

## **Estándares o normas voluntarias ISO para nanotecnologías**

Sistematizado por Mónica Anzaldo Montoya y Sein León-Silva

La ISO (Organización Internacional de Estándares) define estándar como un documento establecido por consenso y aprobado por un organismo reconocido que prevé un uso común y repetido de reglas, lineamientos o características para actividades o sus resultados encaminados a lograr el grado óptimo de orden en un contexto determinado (ISO/IEC Guide 2:2004) (ISO, 2014).

- Normas ISO internacional
- Normas Mexicanas

La ISO (Organización Internacional de Estándares) define estándar como un documento establecido por consenso y aprobado por un organismo reconocido que prevé un uso común y repetido de reglas, lineamientos o características para actividades o sus resultados encaminados a lograr el grado óptimo de orden en un contexto determinado (ISO/IEC Guide 2:2004) (ISO, 2014).

### **International nanotechnology standards for characterization, health, safety and environment.**

<b>Item</b>	<b>Standard</b>	<b>Standard Name</b>	<b>Year</b>
1	ISO/TR 27628:2007	Workplace atmospheres — Ultrafine, nanoparticle and nano-structured aerosols — Inhalation exposure characterization and assessment	2007
2	ISO 29701:2010	Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems—Limulus amebocyte lysate (LAL) test	2010
3	ISO/TS 10801:2010	Nanotechnologies—Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method	2010
4	ISO 10808:2010	Nanotechnologies—Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing	2010
5	ISO/TR 11360:2010	Nanotechnologies — Methodology for the classification and categorization of nanomaterials	2010
6	ISO/TR 13121:2011	Nanotechnologies—Nanomaterial risk evaluation	2011
7	ISO/TS 10798: 2011	Nanotechnologies—Characterization of single-wall carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry analysis	2011
8	ISO/TS 12805:2011	Nanotechnologies — Materials specifications — Guidance on specifying nano-objects	2011
9	ISO 28439:2011	Workplace atmospheres — Characterization of ultrafine aerosols/nanoaerosols — Determination of the size distribution and number concentration using differential electrical mobility analysing systems	2011
10	ISO/TS 12901-1:2012	Nanotechnologies—Occupational risk management applied to engineered nanomaterials—Part 1: Principles and approaches	2012
11	ISO/TR 13329:2012	Nanomaterials—Preparation of material safety data sheet (MSDS)	2012
12	ISO/TR 13014:2012	Nanotechnologies—Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment	2012
13	ISO/TS 10797:2012	Nanotechnologies—Characterization of single-wall carbon nanotubes using transmission electron microscopy	2012

14	ISO/TR 10929:2012	Nanotechnologies—Characterization of multiwall carbon nanotube (MWCNT) samples	2012
15	ISO/TS 14101:2012	Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method	2012
16	ISO/TS 11937:2012	Nanotechnologies — Nanoscale titanium dioxide in powder form — Characteristics and measurement	2012
17	ISO/TS 11931:2012	Nanotechnologies — Nanoscale calcium carbonate in powder form — Characteristics and measurement	2012
18	ISO/TR 11811:2012	Nanotechnologies — Guidance on methods for nano- and microtribology measurements	2012
19	IEC/TS 62607-2-1:2012	Nanomanufacturing - key control characteristics for CNT film applications - Resistivity — Part 2-1:	2012
20	IEC/TS 62622:2012	Artificial gratings used in nanotechnology — Description and measurement of dimensional quality parameters	2012
21	ISO 12830:2019	Paper, board, pulps and cellulose nanomaterials — Determination of acid-soluble magnesium, calcium, manganese, iron, copper, sodium and potassium	2012
22	ISO/TS 13830:2013	Nanotechnologies—Guidance on voluntary labelling for consumer products containing manufactured nano-objects	2013
23	ISO/TS 12901-2:2014	Nanotechnologies—Occupational risk management applied to engineered nanomaterials—Part 2: Use of the control banding approach	2014
24	ISO/TR 16197:2014	Nanotechnologies—Compilation and description of toxicological screening methods for manufactured nanomaterials	2014
25	ISO/TS 16550:2014	Nanotechnologies—Determination of silver nanoparticles potency by release of muramic acid from <i>Staphylococcus aureus</i>	2014
26	ISO/TR 14786:2014	Nanotechnologies — Considerations for the development of chemical nomenclature for selected nano-objects	2014
27	ISO/17466:2015	Use of UV-Vis absorption spectroscopy in the characterization of cadmium chalcogenide colloidal quantum dots	2015
28	ISO 18473-2:2015	Functional pigments and extenders for special applications — Part 2: Nanoscale titanium dioxide for sunscreen application	2015
29	ISO 18473-1:2015	Functional pigments and extenders for special applications — Part 1: Nanoscale calcium carbonate for sealant application	2015
30	ISO/TR 16196:2016	Nanotechnologies—Compilation and description of sample preparation and dosing methods for engineered and manufactured nanomaterials	2016
31	ISO/TR 18637:2016	Nanotechnologies—Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)	2016

32	ISO/TS 19006:2016	Nanotechnologies—5-(and 6)-Chloromethyl-2',7' Dichlorodihydrofluorescein diacetate (CM-H2DCF-DA) assay for evaluating nanoparticle-induced intracellular reactive oxygen species (ROS) production in RAW 264.7 macrophage cell line	2016
33	ISO/TR 18196:2016	Nanotechnologies—Measurement technique matrix for the characterization of nano-objects	2016
34	ISO/CD TS 19337:2016	Nanotechnologies—Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity	2016
35	ISO/TR 19716:2016	Nanotechnologies — Characterization of cellulose nanocrystals	2016
36	ISO/TS 18827:2017	Nanotechnologies—Electron spin resonance (ESR) as a method for measuring reactive oxygen species (ROS) generated by metal oxide nanomaterials	2017
37	ISO/TR 19057:2017	Nanotechnologies—Use and application of acellular in vitro tests and methodologies to assess nanomaterial biodurability	2017
38	ISO/TS 20787:2017	Nanotechnologies—Aquatic toxicity assessment of manufactured nanomaterials in saltwater lakes using <i>Artemia</i> sp. Nauplii	2017
39	ISO/TR 19601:2017	Nanotechnologies—Aerosol generation for air exposure studies of nano-objects and their aggregates and agglomerates (NOAA)	2017
40	ISO/TS 10868:2017	Nanotechnologies—Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy	2017
41	ISO/TS 11888:2017	Nanotechnologies—Characterization of multiwall carbon nanotubes—Mesoscopic shape factors	2017
42	ISO/TS 19590:2017	Nanotechnologies—Size distribution and concentration of inorganic nanoparticles in aqueous media via single particle inductively coupled plasma mass spectrometry	2017
43	ISO/TS 13278:2017	Nanotechnologies—Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry	2017
44	ISO/TS 21623:2017	Workplace exposure — Assessment of dermal exposure to nano-objects and their aggregates and agglomerates (NOAA)	2017
45	ISO/TR 10993-22:2017	Biological evaluation of medical devices — Part 22: Guidance on nanomaterials	2017
46	ISO/TR 12885:2018	Nanotechnologies—Health and safety practices in occupational settings	2018
47	ISO 19007:2018	Nanotechnologies—In vitro MTS assay for measuring the cytotoxic effect of nanoparticles	2018
48	ISO/TS 16195:2018	Nanotechnologies—Specification for developing representative test materials consisting of nano-objects in dry powder form	2018
49	ISO/TR 20489:2018	Nanotechnologies—Sample preparation for the characterization of metal and metal-oxide nano-objects in water samples	2018
50	ISO/TS 21362:2018	Nanotechnologies — Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation	2018
51	ISO 21400:2018	Pulp — Determination of cellulose nanocrystal sulfur and sulfate half-ester content	2018
52	ISO 21083-1:2018	Test method to measure the efficiency of air filtration media against spherical nanomaterials — Part 1: Size range from 20 nm to 500 nm	2018
53	ISO 14644-12:2018	Cleanrooms and associated controlled environments — Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration	2018

54	ISO/TR 21386:2019	Nanotechnologies—Considerations for the measurement of nano-objects and their aggregates and agglomerates (NOAA) in environmental matrices	2019
55	ISO/TR 22019:2019	Nanotechnologies—Considerations for performing toxicokinetic studies with nanomaterials	2019
56	ISO/ 20814: 2019	Nanotechnologies—Testing of the photocatalytic activity of nanoparticles for NADH oxidation	2019
57	ISO/TR 19733:2019	Nanotechnologies—Matrix of properties and measurement techniques for graphene and related two-dimensional (2D) materials	2019
58	ISO/TS 19807-1:2019	Nanotechnologies—Magnetic nanomaterials—Part 1: Specification of characteristics and measurements for magnetic nanosuspensions	2019
59	ISO/TS 20660:2019	Nanotechnologies—Antibacterial silver nanoparticles—Specification of characteristics and measurement methods	2019
60	ISO/TS 21361:2019	Nanotechnologies—Method to quantify air concentrations of carbon black and amorphous silica in the nanoparticle size range in a mixed dust manufacturing environment	2019
61	ISO/TS 10867:2019	Nanotechnologies—Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy	2019
62	ISO/TS 11251:2019	Nanotechnologies—Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry	2019
63	ISO/TS 21236-1:2019	Nanotechnologies — Clay nanomaterials — Part 1: Specification of characteristics and measurement methods for layered clay nanomaterials	2019
64	ISO 2144:2019	Paper, board, pulps and cellulose nanomaterials — Determination of residue (ash content) on ignition at 900 °C	2019
65	ISO 1762:2019	Paper, board, pulps and cellulose nanomaterials — Determination of residue (ash content) on ignition at 525 °C	2019
66	ISO 21683:2019	Pigments and extenders — Determination of experimentally simulated nano-object release from paints, varnishes and pigmented plastics	2019
67	ISO/TS 21083-2:2019	Test method to measure the efficiency of air filtration media against spherical nanomaterials — Part 2: Size range from 3 nm to 30 nm	2019
68	ISO/TR 21624:2020	Nanotechnologies—Considerations for in vitro studies of airborne nano-objects and their aggregates and agglomerates (NOAA)	2020
69	ISO/TS 21975:2020	Nanotechnologies—Polymeric nanocomposite films for food packaging with barrier properties: Specification of characteristics and measurement methods	2020
70	ISO/TS 22082:2020	Nanotechnologies—Assessment of nanomaterials using dechorionated zebrafish embryo	2020
71	ISO/ 17200:2020	Nanotechnology—Nanoparticles in powder form—Characteristics and measurements	2020
72	ISO/TS 11308:2020	Nanotechnologies—Characterization of carbon nanotube samples using thermogravimetric analysis	2020
73	ISO/TS 19808:2020	Nanotechnology—Carbon nanotube suspension: Specification of characteristics and measurement methods	2020
74	ISO/ 21363: 2020	Nanotechnologies—Measurements of particle size and shape distributions by transmission electron microscopy	2020
75	ISO/TS 21412:2020	Nanotechnologies—Nano-object-assembled layers for electrochemical bio-sensing applications—Specification of characteristics and measurements methods	2020

76	ISO/TS 21237:2020	Nanotechnologies — Air filter media containing polymeric nanofibres — Specification of characteristics and measurement methods	2020
77	ISO/TR 14187:2020	Surface chemical analysis — Characterization of nanostructured materials	2020
78	ISO 23044:2020	Guidelines for softening and desalination of industrial wastewater for reuse	2020
79	ISO/ TS 23459:2021	Nanotechnologies—Assessment of protein secondary structure following an interaction with nanomaterials using circular dichroism spectroscopy	2021
80	ISO/ TS 12025:2021	Nanomaterials—Quantification of nano-object release from powders by generation of aerosols	2021
81	ISO/TS 21346:2021	Nanotechnologies—Characterization of individualized cellulose nanofibril samples	2021
82	IEC/TR 63258:2021	Nanotechnologies — A guideline for ellipsometry application to evaluate the thickness of nanoscale films	2021
83	ISO/TS 21236-2:2021	Nanotechnologies — Clay nanomaterials — Part 2: Specification of characteristics and measurements for clay nanoplates used for gas-barrier film applications	2021
84	ISO/TS 21356-1:2021	Nanotechnologies — Structural characterization of graphene — Part 1: Graphene from powders and dispersions	2021
85	ISO 638-2:2021	Paper, board, pulps and cellulosic nanomaterials — Determination of dry matter content by oven-drying method — Part 2: Suspensions of cellulosic nanomaterials	2021
86	ISO 638-1:2021	Paper, board, pulps and cellulosic nanomaterials — Determination of dry matter content by oven-drying method — Part 1: Materials in solid form	2021
87	ISO/TS 22295:2021	Space environment (natural and artificial) — Modelling of space environment impact on nanostructured materials — General principles	2021

Table 3 International nanotechnology standards under development.

Item	Standard	Standard Name
1	ISO/AWI TS 21633	Label-free impedance technology to assess the toxicity of nanomaterials in Vitro
2	ISO/AWI TR 22455	High throughput screening method for nanoparticles toxicity using 3D cells
3	ISO/AWI TS 23034	Method to estimate cellular uptake of carbon nanomaterials using optical absorption
4	ISO/ TS 23362	Nanotechnologies-Nanostructured porous alumina as catalyst support for vehicle exhaust emission control—Specification of characteristics and measurement methods
5	ISO/AWI TR 23463	Nanotechnologies—Characterization of carbon nanotube and carbon nanofiber aerosols in relation to inhalation toxicity tests

6	ISO/AWI TS 23650	Nanotechnologies—Evaluation of the antimicrobial performance of textiles containing manufactured nanomaterials
7	ISO/DTS 21356-1	Nanotechnologies—Structural characterization of graphene—Part 1: Graphene from powders and dispersions
8	ISO/AWI TS 21357	Nanotechnologies—Evaluation of the mean size of nano-objects in liquid dispersions by static multiple light scattering (SMLS)
9	ISO/DIS 19749	Nanotechnologies—Measurements of particle size and shape distributions by scanning electron microscopy
10	ISO/DTS 19807-2	Nanotechnologies—Magnetic nanomaterials—Part 2: Specification of characteristics and measurements for nanostructured superparamagnetic beads for nucleic acid extraction
11	ISO/AWI TR 22293	Evaluation of methods for assessing the release of nanomaterials from commercial, nanomaterial-containing polymer composites
12	ISO/PRF TS 23151	Nanotechnologies—Particle size distribution for cellulose nanocrystals
13	ISO/AWI TS 23302	Nanotechnologies — Requirements and recommendations for the identification of measurands that characterise nano-objects and materials that contain them
14	ISO/DTS 23690	Nanotechnologies — Multiwall carbon nanotubes — Determination of amorphous carbon content by thermogravimetric analysis
15	ISO/TS 22292	Nanotechnologies — 3D image reconstruction of rod-supported nano-objects using transmission electron microscopy
16	ISO/WD TR 5387	Nanotechnologies: Lung burden measurement of nanomaterials for inhalation toxicity studies
17	ISO/AWI TS 22298	Nanotechnologies — Silica nanomaterials — Specifications of characteristics and measurement methods for nanostructured porous silica samples with ordered nanopore array
18	ISO/AWI TS 4971	Nanotechnologies — Performance evaluation of nanosuspensions containing clay nanoplates for quorum quenching
19	ISO/AWI TS 4958	Nanotechnologies — Liposomes terminology
20	ISO/WD TR 24672	Nanotechnologies — Guidance on the measurement of nanoparticle number concentration
21	ISO/WD TS 23367	Nanotechnologies — Performance characteristics of nanosensors for chemical and biomolecule detection
22	ISO/WD TS 23878	Nanotechnologies — Positron annihilation lifetime measurement for nanopore evaluation in materials
23	ISO/WD TR 23652	Nanotechnologies — Considerations for radiolabelling methods of nanomaterials for performance evaluation
24	ISO/WD TS 23366	Nanotechnologies — Performance evaluation requirements for quantifying biomolecules using fluorescent nanoparticles in immunohistochemistry

25	ISO/WD TS 23361	Nanotechnologies — Crystallinity of cellulose nanomaterials by powder X-ray diffraction (Ruland-Rietveld analysis)
26	ISO/WD TS 5094	Nanotechnologies — Assessment of peroxidase-like activity of metal and metal oxide nanoparticles
27	ISO/AWI 4989	Cellulose Nanomaterial (CNM) — Sample Preparation of Pressed CNM Powder for Determination of Optical Properties — ISO Brightness and L* <sup>a</sup> *b* Colour
28	ISO/WD TS 4988	Nanotechnologies — Bioavailability assessment of manufactured nanomaterials in an aquatic environment using Tetrahymena sp.
29	IEC/CD 62565-3-1	Nanomanufacturing — Material specifications — Part 3-1: Graphene — Blank detail specification
30	ISO/CD 24688	Determination of modulation period of nano-multilayer coatings by low-angle X-ray methods
31	ISO/CD 24417	Surface chemical analysis — Analysis of metallic nanolayers on iron based substrates by glow-discharge optical-emission spectrometry
32	ISO/DIS 23170	Surface chemical analysis --- Depth profiling — Non-destructive depth profiling of nanoscale heavy metal oxide thin films on Si substrates with medium energy ion scattering
33	ISO/DIS 18473-4	Functional pigments and extenders for special applications — Part 4: Nanoscale titanium dioxide for photocatalytic application
34	ISO/PRF TR 23173	Surface chemical analysis — Electron spectroscopies — Measurement of the thickness and composition of nanoparticle coatings

**Table 4. International nanotechnology standards for terminology.**

Item	Standard	Standard Name	Year
1	ISO/TR 12802:2010	Nanotechnologies—Model taxonomic framework for use in developing vocabularies—Core concepts	2010
2	ISO/TS 80004-4:2011	Nanotechnologies—Vocabulary—Part 4: Nanostructured materials	2011
3	ISO/TS 80004-5:2011	Nanotechnologies—Vocabulary—Part 5: Nano/bio interface	2011
4	ISO/TS 80004-7:2011	Nanotechnologies—Vocabulary—Part 7: Diagnostics and therapeutics for healthcare	2011
5	ISO/TS 17302:2015	Nanotechnologies—Framework for identifying vocabulary development for nanotechnology applications in human healthcare	2015
6	ISO/TS 18110:2015	Nanotechnologies—Vocabularies for science, technology and innovation indicators	2015
7	ISO/TS 80004-1:2015	Nanotechnologies—Vocabulary—Part 1: Core terms	2015
8	ISO/TS 80004-2:2015	Nanotechnologies—Vocabulary—Part 2: Nano-objects	2015

9	ISO/TS 80004-12:2016	Nanotechnologies—Vocabulary—Part 12: Quantum phenomena in nanotechnology	2016
10	ISO/TR 18401:2017	Nanotechnologies—Plain language explanation of selected terms from the ISO/IEC 80004 series	2017
11	ISO/TS 20477:2017	Nanotechnologies—Standard terms and their definition for cellulose nanomaterial	2017
12	ISO/TS 80004-9:2017	Nanotechnologies—Vocabulary—Part 9: Nano-enabled electrotechnical products and systems	2017
13	ISO/TS 80004-11:2017	Nanotechnologies—Vocabulary—Part 11: Nanolayer, nanocoating, nanofil, and related terms	2017
14	ISO/TS 80004-13:2017	Nanotechnologies—Vocabulary—Part 13: Graphene and related two-dimensional (2D) materials	2017
15	ISO/DTS 80004-3:2020	Nanotechnologies—Vocabulary—Part 3: Carbon nano-objects	2020
16	ISO/TS 80004-8: 2020	Nanotechnologies—Vocabulary—Part 8: Nanomanufacturing processes	2020
17	ISO/DTS 80004-6:2021	Nanotechnologies—Vocabulary—Part 6: Nano-object characterization	2021

---

## **Estándares o normas voluntarias mexicanas para nanotecnologías**

En México las normas para las nanotecnologías son de carácter voluntario y las elabora el Comité Técnico de Normalización Nacional en Nanotecnologías (CTNNN) el cual es coordinado por la Secretaría de Economía en conjunto con el Centro Nacional de Metrología (CENAM), organismo descentralizado del gobierno federal.

### **Normas Mexicanas (NMX) para las nanotecnologías relacionadas con aspectos de ambiente, salud y seguridad**

<b>Item</b>	<b>Estándar</b>	<b>Nombre de la norma</b>	<b>Año de publicación</b>
1	NMX-R-13830-SCFI-2014 NMX-R-13830-SCFI-2020	Guía para el etiquetado de nano-objetos manufacturados y de productos que contengan nano-objetos manufacturados.	2015 Revisada y publicada en 2022
2	NMX-R-12901-1-SCFI-2015 NMX-R-12901-1-SCFI-2020	Gestión de riesgo ocupacional aplicado a nanomateriales manufacturados. Parte 1: principios y enfoques	2017 Revisada y publicada en 2022
3	NMX-R-12901-2-SCFI-2016	Gestión de riesgo ocupacional aplicado a nanomateriales manufacturados. Parte 2: uso del enfoque de control por bandas	2019
4	NMX-R-13121-SCFI-2019	Evaluación del riesgo de nanomateriales	2020
5	NMX-R-16197-SCFI-2019	Compilación y descripción de métodos de detección toxicológica para nanomateriales manufacturados	2020

### **Normas Mexicanas (NMX) para las nanotecnologías relacionadas con terminología, mediciones, caracterización y especificación de nanomateriales**

<b>Item</b>	<b>Estándar</b>	<b>Nombre de la norma</b>	<b>Año de publicación</b>
1	NMX-R-10867-SCFI-2014	Caracterización de nanotubos de carbono de una capa (NTCUC) mediante espectroscopia de fotoluminiscencia en el infrarrojo cercano (EFL-IRC)	2014
2	NMX-R-10929-SCFI-2014	Caracterización de muestras de nanotubos de carbono de múltiples capas (NTCMC)	2014
3	NMX-R-27687-SCFI-2014 NMX-R-80004-2-SCFI-2020	Terminología y definiciones para nano-objetos-nanopartícula, nanofibra y nanoplaca	2014 Revisada y publicada en 2022
4	NMX-R-62622-SCFI-ANCE-2014 NMX-R-J-62622-SCFI-ANCE-2020	Descripción, medición y parámetros de calidad dimensional de rejillas artificiales	2015 Revisada y publicada en 2022
5	NMX-R-80004-1-SCFI-2014 NMX-R-80004-1-SCFI-2020	Vocabulario-parte 1: conceptos básicos	20/oct/2014 Revisada y publicada en 2022