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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

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Contents

Foreword

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~~International Standards are~~ 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 ~~given in~~of the ISO/IEC Directives, Part 2 (see www.iso.org/directives~~.~~).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html~~ISO/TS 12901-1~~.

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

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

The main changes ~~compared to the previous edition~~ are as follows:

— ~~—~~clauses have ~~undergone updates~~been updated and ~~have seen the inclusion of additional~~ new references have been added to reflect recent research findings~~.~~;

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

Clause 6~~within Clause 5 (Nanomaterial types~~ has been reorganized and ~~characteristics).~~

— ~~— clause 6 (Nanomaterial hazard, exposure, and risk) has undergone a reorganization. Furthermore, it now includes~~ eye exposure and accidental injection risks have been added for potential risk considerations from other potential routes of exposure~~.~~;

— subclause 6.3~~— clause 6.3 (Risk of fire and explosion from NOAA)~~ has been expanded and reorganized~~. This includes~~ into two ~~new~~ subclauses~~: "Hazard Information" and "Risk of fire and explosion from NOAA."~~;

— Figure 1~~— Figure 1 (Approach to managing risks from NOAA)~~ has been added to Clause 7~~Clause 7 (General approach to managing risks from NOAA).~~;

— ~~— in clause 11, subclause 11.2 on control measures, there has been the addition of~~ text related to protection from ocular exposure has been added in 11.2~~. Additionally,~~ and substantial changes have been made to the ~~section regarding Personal Protective Equipment (PPE). A~~personal protective equipment subclause;

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

— In 11.3.5~~subclause 11.3.5~~ concerning state-of-the-art approaches, ~~Annex~~ the reference to Clause A.1 has been removed and replaced with references to ISO/TR 12885~~:2018 and other~~ and other relevant documents;

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

Tables 2, 3 and 4~~— clause 12, dealing with measurement methods, has seen important changes in subclause 12.2. This includes the addition of new tables, such as Table 2 listing samplers for collecting airborne particles and NOAA on filters for off-line gravimetric or chemical analysis. Table 3 now lists devices for time-resolved measurement of number, mass, and surface area concentration for both hand-held and personal instruments. Similarly, Table 4 lists devices for time-resolved measurement of number, mass, and surface area concentration, but these are intended for research and benchtop instruments.~~

— ~~—~~ have been added;

— significant changes have been implemented in Clause 15~~the clause 15 (Disposal procedures).~~;

Annexes A, B and C~~— three new annexes have been introduced: Annex A: NOAA categories; Annex B: Additional information on dermal and ocular exposure; Annex C: Guidance and articles on "State of the Art" approaches to control measures.~~

— 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~~www.iso.org/members.html~~.

~~ISO/TS 12901 consists of the following parts, under the general title *Nanotechnologies — Occupational risk management applied to engineered nanomaterials*:~~

~~— *Part 1: Principles and approaches*~~

~~— *Part 2: Use of the control banding approach*~~

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 ~~newnanomaterials.~~new nanomaterials. Several research programs have been launched at the international level to better understand and quantify these risks. Although some research ~~isalready~~is already published, this effort will need to continue for some time, as those involved in the development and use of ~~nanomaterialsneed~~nanomaterials need to assess the risks of nanotechnologies and to implement effective risk management approaches based on the best available evidence. International standardization ~~onnanotechnologies~~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 ~~part ofISO/TS 12901~~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 ~~(NOAA)~~ and gives practical advice on its implementation based on the best current emerging evidence concerning the potential risks of nanomaterials. ISO/TS 12901-2 ~~, which is under revison,~~ describes a specific approach based on control banding to further support the implementation of good practice in this area[1].

~~The term NOAA, as used in this part of ISO TS12901, consists of nano-objects as well as of aggregates and agglomerates of the same. It~~This document applies to such components, whether in their original form or incorporated in materials or preparations from which they ~~could~~can be released during their ~~lifecycle~~life cycle. However, as for many other industrial processes, nanotechnological processes can generate by-products in the form of unintentionally produced ~~NOAA, which might~~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 ~~part of~~ISO/TS 12901~~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 ~~part of~~ISO/TS 12901~~document~~ is intended ~~for use~~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

~~The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.~~

~~CEN EN 17058:2017, Workplace exposure — Assessment of inhalation exposure to nano objects and their aggregates and agglomerates~~

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~~/TS~~ 26824:~~2013, definition~~ 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~~/TS~~ 26824:~~2013, definition~~ 2022, 3.1.3, modified ~~—~~"or ionic" has been added to Note 1 ~~adapted]~~to entry.]

3.3
engineered nanomaterial
nanomaterial designed for a specific purpose or function

[SOURCE: ISO ~~/TS~~ 80004~~-~~-1:~~2015, definition 2~~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 ~~may~~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: ~~[SOURCE:~~ISO/IEC Guide 51:2014, 3.1~~]]~~]

3.6
hazard
potential source of harm

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

3.7
health hazard
potential source of harm to health

~~[SOURCE: ISO 10993-17:2002, definition 3.7]~~

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.

~~Note 2 to entry: The terms nanofibril and nanofilament can also be used.~~

~~Note 3 to entry: If the dimensions differ significantly (typically by more than 3 times), terms such as nanofibre or nanoplate may be preferred to the term nanoparticle.~~

[SOURCE: ISO/TS 80004-2:2015, definition 41:2023, 3.3.5]

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

Note 1 to entry: The second and third external dimensions are orthogonal to the first dimension and to each other.

[SOURCE: ISO/TS 80004-1:2015, definition 22023, 3.1.5]

3.10
nanoparticle
nano-object (3.9) with all external dimensions in the *nanoscale* (3.12where the lengths of the longest and the shortest axes of the nano-object do not differ significantly)

Note 1 to entry: If the dimensions differ significantly (typically by more than 3three times), terms such as *nanofibre* (3.8) or *nanoplate* (3.11may be) are preferred to the term nanoparticle.

Note 2 to entry: Adapted from[SOURCE: ISO/TS 80004-2:2015 definition 1:2023, 3.3.4.4]

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.

Note 2 to entry: If the dimensions differ significantly (typically by more than 3 times), terms such as nanofibre or nanoplate may be preferred to the term nanoparticle.

[SOURCE: ISO/TS 80004-2:2015, definition 41:2023, 3.3.6]

3.12
nanoscale
length range from approximately 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from larger sizes are predominantly exhibited in this size range.

[SOURCE: ISO/TS 80004-1:2015 definition 22023, 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, definition: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~~/TS~~ 26824:2022, ~~definition~~ 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, ~~definition~~ 3.9]

4 ~~Symbols and~~ Abbreviated terms

~~Table 1~~

~~ADME~~	~~adsorption, distribution, metabolism and elimination~~
~~ACGIH~~	~~American Conference of Governmental Industrial Hygienists~~
~~BMD~~	~~benchmark dose~~
~~BMDL~~	~~benchmark dose lower confidence limit~~
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
~~CPC~~	~~chemical protective clothing~~
CPI	Consumer Products Inventory
DMAS	differential mobility analysing system
DW	double-walled
EC	elemental carbon
ECHA	European Chemicals Agency
~~EDXA~~EDX	energy dispersive X-ray ~~analysis~~
eLCOSH	Electronic Library of Construction Occupational Health and Safety
ENM	engineered nanomaterial
~~EDX~~	~~energy dispersive X-ray~~
~~ELPI~~	~~electrostatic low pressure impactor~~
~~ES~~	~~exposure standard~~
GHS	Globally Harmonized System
HARN	high aspect ratio nanomaterial

~~ADME~~	~~adsorption, distribution, metabolism and elimination~~
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
~~LCL~~	~~lower confidence limit~~
LEL	lower explosion limit
LEV	local exhaust ventilation
~~LOAEL~~	~~lowest-observed-adverse-effect-level~~
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 greater than 100 nm
~~NOAEL~~	~~no-observed-adverse-effect-level~~
OECD	Organization for Economic Cooperative Development
OEL	occupational exposure limit
OPC	optical particle counter
OSHA	Occupational Safety and Health Administration
~~PB-ECL~~	~~performance based exposure control limit~~
PLGA	poly(lactic-co-glycolic) acid
PPE	personal protective equipment
R&D	research and development
REACH	Registration, Evaluation, ~~Authorisation~~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

~~ADME~~	~~adsorption, distribution, metabolism and elimination~~
TEOM	tapered element oscillating microbalance
TGA	thermal gravimetric analysis
~~TLV~~	~~threshold limit value~~
UK	United Kingdom
~~WEL~~	~~workplace exposure limit~~
WHO	World Health ~~Organisation~~Organization
XRF	X-ray fluorescence

5 Nanomaterial types and characteristics

5.1 General

Clause 5~~This clause~~ describes some of the more common types of engineered nanomaterials to which this ~~guide might~~document can be applied; a few of these also have naturally ~~occuring~~occurring forms. ~~It~~This document is not intended to provide a full and comprehensive guide ~~or definition for these nanomaterials~~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 ~~nanotubesare~~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 ~~SW (~~single-walled~~), DW (~~ (SW), double-walled (DW), and ~~MW (~~multi-walled (MW) carbon ~~nantube~~nanotube (CNT). Diameters ~~may~~can vary from around 1 nm for SWCNT to more than 100 nm for MWCNT. Their lengths can exceed several hundred ~~μm~~micrometres. Commercial CNT ~~cancontain~~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 ~~nano-platelets~~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 ~~10s~~tens of ~~nm~~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.