated nanotech contamination control WG will be centered in ISO/TC 209 – need policies to facilitate alignment with all WGs in ISO/TC 229 (e.g. common terminology, use and review of documents, identification of experts, participation in road mapping).

**4. Air quality – ISO/TC 146**

a) Area of standardization related to nanotech
   - airborne nanoparticle exposure characterization and assessment.

b) Program drivers
   - regulatory compliance needs.

c) Customers/stakeholders
   - Industrial hygienist professionals, regulators.

d) Pertinent work completed
   - ISO 7708, *Air quality – Particle size fraction definitions for health-related sampling* (1995),
   - ISO TR 27628, *Workplace atmospheres – Ultrafine, nanoparticle and nano-structured aerosols – Inhalation exposure characterization and assessment* (2006).

e) Immediate and medium-term plans
   - proposed standard on sampling conventions for assessing particulate mass as deposited in the human respiratory system.

f) Challenges and obstacles
   - lack of completed research for standards.

g) Measurement strategy is needed, as not one instrument covers all metrics
   - Number or surface or mass?
     - one single parameter will not suffice;
   - No sense regarding limiting values,
     - but experience from surveys:

  - recommended range 5 to 600 nm,
  - integrated concentration up to $10^8$ $cm^{-3}$;
- Temporal variation:
  - leads to artificial peaks in size distribution,
  - need for buffer vessel;
- Assessment of shift versus short time average:
  - depending on future limit values;
- Discrimination from the background:
  - either from other sources nearby, or
  - from external environment;
- Determination of product particles versus ambient particles;
- Personal sampling not currently possible;
- Description of measurement parameters for later comparisons;
- Instrument calibration;
- Measurement uncertainty:
  - How reproducible are the various instruments?
  - How do similar instruments compare?
  - How accurate do the instruments measure, e.g. size distributions in the small-particle region?
- Need for a round-robin comparison of available instruments for addressing uncertainty and lab practices;
- Supporting reference materials:
  - reference particles for characterizing size,
  - particle generators for relative number concentration,
  - coagulation process with predictable concentration profile over time for absolute number concentration (in the future).

**5. Biological evaluation of medical devices – ISO/TC 194**

a) Current programme
- Material characterization; risk management; biological evaluation (safety) and biological evaluation tests;
- Program drivers – Nanotechnology materials (nanoparticles) are starting to be used in medical devices; awareness that physico-chemical and biological properties, body distribution and elimination, chemical reactivity and toxicological effects of nanoparticles might be different to particles of larger dimensions;
- Customers/stakeholders - Patients, healthcare professionals, carers, consumers;
- Pertinent work completed – ISO TS 10993-19, Physico-chemical, morphological and topographical characterization of materials.

b) Prioritization challenges
- Risk management standard ISO 14971 does not refer to potential nanotechnologies hazards;
- Fundamental knowledge issues:
  - very little data available on characterization, exposure and effects of engineered nanoparticles;
- Measurement and characterization is needed;
- Supporting reference materials are needed;
- Market need/demand:
  - Public, patients and healthcare professionals expect/demand technology applications to be safe during manufacture, in use and in disposal.

**6. Dimensional and Geometrical Product Specifications and Verification – ISO/TC 213**

a) Area of nanotech standardization

- Methods for measuring surface texture and heights of surface features.

b) Program drivers
- To accommodate 3D methods (filtering and parameters) in surface texture analysis standards. Previous standards were 2D.

c) Customers/stakeholders
- Metrology suppliers
- Manufacturers of mechanical systems (autos, aircraft,…)

d) Pertinent work completed
- Approximately six existing standards, including ISO 5436 on measurement standards.

e) Work underway
- ISO 25178 – Many parts;
- Part 2 – Terms and parameters – in DIS ballot;
- Part 6 – Classification of methods – passed DIS ballot;
- Parts 601, 602, etc. – Metrological characteristics of individual methods;
- Parts 701, 702, etc. – Standards and procedures for different methods.

f) Prioritization efforts underway (e.g., roadmap development)
- ISO/TC 213 Master plan – ISO 14638;
- WG16 Master plan – unpublished N-doc;
- Part 6 – Useful for setting the context.

g) Collaborations
- Project team on optical methods has produced:
- Chromatic confocal – Pt 602;
- Phase Shifting Interferometry – Pt 603;
- Coherence Scanning Interferometry – Pt 604.

h) Immediate and medium-term plans
- International Standards for Parts 2, 6, 602, 603, 604;
- Developing a comparable standard for AFMs.

i) Challenges and obstacles
- Describing the useful ranges of instruments;
- Establishing correlations between methods.

j) Prioritization challenges
- None – Instrument makers are motivated to participate.

k) Fundamental knowledge issues
- The surface is defined to be the “mechanical” surface.

l) Measurement and characterization needs
- Recognizing the bandwidth limits of measurement;
- Supporting reference materials;
- Calibrations of suppliers’ reference materials.

m) Pre- and co-normative research needs
- Demonstrating agreement between different instruments.

n) Market need/demand
- Calibrating instruments for measuring surface texture of precision mechanical components, optics, and semiconductors.

o) Technical or policy issues
  - Information requirements, automation, file formats, and interoperability
  - Publishing and copyright.

p) Other
  - The committee master plan provides a good context for standardization of different methods.

## 7. Nanotechnology – ASTM E56

a) Committees
  - Three technical subcommittees:
    - Subcommittee on terminology and nomenclature,
    - Subcommittee on characterization: physical, chemical, and toxicological properties,
    - Subcommittee on environment, health and safety;
  - Two resource subcommittees:
    - Subcommittee on international law and intellectual property,
    - Subcommittee on liaison and international cooperation.

b) Scope
  - The Scope of the committee shall be twofold: 1) the development of standards and guidance for nanotechnology and nanomaterials, and 2) the coordination of existing ASTM standardization related to nanotechnology needs. This coordination shall include the apportioning of specific requests for nanotechnology standards through ASTM's existing committee base, as well as the maintenance of appropriate global liaison relationships with activities (internal and external) related to this subject area. The committee shall participate in the development of symposia, workshops, and other related activities to enhance the development of standards.

c) Drivers
  - Based around the needs and the contribution of members and member organizations;
  - Driven by one or two (key?) volunteer individuals (as are most standards activities);
  - These individuals have to fit this (standards writing) in with other activities (unless they're retired).

d) Standards Developed

  E56.01 – Terminology
  - E2456-06, Standard Terminology Relating to Nanotechnology

  E56.02 – Characterization: Physical, Chemical, and Toxicological Properties
  - E2578-07, Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions
  - E2524-08, Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
  - E2525-08, Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
  - E2526-08, Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells

  E56.03 – Environment, Health, and Safety
  - E2535-07, Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings

e) Work in progress/planned
  1. ASTM Interlaboratory Studies (ILS) #166, #201, and #202

  Generate data necessary to develop precision and bias statements for:

- E56 WK8705, Standard guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (PCS),
- E2524-08, Standard Practice for Analysis of Hemolytic Properties of Nanoparticles,
- E2526-08, Standard Practice for Evaluation of Cytotoxicity of Nanoparticulate Materials on Porcine Kidney Cells and Human Hepatocarcinoma cells.

2. Generate ancillary data to support E56 WK8705 bias statement using:

- Atomic force microscopy (AFM),
- Transmission electron microscopy (TEM).

3. Test sample preparation methods for E56 WK10417: Standard Practice for the Preparation of Nanomaterial Samples for Characterization

Test Materials:

- RM 8011, Nominal 10 nm Diameter Gold Nanoparticles,
- RM 8012, Nominal 30 nm Diameter Gold Nanoparticles,
- RM 8013, Nominal 60 nm Diameter Gold Nanoparticles,
- Amine terminated G6 PAMAM dendrimers,
- Hydroxy terminated G6 PAMAM dendrimers.

4. (WK8705) Guide for measurement of particle size distribution of nanomaterials in suspension by photon correlation spectroscopy (pcs).
5. Mobility/Zeta Potential.
6. Prioritize needs for new standards from existing protocols and initiate work on 6-10 new draft standards.
7. Accelerate standard development time through the use of electronic tools (a goal of four months to become a standard after electronic draft approval).
8. Provide “hands-on” testing of draft standards through informal ILS testing.
9. Expand ILS testing to achieve faster dissemination of standards and to qualify laboratories in instrumentation and protocols that are becoming increasingly complex.
10. New work item for nanotechnology ontology.
11. WK8051, Standard Terminology for Nanotechnology – continuous update and revision.

## 8. Nanotechnologies – ISO/TC 229

a) Area of nanotech standardization - TC Scope

“Standardization in the field of nanotechnologies that includes *either* or *both* of the following:
1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, *below 100 nanometers in one or more dimensions* where the onset of size-dependent phenomena usually enables novel applications,
2. 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.”

b) Specific tasks include developing standards for:

- terminology and nomenclature (Joint Working Group 1 with IEC/TC 113),
- metrology and instrumentation, including specifications for reference materials; test methodologies; modeling and simulation (Joint Working Group with IEC/TC 113);
- science-based health, safety, and environmental practices (Working Group 3), and
- materials specifications (Working Group 4).

c) Program drivers

- harmonization of terminology and nomenclature, provision of validated test methods and protocols to research and emerging industries, development of protocols for EH&S in both occupational and societal settings, development of materials specifications for nanomaterials.

d) Customers/stakeholders

- researchers, business, occupational hygienist, regulators, legal profession, patent attorneys, etc.

e) Pertinent work completed

- terminology for nanoparticles – approved March 2008 but awaiting resolution of comments.

f) Work underway

- JWG 1:
    - ISO/TS: Terminology and definitions for nanoparticles – final draft currently out for ballot as ISO/PRF TS 27687;
    - ISO/TR: Terminology and nomenclature for nanotechnologies — Framework and core terms;
    - ISO/TS: Outline of nanomaterials classification ("Nano tree");
    - ISO/TS: Terminology and definitions for carbon nanomaterials;
    - NWIP: ISO/TS: Nanotechnologies - Core terms - Terminology and definitions (ballot closes 6 May 2008).
- JWG 2:
    - Characterization of single-walled carbon nanotubes;
    - ISO/TS: The use of transmission electron microscopy (TEM) in the characterization of single-walled carbon nanotubes;
    - ISO/TS: The use of scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the characterization of single-walled carbon nanotubes;
    - ISO/TS: Technical specification for the use of UV-Vis-NIR absorption spectroscopy in the characterization of single-walled carbon nanotubes;
    - ISO/TS: Technical specification for the use of NIR-photoluminescence (NIR-PL) spectroscopy in the characterization of single-walled carbon nanotubes;
    - ISO/TR: Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-walled carbon nanotubes;
    - ISO/TR: Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-walled carbon nanotubes;
    - ISO/TS: Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes;

    Other measurement and characterization:
    - ISO/TS: Measurement methods for the characterization of multi-walled carbon nanotubes;
    - ISO/TS: Determination of meso-scopic shape factors of multiwalled carbon nanotubes;
    - ISO/TS: General framework for determining nanoparticle content in nanomaterials by generation of aerosols.
- WG 3
    - ISO/TR: Safe practices in occupational settings relevant to nanotechnologies;
    - ISO/IS: Endotoxin test on nanomaterial samples for *in vitro* systems;
    - ISO/IS: Generation of nanoparticles for inhalation toxicity testing;
    - ISO/IS: Monitoring of nanoparticles in inhalation exposure chambers for inhalation toxicity testing;
    - ISO/TR Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment.
- WG 4
    - ISO/IS: Materials specification for nano-titanium dioxide;
    - ISO/IS: Materials specification for nano-calcium carbonate.

g) Future plans

JWG 1

- Nanoscale measurement applications,
- Bio-nano interface applications,
- Nanofabrication applications,
- Medical, health, and personal care applications,
- Nanomaterials applications.

JWG 2

- Carbon Nanotubes and related structures,
- Engineered nanoparticles,
- Coatings,
- Nanostructured materials (composite and porous structures),
- Basic metrology at the nanoscale,
- Guidance for the characterization, specification and production of reference materials,
- Electrotechnical measurement and characterization – IEC/TC 113, IEEE and SEMI.

WG 3

Controlling occupational exposures to nanomaterials:

- Current practices TR,
- Future occupational standards;

Determining relative toxicity/hazard potential of nanomaterials:

- Physico-chemical characterization,
- Nanoparticle toxicity testing,
- Nanoparticle inhalation testing;

Toxicological screening of nanomaterials:

- *In vitro* toxicity test,
- *In vivo* toxicity test,
- Future screening test;

Environmental protection;
Product safety;
Life cycle assessment of nanomaterials.

h) Priority for JWG 2

- Giving high priority to supporting WG 3,
- Developing underpinning M and C standards for industrial products.

i) Challenges

- Communication and harmonization with other committees with an interest in and/or which will be impacted by nanotechnologies.

## 9. Electrical and electronic measurement and characterization - IEC/TC 113

a) Principal challenge

- coordination across the broad range of committees, standards organizations and stakeholders impacted by electrotechnical aspects of nanotechnologies.

b) "Standardization of the technologies relevant to electrical and electronic products and systems in the field of nanotechnology in close cooperation with other IEC committees and ISO/TC 229."

- Components/intermediate assemblies created from nanoscaled materials
- and processes.
- Properties and functionalities of components/intermediate assemblies are
- electrical or electro-optical.
- Final products using these components/intermediate assemblies are
- typically within the scope of other IEC TCs.

c) Fields of activities

- Nano-electronics,
- Optical aspects addressed by IEC TCs,
- Magnetics and electromagnetics,
- Electro-acoustics,
- Multimedia and telecommunication,
- Energy production (direct conversion into electrical power like in fuel cells, photovoltaic devices, storage of electrical energy).

d) Specific topics
- Terminology, measurement, characterization, performance, reliability and safety and environment related to the nanoscale.

e) Standards to characterize nano-specific product performance
- Fast "screening methods" to assess reliability and durability;
- Modelling of nano-related failure mechanisms;
- Fast standardized test methods for nano fabrication:
    - Identification of "nano key control characteristics" for material and process SPC;
- Electronic-grade nanomaterials specifications:
    - Generic nanomaterial specification,
    - Electronic grade CNT specification.

f) EHS
- Who is responsible for EHS at each stage?
- Who determines measurements and standards for benefits and risk management at each stage?
- Will they be traceable to national measurement institutes?

**10. IEEE**

a) The IEEE Nanotechnology Council (NTC) was formed as a multidisciplinary group to advance and coordinate the many nanotechnology scientific, literary and educational endeavors within the IEEE.
- NTC has become a focal point in the field and is helping to unite the global nanotechnology community.
- The IEEE through the NTC has taken the lead in developing nanotechnology-based electronics standards.
- Key drivers are:
- The need for reproducibility of results,
- International collaboration.
- Common means for communicating across traditional scientific disciplines.
- IEEE-SA provides representation and expertise to the international IEC/TC113/WG 3

b) IEEE Agreement with IEC
- IEC/IEEE Dual Logo Agreement

c) Nanoelectronics Standards Roadmap (NESR)
- Created as a framework through which the IEEE Standards Association (IEEE-SA) and the Nanoelectronics community may collaborate to define a roadmap for Nanoelectronics standards.
- Designed to facilitate the movement of nanotechnology innovations from a research to a market environment.
- Identify nanoelectronic technologies likely to generate products and services having high commercial and/or societal value.
- Areas where new standards can aid rapid commercialization, technology transfer and diffusion into the market.
- To Date: 700+ downloads, from 60+ countries.

d) Priorities for standardization
- Technology maturity:
    - Well-enough understood to standardize;
- Clear near-term applications:
    - Standard eliminates near-term roadblocks – rapid payback;
- High business value;
- Multiple device-circuit-application “threads”;

- Fits IEEE role – Nanoelectronics;
- Does the definition of electronics stretch a bit at the nanoscale level?

e) Challenges
- Prioritizing the best choice of standards to be developed.
- People, People, People!
- Getting real people to work on these projects.
- Do we really know the best measurement and characterization processes?
- What are the best practices?
- Are the latest measurement tools the right tools?
- International acceptance
- Environment, health, safety

**11. SEMI**

- Work on nanotechnology standards is just starting in SEMI.
- Strategic alliances and liaisons have been formed:
  - keep SEMI corporate members aware of developments,
  - enable SEMI to contribute on standardization topics relevant to industries served by SEMI.
- Currently 30+ SEMI corporate members are active in nanotechnology.
- SEMI is contributing to efforts in ASTM E56, ISO/TC 229, IEC/TC113 and IEEE Standards.
- SEMI is in D Liaison with IEC/TC 113/WG 3 and will continue to pursue collaborative efforts with other standards developing organizations (SDOs).
- SEMI serves the semiconductor and related industries (FPD, MEMS, PV, nano) .
- Future standardization efforts will focus on needs and requirements of constituencies not usually addressed by other SDOs.
- The technical expertise needed to support SEMI standards development in new fields requires attracting new experts into the existing team of 1,500 volunteer experts now enrolled in the SEMI International Standards Program.
- SEMI aims to become a resource, information clearing house, and active contributor to on-going efforts in other organizations.

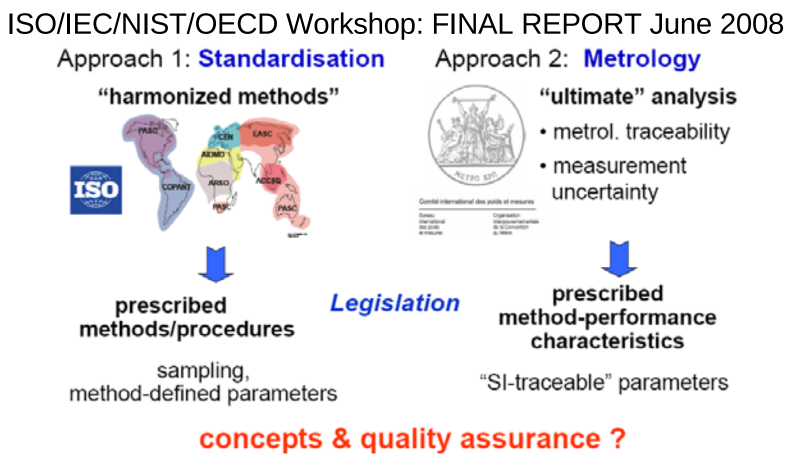
**12. ISO Committee on reference materials – ISO REMCO**

a) ISO REMCO = 31 P-members; 38 O-members; 21 liaisons

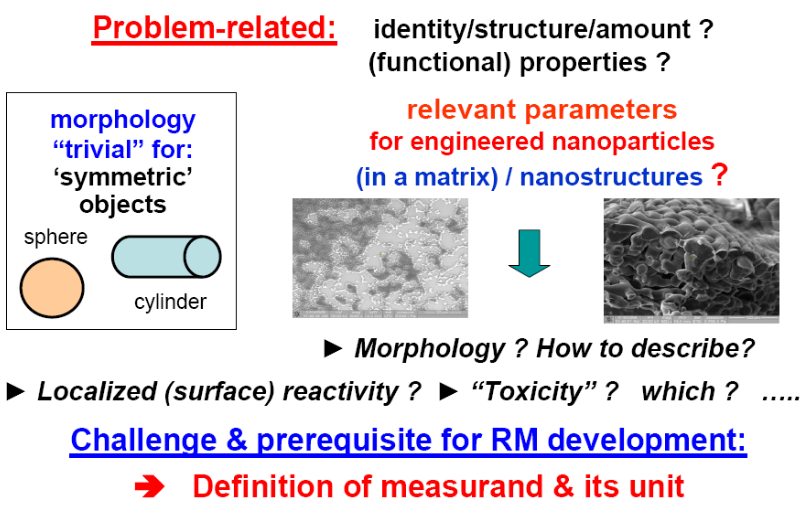
b) Stakeholders
- Standardization bodies,
- Metrology institutions,
- International and regional liaison partners.

c) Clients
- ISO committees (horizontal advisory function),
- Users of reference materials (e.g. analytical laboratories),
- Producers of reference materials,
- Accreditation laboratories (particularly for RM producers).

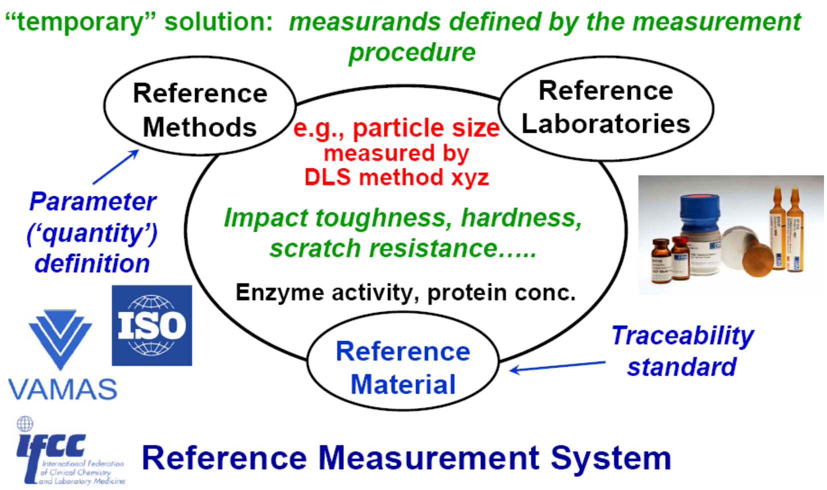
d) Reliable measurement results




e) What to measure




f) Standardization and metrology



## 13. OECD Working Party on Manufactured Nanomaterials (WPMN)

Of the eight Steering Groups (SG) working under the auspices of the WPMN, the following have a specific interest in nanoscale measurement and characterization.

a) SG 3, Safety Testing of a Representative Set of Manufactured Nanomaterials

- Objective: to agree and test a representative set of manufactured nanomaterials using appropriate test methods.
- Status: Testing program agreed, encompassing 14 nanomaterials and a range of endpoints; Sponsorship program agreed; Guidance manual under development.
- Fundamental knowledge issues: Appropriateness of existing test methods or guidelines for listed endpoint. In vitro/alternative methods. Links to SG 4 and SG 7.
- Measurement and characterization needs: Test methods and guidelines, as above.
- Supporting reference materials will be needed in relation to parallel work with e.g. SG 4 and SG 7.
- Pre- and co-normative research needs: From SG 2 (EHS Research strategies on Manufactured Nanomaterials).
- Market need/demand: work required to support the confident application, use and consumption of products containing manufactured nanomaterials through the development of validated test protocols for evaluating the health and environmental impacts of manufactured nanomaterials.
- Technical or policy issues: Test materials. Relationship to national and other research and testing programs. How or where to use existing data, decision logic.

b) SG4, Manufactured Nanomaterials and Test Guidelines

- Drivers: concern that current OECD Test Guidelines have typically not been validated for use in testing NMs and may not be adequate to appropriately address NM characterization and assessment of their (eco-)toxicological properties.
- General Objectives:
    1) Review existing OECD TGs and other standards,
    2) Identify need for development of new or revision of existing TGs,
    3) work plan/proposal(s) for revising or developing, validating and gaining acceptance, including an Integrated Testing Strategy (ITS).
- Players/customers: regulators, industry and NGOs are stakeholders.
- Pertinent work completed:
    a) Operational Plan,
    b) Information sources compilation,
    c) Compilation of Considerations for Evaluating OECD Test Guidelines for the assessment of Manufactured Nanomaterials,
    d) Preliminary priority properties and end-points with SG3,
    e) Work plans for 4 sub-groups (Section 1 - Physical Chemical Properties; Section 2- Effects on Biotic Systems; Section 3 - Degradation and Accumulation; Section 4 - Health Effects),
    f) Preliminary assessment of Physical-Chemical Test Guidelines and existing standards,
    g) Preliminary assessment of Human Health standards and proposal for Guidance Documents.
- Challenges and obstacles: Availability of test results, identity, variety and variability of materials, critical endpoints and characteristics, characterization, dose-metrics, agglomeration-disagglomeration, aggregates, actual exposure vs experimental exposure, translocation, preparation and dosing (*in vivo* and *in vitro*; environment), ADME, transport, deposition, degradation, accumulation.
- Fundamental knowledge issues: Establish suitability of methodology per se and adequacy of data.
- Supporting reference materials will be needed in relation to parallel work with e.g. SG 3 and SG 7.
- Pre- and co-normative research needs: A lot!!
- Market need/demand: Need to ensure and demonstrate safe use of NMs.

- Technical or policy issues: Nanomaterials safety needs to be assessed in the frame of REACH (e.i.f. June 2008) and other regulations. Demand appropriate methods and ITS for hazard and risk assessment in order to adequately manage possible risks.

c) SG 7, The role of alternative methods in nanotoxicology

- Areas of standardization: Validation of *in vitro* testing methods and subsequent test guideline development through OECD.
- Drivers: Reduction in use of animals in testing methods/ mode of action studies/ cost considerations in testing.
- Stakeholders: Industry, regulators, NGOs and general public are stakeholders.
- Work completed: OECD *in vitro* guidelines (428, 430, 470 series); Validated skin corrosion and irritation tests (ECVAM – European Centre for the Validation of Alternative Methods).
- Prioritization challenges: Establish suitability of methodology per se and adequacy of data to replace an animal test or to adapt standard testing regimes.
- Criteria for validation of *in vitro* assays are laid down in OECD Guidance Document 34.
- Use of non-testing methods – QSARs (Quantitative Structure Activity Relationships) – OECD Principles of validation of (Q)SAR models.
- Measurement and characterization are needed for materials used in *in vitro* tests (similar to *in vivo?)*.
- Supporting reference materials will be needed.
- A number of *in vitro* methods at the research stage.
- Market need for alternative approaches to testing – integrated testing strategies.
- Policy issues - Animal welfare (3Rs) important policy driver for alternative methods - for example in REACH regulation.

d) SG 8, Cooperation on exposure measurement and exposure mitigation

- Area of standardization in nanotech related areas: guidance for exposure measurement (including sampling techniques and protocols) and exposure mitigation for manufactured nanomaterials:
  - exposure in occupational settings,
  - exposure to humans resulting from contact with consumer products and environmental releases of manufactured nanomaterials,
  - exposure to environmental species resulting from environmental releases of manufactured nanomaterials, including releases from consumer products containing manufactured nanomaterials.
- Challenges and obstacles: Lack of national or international consensus standards on measurement techniques for nanoparticles in the workplace.
- Research needs for exposure measurement:
  - commercially available personal samplers designed to measure the particle number, surface area, or mass concentration of nanoaerosols,
  - techniques to discriminate between engineered and incidental airborne nanomaterials and to analyse nanomaterials on surfaces,
  - evaluate sampling and analytical methods developed for assessing dermal exposures for their applicability to characterize dermal exposures to nanomaterials in the workplace,
  - metrics of exposure to nanomaterials,
  - biomarkers of exposure to nanoparticles,
  - correlations between exposures to low concentrations of nanomaterials and changes in biological indicators.
- Research needs for exposure mitigation:
  - effectiveness of engineering controls to reduce exposure levels,
  - limitations of personal protection equipment,
  - applicability of exposure mitigation frameworks, such as control banding, to nanomaterials.

***Pre-normative research***

## 14. VAMAS

a) Mission: To support world trade in products dependent on advanced materials technologies by providing the technical basis for harmonized measurements, testing, specifications, and standards.

b) New efforts in nanotechnology

- TWA 29: Nanomechanics Applied to SPM:
  - Co-leadership by NPL (David Mendels) and NIST (Richard Gates),
  - Developing methods for accurately measuring the spring constant for SPM,
  - Standard Reference Springs to be available.
- TWA 33: Polymer Nanocomposites (New):
  - Led by Industrial Materials Institute, Canada (Les Utracki).
  - Two projects begun:
  - Determination of the shape, size and size distribution of nano-filler particles,
  - Determination of the dielectric characteristics of polymer nanocomposites.
- Proposed New TWAs.
- Airborne nanoparticles (LNE, France).
- Multiwall carbon nanotubes (NIMS, Japan).
- Nano-EHS (NIST, US).