Technical Specification

ISO/TS 12901-1

Second edition
2024-08

Nanotechnologies — Occupational risk management applied to engineered nanomaterials —

Part 1: Principles and approaches

Nanotechnologies — Gestion du risque professionnel appliquée aux nanomatériaux manufacturés —

Partie 1: Principes et approches

Reference number
ISO/TS 12901-1:2024(en)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

This second edition cancels and replaces the first edition (ISO/TS 12901-1:2012), which has been technically revised.

The main changes are as follows:

— clauses have been updated and new references have been added to reflect recent research findings;

— a new subclause dedicated to graphene has been introduced in Clause 5;

— Clause 6 has been reorganized and eye exposure and accidental injection risks have been added for potential risk considerations from other potential routes of exposure;

— subclause 6.3 has been expanded and reorganized into two subclauses;

— Figure 1 has been added to Clause 7;

— text related to protection from ocular exposure has been added in 11.2 and substantial changes have been made to the personal protective equipment subclause;

— a new subclause, 11.3.4, has been introduced, focusing on safety by design;

— In 11.3.5 concerning state-of-the-art approaches, the reference to Clause A.1 has been removed and replaced with references to ISO/TR 12885 and other relevant documents;

— in 11.4, which discusses the evaluation of control measures, Clauses A.2 to A.4 have been removed and references to ISO/TR 18637:2016 and other relevant documents have been incorporated;

— Tables 1, 2 and 3 have been added;

— significant changes have been implemented in Clause 15;

— Annexes A, B and C have been added.

A list of all parts in the ISO 12901 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The field of nanotechnologies continues to advance rapidly through the development of new materials, products and applications. At the same time, many questions have been raised relating to the potential risks to human health and to the environment of some of these new nanomaterials. Several research programs have been launched at the international level to better understand and quantify these risks. Although some research is already published, this effort will need to continue for some time, as those involved in the development and use of nanomaterials need to assess the risks of nanotechnologies and to implement effective risk management approaches based on the best available evidence. International standardization on nanotechnologies should contribute to realizing the potential of this technology for the betterment and sustainability of our world through economic development, improving the quality of life, and also for improving and protecting public health and the environment.

This document supports this aim by describing the principles of an occupational risk management framework for nano-objects, and their aggregates and agglomerates (NOAA) greater than 100 nm and gives practical advice on its implementation based on the best current emerging evidence concerning the potential risks of nanomaterials. ISO/TS 12901-2 describes a specific approach based on control banding to further support the implementation of good practice in this area[1].

This document applies to such components, whether in their original form or incorporated in materials or preparations from which they can be released during their life cycle. However, as for many other industrial processes, nanotechnological processes can generate by-products in the form of unintentionally produced NOAAs, that can be linked to health and safety issues that need to be addressed as well.

Nanotechnologies — Occupational risk management applied to engineered nanomaterials —

Part 1: Principles and approaches

1 Scope

This document provides guidance on occupational health and safety measures relating to materials that contain and release engineered or manufactured NOAA during their life cycle, including the use of engineering controls and appropriate personal protective equipment, guidance on dealing with spills and accidental releases and guidance on appropriate handling of these materials during disposal.

This document is intended to be used by competent personnel, such as health and safety managers, production managers, environmental managers, industrial/occupational hygienists and others with responsibility for the safe operation of facilities engaged in production, handling, processing and disposal of these materials.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
agglomerate
collection of weakly or medium strongly bound particles where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces, or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO 26824:2022, 3.1.2]

3.2
aggregate
particle comprising of strongly bonded or fused particles where the resulting external surface area is significantly smaller than the sum of surface areas of the individual components

Note 1 to entry: The forces holding an aggregate together are strong forces, for example covalent or ionic bonds, or those resulting from sintering or complex physical entanglement, or otherwise combined former primary particles.

Note 2 to entry: Aggregates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO 26824:2022, 3.1.3, modified —"or ionic" has been added to Note 1 to entry.]

3.3
engineered nanomaterial
nanomaterial designed for a specific purpose or function

[SOURCE: ISO 80004-1:2023, 3.1.8]

3.4
exposure
contact with a chemical, physical or biological agent by swallowing, breathing, or touching the skin or eyes

Note 1 to entry: Exposure can be short-term (acute exposure), of intermediate duration or long-term (chronic exposure).

3.5
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.6
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.7
health hazard
potential source of harm to health

3.8
nanofibre
nano-object with two external dimensions in the nanoscale and the third dimension significantly larger

Note 1 to entry: The largest external dimension is not necessarily in the nanoscale.

[SOURCE: ISO 80004-1:2023, 3.3.5]

3.9
nano-object
discrete piece of material with one, two or three external dimensions in the nanoscale

[SOURCE: ISO 80004-1:2023, 3.1.5]

3.10
nanoparticle
nano-object (3.9) with all external dimensions in the *nanoscale* (3.12)

Note 1 to entry: If the dimensions differ significantly (typically by more than three times), terms such as *nanofibre* (3.8) or *nanoplate* (3.11) are preferred to the term nanoparticle.

[SOURCE: ISO 80004-1:2023, 3.3.4]

3.11
nanoplate
nano-object with one external dimension in the nanoscale and the other two external dimensions significantly larger

Note 1 to entry: The larger external dimensions are not necessarily in the nanoscale.

[SOURCE: ISO 80004-1:2023, 3.3.6]

3.12
nanoscale
length range approximately 1 nm to 100 nm

[SOURCE: ISO 80004-1:2023, 3.1.1]

3.13
NOAA
nano-objects, and their agglomerates and aggregates
material comprising *nano-object* (3.9), and their aggregates and agglomerates

Note 1 to entry: NOAAs include structures with one, two or three external dimensions in the nanoscale, which might be spheres, fibres, tubes and others as primary structures. NOAAs can consist of individual primary structures in the nanoscale and aggregated or agglomerated structures, including those with sizes larger than 100 nm.

[SOURCE: ISO 80004-1:2023, 3.2.6]

3.14
particle
minute piece of matter with defined physical boundaries

Note 1 to entry: A physical boundary can also be described as an interface.

Note 2 to entry: A particle can move as a unit.

Note 3 to entry: This general particle definition applies to nano-objects.

[SOURCE: ISO 26824:2022, 3.1.1]

3.15
risk
combination of the probability of occurrence of harm and the severity of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event and the possibility to avoid or limit the harm.

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

4 Abbreviated terms

CB	control banding
CIB	Current Intelligence Bulletin
CNT	carbon nanotube
COPD	chronic obstructive pulmonary disease
COSHH	Control of Substances Hazardous to Health Regulations
CPC	condensation particle counter
CPI	Consumer Products Inventory
DMAS	differential mobility analysing system
DW	double-walled
EC	elemental carbon

ECHA	European Chemicals Agency
EDX	energy dispersive X-ray
eLCOSH	Electronic Library of Construction Occupational Health and Safety
ENM	engineered nanomaterial
GHS	Globally Harmonized System
HARN	high aspect ratio nanomaterial
HEPA	high-efficiency particulate matter
ICS	International Classification for Standards
ICP-AES	inductively coupled plasma atomic emission spectroscopy
ICP-MS	inductively coupled plasma mass spectrometry
LDSA	lung deposited surface area
LEL	lower explosion limit
LEV	local exhaust ventilation
MIE	minimum ignition energy
MIT	minimum ignition temperature
MNM	manufactured nanomaterial
MWCNT	multi-walled carbon nanotube
NEAT	nanoparticles exposure assessment technique
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NOAA	nano-objects, and their agglomerates and aggregates
OECD	Organization for Economic Cooperative Development
OEL	occupational exposure limit
OPC	optical particle counter
OSHA	Occupational Safety and Health Administration
PLGA	poly(lactic-co-glycolic) acid
PPE	personal protective equipment
R&D	research and development
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RPE	respiratory protective equipment
SbD	safety-by-design

SDS	safety data sheet
SEM	scanning electron microscopy
SW	single-walled
SWCNT	single-walled carbon nanotube
TDS	technical data sheet
TEM	transmission electron microscopy
TEOM	tapered element oscillating microbalance
TGA	thermal gravimetric analysis
UK	United Kingdom
WHO	World Health Organization
XRF	X-ray fluorescence

5 Nanomaterial types and characteristics

5.1 General

Clause 5 describes some of the more common types of engineered nanomaterials to which this document can be applied; a few of these also have naturally occurring forms. This document is not intended to provide a full and comprehensive guide of all nanomaterial types.

5.2 Fullerenes

Fullerenes comprise one of four types of naturally-occurring forms of carbon, first discovered in the 1980s.[2],[3] Their molecules are composed entirely of carbon and take the form of a hollow sphere. Fullerenes are similar in structure to graphite which comprises sheets of hexagonal carbon rings, but can also contain pentagonal or heptagonal rings which enable 3D structures to be formed. One of the most commonly described fullerenes is C60, known as a Buckminster fullerene or a buckyball. Fullerenes are chemically stable materials and insoluble in aqueous solutions. Potential applications include drug delivery, coatings and hydrogen storage.

5.3 Carbon nanotubes

Carbon nanotubes are allotropes of carbon with cylindrical structure, high-aspect ratio different tube diameters and lengths as well as tube structures principally consisting of one to many layers of tubular graphene-like sheets[4].The principal types are usually grouped into single-walled (SW), double-walled (DW), and multi-walled (MW) carbon nanotube (CNT). Diameters can vary from around 1 nm for SWCNT to more than 100 nm for MWCNT. Their lengths can exceed several hundred micrometres. Commercial CNT can contain a significant amount of other carbon allotropes and inorganic nanoparticle catalysts.

5.4 Graphene

Graphene is a two-dimensional carbon-based material up to 10 layers thick for electrical measurements, beyond which the electrical properties of the material are not distinct from those for the bulk (also known as graphite). Graphene nanoplates can have a high aspect ratio with lateral sizes ranging from sub-micrometre to a 100 micrometres[5].

5.5 Nanowires

Nanowires are small conducting or semi-conducting nanofibres with a single crystal structure, a typical diameter of a few tens of nanometres and a large aspect ratio. Various metals have been used to manufacture nanowires, including cobalt, gold and copper. Silicon nanowires have also been produced. Potential applications of nanowires include inter-connectors in nano-electronic devices, photovoltaics and sensors.

5.6 Quantum dots

Quantum dots are small (2 nm to 10 nm) assemblies of semiconductor materials with novel electronic, optical, magnetic and catalytic properties. Typically containing 1 000 to 100 000 atoms, quantum dots are considered to be something between an extended solid structure and a single molecular entity. Semiconductor quantum dots exhibit distinct photo-electronic properties which relate directly to their size. For example, by altering the particle size, the light emitted by the particle on excitation can be tuned to a specific desired wavelength. Applications include catalysis, medical imaging, optical devices and sensors.

5.7 Metals and metal oxides, ceramics

This category includes a wide range of nanoparticles, including ultrafine titanium dioxide and fumed silica. Such nanoparticles can be formed from many materials, including metals, oxides and ceramics. These materials are often available only in agglomerated or aggregated form. They can be composites having, for example, a metal core with an oxide shell, or alloys in which mixtures of metals are present. This group of nanoparticles is generally less well defined in terms of size and shape, and likely to be produced in larger bulk quantities than other forms of nanoparticles. Applications include coatings and pigments, catalysis, personal care products, cosmetics and composites.

5.8 Carbon black

Carbon black is virtually pure elemental carbon in the form of particles that are produced by incomplete combustion or thermal decomposition of gaseous or liquid hydrocarbons under controlled conditions. Its physical appearance is that of a black, finely divided powder or pellet. Its use in tyres, rubber and plastic products, printing inks and coatings is related to properties of specific surface area, particle size and structure, conductivity and colour. The primary particle size of carbon black is most commonly less than 100 nm, but commercial forms are aggregated, typically with dimensions greater than 100 nm. Carbon black is one of the top 50 industrial chemicals manufactured worldwide, based on annual tonnage.

5.9 Organic nanoparticles

Examples of organic nanoparticles are chitosan, silk fibroin or other biodegradable polymers, including poly(lactic-co-glycolic) acid (PLGA) for biomedical applications.

5.10 Dendrimers

Dendrimers are polymer particles in which the atoms are arranged in a branching structure, usually symmetrically about a core. Dendrimers are typically monodisperse with a large number of functionalizable peripheral groups. They are currently being evaluated as drug delivery vehicles.

5.11 Nanoclays

Nanoclays are ceramic nanoparticles of layered mineral silicates. Nanoclays can be naturally occurring or engineered to have specific properties. Naturally occurring forms include several classes such as: montmorillonite, bentonite, kaolinite, hectorite and halloysite. Nanoclays also include organo-clays, i.e. clays that have been subjected to cation exchange, typically with large organic molecules, which partially or completely de-laminate the primary sheets.