

Global Summit on Regulatory Science¹ (GSRS16) Nanotechnology Standards and Applications

Read-Ahead Material

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<http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/WhatWeDo/ucm289679.htm>.
The Global Summit on Regulatory Science (GSRS) is an international conference for discussion of innovative technologies and partnerships to enhance translation of basic science into regulatory applications within the global context.

Regulatory Agency Guidance Documents

US FDA

Relevant Guidances for industry when designing drug products containing nanomaterials

Nanotechnology

1. **General and cross-cutting topics**

Nanotechnology: A report of the U.S. Food and Drug Administration Nanotechnology Task Force

<http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/ucm110856.pdf>

Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM401695.pdf>

2. **Food**

Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives

<http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300927.pdf>

3. **Cosmetics**

Safety of Nanomaterials in Cosmetic Products

<http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300932.pdf>

4. **Animal and Veterinary**

Use of Nanomaterials in Food for Animals

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM401508.pdf>

5. **Chemistry, Manufacturing, and Controls (CMC)**

Draft Guidance for Industry: Liposome Drug Products Chemistry, Manufacturing and Controls; Human Pharmacokinetics and Bioavailability; and Labelling Documentation

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070570.pdf>

Generic Drug Products: Bioequivalence Recommendations

Draft Guidance on Doxorubicin Hydrochloride

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM199635.pdf>

Draft Guidance on Amphotericin B

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384094.pdf>

Draft Guidance on Verteporfin

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384173.pdf>

Draft Guidance on Paclitaxel

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM320015.pdf>

Draft Guidance on Sodium Ferric Gluconate Complex

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358142.pdf>

Draft Guidance on Ferumoxytol

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333051.pdf>

Draft Guidance on Iron Sucrose

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM297630.pdf>

Draft Guidance on Sirolimus

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM089640.pdf>

Draft Guidance on Paliperidone Palmitate

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM270384.pdf>

Additional Relevant Guidances

1. Chemistry, Manufacturing, and Controls
Analytical Procedures and Methods Validation for Drugs and Biologics
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM386366.pdf>
2. CDRH
Guidance for Industry and FDA Staff - Frequently Asked Questions on Recognition of Consensus Standards
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm075064.pdf>
3. CDRH
Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf>

CDRH/FDA recognized documentary standards:

1. ASTM E2490-09: Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)
2. ASTM E2535-07: Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings
3. ISO TS 14101: Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method
4. ISO TS 80004-6: Nanotechnologies - Vocabulary - Part 6: Nano-object characterization

APVMA

Australia Nanotechnologies-pesticides-veterinary-medicines-regulatory-considerations-july2015



6.3 Australia
Nanotechnologies-pe:

MHLW

Joint MHLW/EMA Reflection Paper on the Development of Block Copolymer Micelle Medicinal Products
<http://www.nihs.go.jp/drug/section4/20140110micelle%20PFSB-ELD%20Notification%20No.0110-1.pdf>

Guideline for the Development of Liposome Drug Products
http://www.nihs.go.jp/drug/section4/160328_MHLW_liposome_guideline.pdf

Reflection Paper on Nucleic Acids (siRNA)-Loaded Nanotechnology-Based Drug Products
http://www.nihs.go.jp/drug/section4/160328_MHLW_siRNA_RP.pdf

ECHA

European Chemicals Agency (ECHA) Nanomaterials:
<https://echa.europa.eu/regulations/nanomaterials>

Information and guidance on nanomaterials concerning REACH, CLP and Biocidal Products Regulation, e.g.,

- Best practices on physicochemical and substance identity information for nanomaterials
- Assessing human health and environmental hazards of nanomaterials
- Human health and environmental exposure assessment and risk characterisation of nanomaterials

EFSA

EFSA Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain” mentioning the physico-chemical properties that we would like to see tested in regulatory dossiers (Table 1 + Appendix A):
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2140.pdf

EMA

Topic	Documents	Publication date	Remarks
Data requirements for intravenous iron-based nano-colloidal products developed with reference to an innovator medicinal product	Reflection paper	March 2015	
Surface coatings: general issues for consideration regarding parenteral administration of coated nanomedicine products	Reflection paper	August 2013	
Data requirements for intravenous liposomal products developed with reference to an innovator liposomal product	Reflection paper	February 2013	
Development of block-copolymer-micelle medicinal products	Reflection paper	January 2014	Joint Ministry for Health, Labour and Welfare / European Medicines Agency document

EC

Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results



en_2002D0657_do_001.pdf

Working Safely with Manufactured Nanomaterials - Guidance for Workers

<http://ec.europa.eu/social/BlobServlet?docId=13088&langId=en>

Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work - Guidance for employers and health and safety practitioners

<http://ec.europa.eu/social/BlobServlet?docId=13087&langId=en>

European Commission Scientific Committees

Guidance on the Safety Assessment of Nanomaterials in Cosmetics



SCCS Guidance
nanomaterials in cosm

Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices



SCENIHR
Nanomaterials in med

European Commission Joint Research Centre

Science for Standards: a driver for innovation - JRC Thematic Report

(<http://publications.jrc.ec.europa.eu/repository/handle/JRC80915>)

Towards a Review of the EC recommendation for a definition of the term "nanomaterial" – Part 3:
Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation

(<http://publications.jrc.ec.europa.eu/repository/handle/JRC95675>)

Considerations on information needs for nanomaterials in consumer products. Discussion of a labelling
and reporting scheme for nanomaterials in consumer products in the EU

(<http://publications.jrc.ec.europa.eu/repository/handle/111111111/31575>)

Requirements on measurements for the implementation of the European Commission definition of the
term 'nanomaterial' (JRC Reference Report)

(<http://publications.jrc.ec.europa.eu/repository/handle/111111111/26399>)

Guidance Documents from Other Organizations

OECD WPMN

OECD Testing programme of manufactured nanomaterials

<http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm>

Many reports have been published, e.g.,

- Physical-chemical properties of nanomaterials: evaluation of methods applied in the OECD-WPMN Testing Programme
- Physical-chemical parameters: measurements and methods relevant for the regulation of nanomaterials
- Approaches on nano grouping/ equivalence/ read-across concepts based on physical-chemical properties (gera-pc) for regulatory regimes
- Considerations for using dissolution as a function of surface chemistry to evaluate environmental behaviour of nanomaterials in risk assessments
- Guidance manual towards the integration of risk assessment into life cycle assessment of nano-enabled applications
- Analysis of the survey on available methods and models for assessing exposure to manufactured nanomaterials
- Ecotoxicology and environmental fate of manufactured nanomaterials: test guidelines
- Guidance on sample preparation and dosimetry for the safety testing of manufactured nanomaterials

ICCR

www.iccrnet.org

- 2016-08 ICCR WG Report International Standards in Cosmetics
- 2013-11 Safety Approaches to Nanomaterials in Cosmetics
- 2013-05 Characterization Approaches to Nanomaterials in Cosmetics III
- 2012-07 Characterization Approaches to Nanomaterials in Cosmetics II
- 2011-06 Characterization Approaches to Nanomaterials in Cosmetics
- 2011-06 ICCR Associations Survey of Nano Materials in Cosmetics
- 2010-07 Nanotechnology in Cosmetics - Criteria and Methods for Detection

Documentary Standards

International Organization for Standardization (ISO)

ISO Technical Committee 229 on Nanotechnologies

Documents and Standards as of 18/8/2016

http://www.iso.org/iso/iso_technical_committee?commid=381983

Definitions:

International Standard: *A normative document that requires approval of all ISO member bodies*

Normative Document: *Contains elements that describe the scope of the document and which set out provisions (requirements, recommendations, and statements) that shall be followed.*

Technical Report (document): *An informative document that requires only a TC229 Working Group-level approval and containing information of a different kind from that normally published in a normative document.*

Technical Specification (document): *A normative document that requires TC229 Committee-level approval*

Process: *Developed by consensus; requires approval of a (large) majority of the members of the relevant body*

There are two major sections below: “Published” and “In Publication, Development, or Proposed”. Within each section, “International Standards”, “Technical Specifications”, and “Technical Reports” are listed separately. The documents are further subdivided as “Characterization”, “Vocabulary and Classification”, and “Health, Safety, and Risk”.

I. Published

A. International Standards

1. Characterization

ISO/29701:2010 - *Nanotechnologies --Endotoxin test on nanomaterial samples for in vitro systems -- Limulus ameocyte lysate (LAL) test*

ISO 10801:2010 – *Nanotechnologies --Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method*

ISO 10808:2010 – *Nanotechnologies --Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing*

2. Vocabulary and Classification

3. Health, Safety, and Risk

B. Technical Specifications

1. Characterization

ISO/TS 10867:2010 – *Nanotechnologies -- Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy*

ISO/TS 11251-2010 – *Nanotechnologies – Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry*

ISO/TS 10798:2011 - *Nanotechnologies -- Characterization of carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry (currently under revision)*

ISO/TS 10868:2011 - *Nanotechnologies -- Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy (currently under revision)*

ISO/TS 13278:2011 – *Nanotechnologies – Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry (currently under revision)*

ISO/TS 11308:2011 – *Nanotechnologies – Characterization of carbon nanotubes using thermogravimetric analysis (currently under revision)*

ISO/TS 11888:2011 – *Nanotechnologies - Characterization of multiwall carbon nanotubes -- Mesoscopic shape factors (currently under revision)*

ISO/TS 10797:2012 – *Nanotechnologies -- Characterization of single-wall carbon nanotubes using transmission electron microscopy (TEM)*

IEC/ISO TS 62622 – *Artificial gratings used in nanotechnology -- Description and measurement of dimensional quality parameters*

ISO/TS 14101:2012 - *Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method*

ISO/TS 11931:2012 - *Nanotechnologies -- Nanoscale calcium carbonate in powder form -- Characteristics and measurement*

ISO/TS 11937:2012 - *Nanotechnologies -- Nanoscale titanium dioxide in powder form -- Characteristics and measurement*

ISO/TS 17200:2013 - *Nanotechnology -- Nanoparticles in powder form -- Characteristics and measurements*

ISO/ TS 16195:2013 - *Nanotechnologies - Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nano-particle and nano-fiber powders*

ISO/TS 17466:2015 - *Use of UV-Vis absorption spectroscopy in the characterization of cadmium chalcogenide colloidal quantum dots*

IEC/ISO TS 62607 – *Nanomanufacturing - key control characteristics for CNT film applications - Resistivity -- Part 2-1*

ISO/TS 12025:2012 - *Nanomaterials -- Quantification of nano-object release from powders by generation of aerosols*

ISO/TS 16550:2014 - *Nanotechnologies -- Determination of silver nanoparticles potency by release of muramic acid from Staphylococcus aureus*

ISO/TS 19337:2016 - *Nanotechnologies -- Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity*

ISO/TS 19006:2016 - *Nanotechnologies -- 5-(and 6)-Chloromethyl-2',7'-Dichloro-dihydrofluorescein diacetate (CM-H2DCF-DA) assay for evaluating nanoparticle-induced intracellular reactive oxygen species (ROS) production in RAW 264.7 macrophage cell line*

2. Vocabulary and Classification

ISO/TS 80004-1:2015 – *Nanotechnologies – Vocabulary – Part 1: Core terms*

ISO/TS 80004-2:2015 - *Nanotechnologies -- Vocabulary -- Part 2: Nano-objects*

ISO/TS 80004-3:2010 – *Nanotechnologies --Terminology and definitions --Part 3: Carbon nano-objects*

ISO/TS 80004-4:2011 – *Nanotechnologies – Vocabulary – Part 4: Nanostructured materials*

ISO/TS 80004-5:2011 – *Nanotechnologies – Vocabulary – Part 5: Nano/bio interface*
ISO/TS 80004-6:2013 - *Nanotechnologies -- Vocabulary -- Part 6: Nano-object characterization*
ISO/TS 80004-7:2011 - *Nanotechnologies -- Vocabulary -- Part 7: Diagnostics and therapeutics for healthcare*
ISO/TS 80004-8:2013 - *Nanotechnologies -- Vocabulary -- Part 8: Nanomanufacturing processes*
ISO/TS 12805:2011 – *Nanotechnologies -- Materials specifications -- Guidance on specifying nano-objects*
ISO/TS 18110:2015 - *Nanotechnologies - Vocabularies for Science, Technology and Innovation Indicators*
ISO/TS 80004-12:2016 - *Nanotechnologies -- Vocabulary -- Part 12: Quantum Phenomena*

3. Health, Safety, and Risk

ISO/TS 12901-1:2012 - *Nanotechnologies – Occupational risk management applied to engineered nanomaterials Part 1: Principles and approaches*
ISO/TS 12901-2:2014 – *Nanotechnologies – Occupational risk management applied to engineered nanomaterials – Part 2: Use of the control banding approach*
ISO/TS 13830:2013 – *Nanotechnologies – Guidance on voluntary labelling for consumer products containing manufactured nano-objects*

C. Technical Reports

1. Characterization

ISO/TR 13014:2012 - *Nanotechnologies - Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment*
ISO/TR 11811-2012 – *Nanotechnologies -- Guidance on methods for nano- and microtribology instruments*
ISO/TR 13329:2012 - *Nanomaterials -- Preparation of material safety data sheet (MSDS)*
ISO/TR 16197:2014 - *Nanotechnologies -- Compilation and description of toxicological screening methods for manufactured nanomaterials*
ISO/TR 19716:2016 - *Nanotechnologies -- Characterization of cellulose nanocrystals*
ISO/TR 16196 - *Compilation and description for sample preparation and dosing methods for engineered and manufactured nanomaterials*

2. Vocabulary and Classification

ISO/TR 11360:2010 – *Nanotechnologies – Methodology for the classification and categorization of nanomaterials*
ISO/TR 12802-2010 – *Nanotechnologies – Model taxonomic framework for use in developing vocabularies – Core concepts*
ISO/TR 14786:2014 - *Nanotechnologies — Considerations for the development of chemical nomenclature for selected nano-objects*
ISO/TR 17302:2015 - *Framework for identifying vocabulary development for nanotechnology applications in human healthcare*

3. Health, Safety, and Risk

ISO/TR 12885:2008 – *Nanotechnologies – Health and safety practices in occupational settings relevant to nanotechnologies (currently under revision)*

ISO/TR 13121:2011 – *Nanotechnologies -- Nanomaterial risk evaluation*

ISO/TR 18637 - *General framework for the development of occupational exposure limits for nano-objects and their aggregates and agglomerates*

II. In Publication, Development, or Proposal Stages

A. International Standards

1. Characterization

ISO/DIS 19007 - *In vitro MTS Assay for measuring the cytotoxic effect of nanoparticles*

2. Vocabulary and Classification

3. Health, Safety, and Risk

B. Technical Specifications

1. Characterization

ISO/DTS 19590 - *Nanoparticles: Detection and characterization using single-particle ICP-MS*

ISO/DTS 19809 - *Guidelines for collection and sample preparation of airborne nanoparticles for microscopy techniques*

ISO/PWI - *Determination of size and size distribution of nano-objects by scanning electron microscopy*

ISO/PWI - *'Nanotechnologies -- Structural characterization of graphene'*

ISO/PWI - *Nanotechnologies -- Measurement of average nanoparticle size and assessment of agglomeration state by static multiple light scattering (SMLS) in concentrated media*

ISO/PWI - *Identification and quantification of airborne nano-objects in a mixed dust industrial environment*

ISO/PWI - *Nanotechnologies -- Application of field flow fractionation for characterization of nanomaterial contents*

ISO/PWI - *Nanotechnologies -- Protocol for particle size distribution by transmission electron microscopy*

ISO/PWI - *Nanotechnologies – Characterization of cellulose elementary fibril samples*

ISO/DTS 18827 - *ESR as a method for measuring ROS generated by metal oxide nanomaterials*

ISO/DTS 20787 - *Nanotechnologies -- Aquatic toxicity assessment of nanomaterials using Artemia sp*

ISO/AWI 20814 - *Photocatalytic activity assay for nanoparticles in aqueous suspension*

ISO/DTS 21633 - *Label-free impedance technology to assess the toxicity of nanomaterials in vitro*

ISO/DTS 19807 - *Specification for magnetic nanoparticle suspensions*

ISO/DTS 20660 - *Nanotechnologies -- Materials specification -- Antibacterial silver nanoparticles*

ISO/DTS 21236 - *Nanotechnologies: nanoclays: characteristics and measurements*

ISO/DTS 21237 - *Nanotechnologies- Nano-enhanced air filter media using nanofibres; Characteristics, Performances and Measurement Methods*

ISO/DTS 19808 - *Nanotechnology - Specifications for Carbon Nanotube Suspension: characteristics and test methods*

ISO/DTS 21412 - *Nanotechnologies -- Nanostructured layers for enhanced electrochemical bio-sensing applications -- Characteristics and measurements*

2. Vocabulary and Classification

ISO/TS 80004-4 Rev *Nanotechnologies – Vocabulary – Part 4: Nanostructured materials*

ISO/DTS 80004-11 - *Nanotechnologies - Vocabulary - Part 11: Nanolayer, nanocoating, nanofilm and related terms*

ISO/DTS 80004-13 - *Nanotechnologies - Vocabulary - Part 13: Graphene and other 2d materials*

ISO/DTS 20477 - *Standard terms and their definition for cellulose nanomaterials*

ISO/DTS 80004-9 - *Nanotechnologies - Vocabulary - Part 9: Nano-enabled electrotechnical products and systems* (jointly developed with IEC TC 113)

ISO/DTS 80004-10 - *Nanotechnologies - Vocabulary - Part 10: Nano-enabled photonic components and systems* (jointly developed with IEC TC 113)

(IEC 62565-3-1 - *Nanomanufacturing — Material specifications — Part 3-1: Graphene — Blank detail specification*)

3. Health, Safety, and Risk

C. Technical Reports

1. Characterization

ISO/DTR 18196 - *Measurement technique matrix for nano-objects*

ISO/DTR 19733 - *Matrix of characterization and measurement methods for Graphene*

ISO/DTR 20489 - *Separation and size fractionation for the characterization of metal-based nanoparticles in water samples*

ISO/DTR 19057 - *Nanotechnologies – the use and application of acellular in Vitro Tests and Methodologies to assess Nanomaterial Biodurability*

ISO/DTR 19601 - *Aerosol generation for NOAA air exposure studies*

ISO/DTR 21386 - *Considerations for the measurement of nano-objects, and their aggregates and agglomerates (NOAA), in the environment*

ISO/DTR 21624 - *Considerations for in vitro studies of airborne engineered nanomaterials*

ISO/AWI TR 11808 - *Nanotechnologies --Guidance on nanoparticle measurement methods and their limitations* (CEN-Led Work Items being Jointly Developed under the Vienna Agreement)

2. Vocabulary and Classification

ISO/DTR 18401 - *Nanotechnologies - Plain Language Guide for Terminology*

3. Health, Safety, and Risk

ISO Technical Committee 24, Subcommittee 4 on Particle Characterization

Documents and Standards as of 18/8/2016

http://www.iso.org/iso/standards_development/technical_committees/other_bodies/iso_technical_committee.htm?commid=47176

I. Published

A. International standards

- ISO 9276-1:1998/Cor 1:2004 - *Representation of results of particle size analysis -- Part 1: Graphical representation*
- ISO 9276-2:2014 - *Representation of results of particle size analysis -- Part 2: Calculation of average particle sizes/diameters and moments from particle size distributions*
- ISO 9276-3:2008 - *Representation of results of particle size analysis -- Part 3: Adjustment of an experimental curve to a reference model*
- ISO 9276-4:2001 - *Representation of results of particle size analysis -- Part 4: Characterization of a classification process*
- ISO 9276-5:2005 - *Representation of results of particle size analysis -- Part 5: Methods of calculation relating to particle size analyses using logarithmic normal probability distribution*
- ISO 9276-6:2008 - *Representation of results of particle size analysis -- Part 6: Descriptive and quantitative representation of particle shape and morphology*
- ISO 9277:2010 - *Determination of the specific surface area of solids by gas adsorption -- BET method*
- ISO 10630:1994 - *Industrial plate screens -- Specifications and test methods*
- ISO 12154:2014 - *Determination of density by volumetric displacement -- Skeleton density by gas pycnometry*
- ISO/TR 13097:2013 - *Guidelines for the characterization of dispersion stability*
- ISO 13099-1:2012 - *Colloidal systems -- Methods for zeta-potential determination -- Part 1: Electroacoustic and electrokinetic phenomena*
- ISO 13099-2:2012 - *Colloidal systems -- Methods for zeta-potential determination -- Part 2: Optical methods*
- ISO 13099-3:2014 - *Colloidal systems -- Methods for zeta potential determination -- Part 3: Acoustic methods*
- ISO 13317-1:2001 - *Determination of particle size distribution by gravitational liquid sedimentation methods -- Part 1: General principles and guidelines*
- ISO 13317-2:2001 - *Determination of particle size distribution by gravitational liquid sedimentation methods -- Part 2: Fixed pipette method*
- ISO 13317-3:2001 - *Determination of particle size distribution by gravitational liquid sedimentation methods -- Part 3: X-ray gravitational technique*
- ISO 13317-4:2014 - *Determination of particle size distribution by gravitational liquid sedimentation methods -- Part 4: Balance method*
- ISO 13318-1:2001 - *Determination of particle size distribution by centrifugal liquid sedimentation methods -- Part 1: General principles and guidelines*
- ISO 13318-2:2007 - *Determination of particle size distribution by centrifugal liquid sedimentation methods -- Part 2: Photocentrifuge method*

ISO 13318-3:2004 - *Determination of particle size distribution by centrifugal liquid sedimentation methods -- Part 3: Centrifugal X-ray method*

ISO 13319:2007 - *Determination of particle size distributions -- Electrical sensing zone method*

ISO 13320:2009 - *Particle size analysis -- Laser diffraction methods*

ISO 13321:1996 - *Particle size analysis -- Photon correlation spectroscopy*

ISO 13322-1:2014 - *Particle size analysis -- Image analysis methods -- Part 1: Static image analysis methods*

ISO 13322-2:2006 - *Particle size analysis -- Image analysis methods -- Part 2: Dynamic image analysis methods*

ISO 14488:2007 - *Particulate materials -- Sampling and sample splitting for the determination of particulate properties*

ISO 14887:2000 - *Sample preparation -- Dispersing procedures for powders in liquids*

ISO 15900:2009 - *Determination of particle size distribution -- Differential electrical mobility analysis for aerosol particles*

ISO 15901-1:2016 - *Evaluation of pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption -- Part 1: Mercury porosimetry*

ISO 15901-2:2006/Cor 1:2007 - *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 15901-3:2007 - *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption -- Part 3: Analysis of micropores by gas adsorption*

ISO 17867:2015 - *Particle size analysis -- Small-angle X-ray scattering*

ISO 20998-1:2006 - *Measurement and characterization of particles by acoustic methods -- Part 1: Concepts and procedures in ultrasonic attenuation spectroscopy*

ISO 20998-2:2013 - *Measurement and characterization of particles by acoustic methods -- Part 2: Guidelines for linear theory*

ISO 21501-1:2009 - *Determination of particle size distribution -- Single particle light interaction methods -- Part 1: Light scattering aerosol spectrometer*

ISO 21501-2:2007 - *Determination of particle size distribution -- Single particle light interaction methods -- Part 2: Light scattering liquid-borne particle counter*

ISO 21501-3:2007 - *Determination of particle size distribution -- Single particle light interaction methods -- Part 3: Light extinction liquid-borne particle counter*

ISO 21501-4:2007 - *Determination of particle size distribution -- Single particle light interaction methods -- Part 4: Light scattering airborne particle counter for clean spaces*

ISO 22412:2008 - *Particle size analysis -- Dynamic light scattering (DLS)*

ISO 26824:2013 - *Particle characterization of particulate systems -- Vocabulary*

ISO 27891:2015 - *Aerosol particle number concentration -- Calibration of condensation particle counters*

II. In Publication, Development, or Proposal Stages

A. International standards

ISO/CD 13320 - *Particle size analysis -- Laser diffraction methods*

ISO/CD 18747-1 - *Determination of particle density by sedimentation methods -- Part 1: Isopycnic interpolation approach*

ISO/AWI 18747-2 - *Determination of the particle density by sedimentation methods -- Part 2: Multivelocitv approach*

ISO/AWI 18748 - *Characterization of dispersibility of solid particulate objects into a liquid*

ISO/DIS 19430.2 - *Particle size analysis -- Particle tracking analysis (PTA) method*

ISO/DIS 20998-3 - *Measurement and characterization of particles by acoustic methods -- Part 3: Guidelines for non-linear theory*

ISO/DIS 21501-4 - *Determination of particle size distribution -- Single particle light interaction methods -- Part 4: Light scattering airborne particle counter for clean spaces*

ISO/FDIS 22412 - *Particle size analysis -- Dynamic light scattering (DLS)*

B. Technical Specifications

ISO/DTS 14411-1- *Preparation of particulate reference materials -- Part 1: Polydisperse material based on picket fence of monodisperse spherical particles*

Acronym Key:

AWI – Approved Work Item

CD – Committee Draft (ballot at TC)

DIS – Draft International Standard

DTR – Draft Technical Report

DTS – Draft Technical Specification

FDIS – Final Draft International Standard

PWI – Preliminary Work Item

WD – Working Draft (being developed by WG)

TR – Technical Report

TS – Technical Specification

ASTM International

Technical Committee E56 on Nanotechnology

Standards as of 29/8/16

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

Definitions

Process: *Developed by consensus and requires that 60% of the Subcommittee members and 60% of the Main Committee members vote; all negative votes and comments must be resolved before publication*

Standard Guide: *A compendium of information or series of options that does not recommend a specific course of action. Guides are intended to increase the awareness of information and approaches in a given subject area.*

Standard Practice: *A definitive set of instructions for performing one or more specific operations that does not produce a test result. Examples of practices include selection, preparation, application, inspection, necessary precautions for use or disposal, installation, maintenance, and operation of testing apparatus.*

Standard Test Method: *A definitive procedure that produces a test result with precision and bias statements that are established by an interlaboratory study*

Standard Terminology: *A document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms*

There are two major sections below: “Published” and “Work Items”. Within each section, “Standard Test Methods”, “Standard Practices”, “Standard Guides”, and “Standard Terminology” are listed separately. The documents are further subdivided as “Characterization”, “Health, Safety, and Risk”, “Education”, and “Informatics”.

I. Published

A. Standard Test Methods

1. Characterization

E2864-13—*Standard Test Method for Measurement of Airborne Metal and Metal Oxide Nanoparticle Surface Area Concentration in Inhalation Exposure Chambers using Krypton Gas Adsorption*

E2524-08(2013)—*Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles*

E2525-08(2013)—*Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies*

E2526-08(2013)—*Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells*

B. Standard Practices

1. Characterization

E2578-07(2012)—*Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions*

2. Health, Safety, and Risk

3. Education

E3001-15—*Standard Practice for Workforce Education in Nanotechnology Characterization*

C. Standard Guides

1. Characterization

E2490-09(2015)—*Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS)*

E2834-12—*Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Nanoparticle Tracking Analysis (NTA)*

E2859-11—*Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy*

E2865-12—*Standard Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Nanosized Biological Materials*

E3025-2016—*Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles*

2. Health, Safety, and Risk

E2535-07(2013)—*Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings*

3. Education

E2996-15—*Standard Guide for Nanotechnology Workforce Education in Health and Safety*

E3034-15—*Standard Guide for Workforce Education in Nanotechnology Pattern Generation*

E3059-16—*Standard Guide for Workforce Education in Nanotechnology Infrastructure*

4. Informatics

E2909-13—*Standard Guide for Investigation/Study/Assay Tab-Delimited Format for Nanotechnologies (ISA-TAB-Nano): Standard File Format for the Submission and Exchange of Data on Nanomaterials and Characterizations*

D. Standard Terminology

E3001-15—*Practice for Workforce Education in Nanotechnology Characterization*

II. Work Items

A. New Standard Test Methods

WK52417—*New Standard Test Method for Detection of Total Silver in Textiles by ICP Analysis*

B. New Standard Practices

C. New Standard Guides

WK54613—*New Standard Guide for the Analysis of Nanoparticles by Single Particle Inductively Coupled Plasma Mass Spectrometry (SP-ICP-MS)*

WK54615—*New Standard Practice for Performing Electron Cryo-Microscopy of Liposomes –*

WK48313—*New Standard Guide for Collection and Generation of Environment, Health, and Safety Information for Nanomaterials and Nanoenabled Products*

WK54048—*New Standard Guide for Nanotechnology Workforce Education in Materials Synthesis and Processing*

WK54760—*New Standard Guide for Nanotechnology Workforce Education in Material Properties and Scale*

European Committee for Standardization

CEN Technical Committee 352 on Nanotechnologies

Documents and Standards as of 15/6/16

I. Published jointly with ISO TC229

A. International Standards

EN ISO/29701:2010 - *Nanotechnologies --Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amoebocyte lysate (LAL) test*

EN ISO 10801:2010 – *Nanotechnologies --Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method*

EN ISO 10808:2010 – *Nanotechnologies --Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing*

B. Technical Specifications

CEN ISO/TS 13830:2013 – *Nanotechnologies – Guidance on voluntary labelling for consumer products containing manufactured nano-objects*

CEN ISO/TS 27687:2009 - *Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofiber, and nanoplate Vocabulary*

CEN ISO/TS 12025:2012 - *Nanomaterials -- Quantification of nano-object release from powders by generation of aerosols*

CEN ISO/TS 17200:2013 - *Nanotechnology -- Nanoparticles in powder form -- Characteristics and measurements*

CEN ISO/TS 80004-1:2015 – *Nanotechnologies – Vocabulary – Part 1: Core terms*

CEN ISO/TS 80004-3:2010 – *Nanotechnologies --Terminology and definitions --Part 3: Carbon nano-objects*

CEN ISO/TS 80004-4:2011 – *Nanotechnologies – Vocabulary – Part 4: Nanostructured materials*

CEN ISO/TS 80004-6:2013 - *Nanotechnologies -- Vocabulary -- Part 6: Nano-object characterization*

CEN ISO/TS 80004-8:2013 - *Nanotechnologies -- Vocabulary -- Part 8: Nanomanufacturing processes*

C. Technical Reports

CEN ISO/TR 11811-2012 – *Nanotechnologies -- Guidance on methods for nano- and microtribology instruments*

II. CEN only

A. Technical Specifications

CEN/TS 16937 - *Nanotechnologies – Guidance for the responsible development of nanotechnologies*

prCEN/TS - PWI 00352010 - *Nanotechnologies - Guidance on measurands for characterising nano-objects and materials that contain them*

- prCEN/TS - PWI 00352011 - *Nanotechnologies – Guidelines for aspects of Life Cycle Assessment specific*
- prCEN/TS - PWI 00352012 - *Nanotechnologies – Guidance on detection and identification of nano-objects in complex matrices*
- prCEN/TS - PWI 00352013 - *Nanotechnologies – Guidelines for determining protocols for the explosivity and flammability of powders containing nano-objects (for transport, handling and storage)*
- prCEN/TS - PWI 00352014 - *Nanotechnologies – Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects*
- prCEN/TS - PWI 00352015 - *Nanotechnologies – Determination of hydrochemical reactivity of nano-objects for toxicity studies*
- prCEN/TS - WI 00352023 - *Nanotechnologies – Manufactured nanomaterials (MNMs) in the construction industry. Guidelines for occupational risk management*
- prCEN/TS - *Nanotechnologies – Nano and micro scratch testing*

Publicly Available Protocols

Definition: step-by-step, reproducible, and validated procedures. Protocols may address, either separately or conjointly, sample preparation, conduct of measurements, and data analysis.


Uses: essential first step in the harmonization of nanomaterial property measurements to enable direct comparisons between laboratories and greater consistency in reporting. Protocols can form the basis for the development of documentary standards or guidance documents published by, *e.g.*, ISO/TC229, ASTM E56, and OECD-WPMN.

NCL

Some protocols are jointly developed with NIST

The Nanotechnology Characterization Laboratory has developed a standardized analytical cascade that tests the preclinical toxicology, pharmacology, and efficacy of nanoparticles and devices. Protocols on Physicochemical, *In Vitro*, and *In Vivo* Characterization have been developed.

http://ncl.cancer.gov/working_assay-cascade.asp

Physicochemical Characterization	Method ID
Size, Size Distribution	
Measuring the Size of Nanoparticles in Aqueous Media Using Batch-Mode DLS  See the DLS Video Protocol demonstration	NIST-NCL PCC-1
Size Measurement of Nanoparticles Using Atomic Force Microscopy	NIST-NCL PCC-6
Measuring the Size of Nanoparticles Using Transmission Electron Microscopy	NIST-NCL PCC-7
Analysis of Gold Nanoparticles by Electrospray Differential Mobility Analysis	NIST-NCL PCC-10
Measuring the Size of Colloidal Gold Nanoparticles Using High-Resolution Scanning Electron Microscopy	NIST-NCL PCC-15
Chemical Composition	
Determination of Gold in Rat Tissue with Inductively Coupled Plasma-Mass Spectrometry	NIST-NCL PCC-8
Determination of Gold in Rat Blood with Inductively Coupled Plasma-Mass Spectrometry	NIST-NCL PCC-9
Method for Determination of the Mass Fraction of Particle-Bound Gold in Suspensions of Gold Nanoparticles	NIST-NCL PCC-11
Quantification of Free and Chelated Gadolinium Species in Nanoemulsion-Based Magnetic Resonance Imaging Contrast Agent Formulations using Hyphenated Chromatography Methods	NIST-NCL PCC-14

Zeta Potential and other

Measuring Zeta Potential of Nanoparticles	PCC-2
Measuring the Electrolytic Conductivity of Nanoparticle Suspensions	NIST-NCL PCC-12
Measuring the pH of Nanoparticle Suspensions	NIST-NCL PCC-

In Vitro Characterization		Method ID
Sterility		
Detection of Endotoxin Contamination		
	End Point Chromogenic LAL Assay	STE-1.1
	Kinetic Turbidity LAL Assay	STE-1.2
	Gel-Clot LAL Assay	STE-1.3
	Kinetic Chromogenic LAL Assay	STE-1.4
Detection of Microbial Contamination		
		STE-2.1
Detection of Bacterial Contamination		
		STE-2.2
Detection of Mycoplasma Contamination		
		STE-3
Targeting		
Cell Binding/Internalization		
Drug Release		
	In Vitro Blood Partitioning Assay	GTA-13
<i>In Vitro</i> Immunology		
Blood Contact Properties		
	Analysis of Hemolytic Properties of Nanoparticles	ITA-1
	Analysis of Platelet Aggregation by Cell Counting	ITA-2.1
	Analysis of Platelet Aggregation by Light Transmission Aggregometry	ITA-2.2
	Analysis of Nanoparticle Interaction with Plasma Proteins by 2D PAGE	ITA-4
	Qualitative Analysis of Total Complement Activation by Western Blot	ITA-5.1
	Quantitative Analysis of Complement Activation	ITA-5.2
	Coagulation Assay	ITA-12
Cell-Based Assays		
	Mouse Granulocyte Macrophage Colony-Forming Unit Assay	ITA-3
	Leukocyte Proliferation Assay	ITA-6
	Macrophage/Neutrophil Function (4 categories):	
	Detection of Nitric Oxide Production by RAW 264.7	ITA-7

	Macrophage Cell Line	
	Chemotaxis Assay	<u>ITA-8</u>
	Phagocytosis Assay	<u>ITA-9</u>
	<u>Analysis of Cytokines, Chemokines, and Interferons</u>	<u>ITA-10</u>
	ELISA for Detection of IL-8 in Culture Supernatants	<u>ITA-22</u>
	ELISA for Detection of IL-1b in Culture Supernatants	<u>ITA-23</u>
	ELISA for Detection of TNF-a in Culture Supernatants	<u>ITA-24</u>
	ELISA for Detection of IFNg in Culture Supernatants	<u>ITA-25</u>
	Measurement of Nanoparticle Effects on Cytotoxic Activity of NK Cells by Label-Free RT-CES System	<u>ITA-11</u>
	Analysis of Nanoparticle Effects on Maturation of Monocyte Derived Dendritic Cells In Vitro	<u>ITA-14</u>
	In Vitro Induction of Leukocyte Procoagulant Activity by Nanoparticles	<u>ITA-17</u>
	Human Leukocyte Proliferation Assay	<u>ITA-18</u>
Toxicity		
	Oxidative Stress	
	Hep G2 Hepatocyte Glutathione Assay	<u>GTA-3</u>
	Hep G2 Hepatocyte Lipid Peroxidation Assay	<u>GTA-4</u>
	Hepatocyte Primary ROS Assay	<u>GTA-7</u>
	Cytotoxicity (necrosis)	
	LLC-PK1 Kidney Cytotoxicity Assay (MTT and LDH Release)	<u>GTA-1</u>
	Hep G2 Hepatocarcinoma Cytotoxicity Assay (MTT and LDH Release)	<u>GTA-2</u>
	Cytotoxicity (apoptosis)	
	LLC-PK1 Kidney Apoptosis Assay (Caspase 3 Activation)	<u>GTA-5</u>
	Hep G2 Hepatocarcinoma Apoptosis Assay (Caspase 3 Activation)	<u>GTA-6</u>
	Hep G2 Hepatocarcinoma Homogeneous Apoptosis Assay (Caspase 3/7 Activation)	<u>GTA-14</u>
	Autophagy	
-	Autophagic Dysfunction Assay: Qualitative Analysis of MAP LC3I to LC3-II Conversion by Western Blot	<u>GTA-11</u>
-	Autophagic Dysfunction in LLC-PK1 Cells	<u>GTA-12</u>

NIST

NIST has been developing protocols of relevance to nanotechnology since 2007; some of these protocols have been published in a series of NIST Special Publications (SPs) with citable DOI names to provide persistent identification. A number of the NIST protocols were developed in conjunction with external collaborators. Protocols are available for Sample Preparation, Physico-chemical Measurements, and Biological Measurements. <http://www.nist.gov/mml/nanoehs-protocols.cfm>

Physico-chemical measurements:

NIST SP 1200-6: Measuring the Size of Nanoparticles in Aqueous Media Using Batch-Mode Dynamic Light Scattering, Version 1.2

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-6>

NIST SP 1200-10: Challenges, Strategies and Opportunities for Measuring Carbon Nanotubes within a Polymer Composite by X-ray Photoelectron Spectroscopy

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-10>

NIST SP 1200-13: Measurement of silver nanoparticle dissolution in complex biological and environmental matrices using UV/visible absorbance measurements

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-13>

NIST SP 1200-15: Protocols for Accelerating Laboratory Weathering and Measurements of Degradation of Polymer-Multiwalled Carbon Nanotube Composites

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-15>

NIST SP1200-17: Strategies for Scanning Electron Microscopy Sample Preparation and Characterization of Multiwall Carbon Nanotube Polymer Composites

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-17>

NIST SP 1200-21: Characterization of Nanoparticle Suspensions Using Single Particle Inductively Coupled Plasma Mass Spectrometry

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-21>

Biological Measurements:

NIST SP: 1200-11 Control Experiments to Avoid Artifacts and Misinterpretations in Nanoecotoxicology Testing

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-11>

NIST SP1200-18: GC/MS Measurement of Nanomaterial-Induced DNA Modifications in Isolated DNA

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-18>

NIST SP1200-19: GC-MS/MS Measurement of Nanomaterial- Induced DNA Modifications in Isolated DNA

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-19>

NIST SP1200-20: LC-MS/MS Measurement of Nanomaterial- Induced DNA Modifications in Isolated DNA

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-20>

Sample Preparation:

NIST SP-1200-1: Reporting Guidelines for the Preparation of Aqueous Nanoparticle Dispersions from Dry Materials, Version 2.1

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-1>

NIST SP-1200-2: Preparation of Nanoparticle Dispersions from Powdered Material Using Ultrasonic Disruption, Version 1.1

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-2>

NIST SP-1200-3: Preparation of a Nanoscale TiO₂ Aqueous Dispersion for Toxicological or Environmental Testing, Version 1.2

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-3>

NIST SP-1200-4: Preparation of Nanoscale TiO₂ Dispersions in Biological Test Media for Toxicological Assessment, Version 1.1

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-4>

NIST SP-1200-5r: Preparation of Nanoscale TiO₂ Dispersions in an Environmental Matrix for Eco-Toxicological Assessment, Version 1.2

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-5r1>

NIST SP-1200-8: Preparation of Silver Nanoparticle Loaded Cotton Threads to Facilitate Measurement Development for Textile Applications

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-8>

NIST SP 1200-9: Preparation of Nanoscale Multi-walled Carbon Nanotube Dispersions in a Polyetheramine Epoxy for Eco- Toxicological Assessment

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-9>

NIST SP 1200-12: Reconstitution of 2 nm diameter Silicon Nanoparticles (RM 8027) into aqueous solvents

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-12>

NIST SP 1200-14: Reliable Preparation of Nanoparticle Agglomerates of Different Sizes in Cell Culture Media

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-14>

NIST SP 1200-16: Strategies for Transmission Electron Microscopy Specimen Preparation of Polymer Composite

DOI: <http://dx.doi.org/10.6028/NIST.SP.1200-16>

Nanoscale Reference Materials from Selected Governmental Organizations

List as of 29-8-16. NP: nanoparticle; CNT: carbon nanotube

Note: The private sector produces RMs of variable quality and traceability, including NIST Traceable RMs™ and certified RMs.

Material Type	Form	Reference Property	Nominal Value(s)	Institution*	Identifier(s)
gold NPs	aqueous suspension	mean diameter	10 nm, 30 nm, and 60 nm	NIST	RMs 8011, 8012, 8013
silicon dioxide NPs	aqueous suspension	mean diameter	20 nm	JRC	ERM-FD100
	aqueous suspension	mean diameter	40 nm	JRC	ERM-FD304
	aqueous suspension	mean diameters	20 nm and 80 nm mixture	JRC	ERM-FD102
titanium dioxide NPs	dry powder	specific surface area	55 m ² /g	NIST	SRM 1898
	dry powder	specific surface area	76 m ² /g	AIST/NMIJ	NMIJ-5713a*
	dry powder	specific surface area	11 m ² /g	AIST/NMIJ	NMIJ-5711a*
	dry powder	specific surface area	57 m ² /g	AIST/NMIJ	NMIJ-5712a*
silver NPs	freeze-dried	mean diameter	75 nm	NIST	RM 8017
	freeze-dried	mean diameter	10 nm	NIST	in production
	suspension	particle size distribution	7 nm to 36 nm	BAM	BAM-N001
single-wall CNTs	dry soot	mass fraction	impurity elements	NIST	SRM 2483
	dry soot	mass fraction	impurity elements	NRC	SWCNT-1
	aqueous suspension	length	"long", "medium", "short"	NIST	RM 8281
multiwall CNTs	dry soot	mass fraction	impurity elements	NIST	in production
polystyrene NPs	aqueous suspension	mean diameter	100 nm	NIST	SRM 1963a
	aqueous suspension	mean diameter	60 nm	NIST	SRM 1964
	aqueous suspension	mean diameter	120 nm	AIST/NMIJ	5701-a
	aqueous suspension	particle size	115 nm	NIM	GBW 12019
	aqueous suspension	particle size	84 nm	NIM	GBW (E)120090
	aqueous suspension	particle size	65 nm	NIM	GBW (E)120091
silicon NPs	toluene suspension	mean diameter	2 nm	NIST	RM 8027
nano-alumina	dry powder	specific surface area	445.4 m ² /g	NIM	GBW 13901
	dry powder	specific surface area	359.4 m ² /g	NIM	GBW 13906
	dry powder	specific surface area	515.3 m ² /g	NIM	GBW 13907
cellulose nanocrystal	dry powder	mass fraction	trace metals	NRC	CNC-1
	aqueous suspension	mass fraction	trace metals	NRC	CNCS-1

*NIST: National Institute for Standards and Technology (US); AIST: Japanese National Inst. of Advanced Industrial Science/National Metrology Inst. of Japan; NIM: National Inst. of Metrology (China); NRC: National Research Council (Canada); JRC: Joint Research Centre of the European Commission; BAM: Federal Inst. for Materials Research and Testing (Germany)

Additional Sources

“Nanoscaled Reference Material” database on the BAM web site:

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

"JRC Nanomaterials Repository" on the EU Science Hub:

<https://ec.europa.eu/jrc/en/scientific-tool/jrc-nanomaterials-repository>

Representative Test Materials

ISO/ TS 16195:2013 - *Nanotechnologies - Generic requirements for reference materials for development of methods for characteristic testing, performance testing and safety testing of nano-particle and nano-fiber powders*

Reference materials and representative test materials to develop nanoparticle characterization methods: the NanoChOp project case

G. Roebben et al., Frontiers Research Foundation, 2015. DOI: 10.3389/fchem.2015.00056

<http://journal.frontiersin.org/article/10.3389/fchem.2015.00056/full>

Abstract:

This paper describes the production and characteristics of the nanoparticle test materials prepared for common use in the collaborative research project NanoChOp (Chemical and optical characterization of nanomaterials in biological systems), *in casu* suspensions of silica nanoparticles and CdSe/CdS/ZnS quantum dots (QDs). This paper is the first to illustrate how to assess whether nanoparticle test materials meet the requirements of a “reference material” (ISO Guide 30, 2015) or rather those of the recently defined category of “representative test material (RTM)” (ISO/TS 16195, 2013). The NanoChOp test materials were investigated with small-angle X-ray scattering (SAXS), dynamic light scattering (DLS), and centrifugal liquid sedimentation (CLS) to establish whether they complied with the required monomodal particle size distribution. The presence of impurities, aggregates, agglomerates, and viable microorganisms in the suspensions was investigated with DLS, CLS, optical and electron microscopy and via plating on nutrient agar. Suitability of surface functionalization was investigated with attenuated total reflection Fourier transform infrared spectrometry (ATR-FTIR) and via the capacity of the nanoparticles to be fluorescently labeled or to bind antibodies. Between-unit homogeneity and stability were investigated in terms of particle size and zeta potential. This paper shows that only based on the outcome of a detailed characterization process one can raise the status of a test material to RTM or reference material, and how this status depends on its intended use.