



BSI Standards Publication

Nanotechnologies — Health and safety practices in occupational settings

National foreword

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Nanotechnologies — Health and safety practices in occupational settings

*Nanotechnologies — Pratiques de santé et de sécurité en milieux
professionnels*





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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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

This second edition cancels and replaces the first edition (ISO/TR 12885:2008), which has been technically revised.

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

- widespread reference to 'nano-objects, and their aggregates and agglomerates greater than 100 nm' ('NOAAs'), in place of alternative terms;
- addition of annexes addressing:
 - primary chemical composition of nanomaterials;
 - nanomaterial-specific animal and cell culture toxicity studies;
 - characteristics of selected instruments and techniques for monitoring nano-aerosol exposure;
 - characteristics of biosafety cabinets;
 - advantages and disadvantages of different types of air-purifying particulate respirators;
- consolidation of bibliographical information.

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 is advancing rapidly and is expected to impact virtually every facet of global industry and society. International standardization on nanotechnologies should contribute to realizing the potential of this technology through economic development, improving the quality of life, and for improving and protecting public health and the environment. One can expect many new manufactured nanomaterials coming to the market and workplace. The introduction of these new materials into the workplace raises questions concerning occupational safety and health. This document assembles useful knowledge on occupational safety and health practices in the context of nanotechnologies. Use of the information in this document could help companies, researchers, workers and other people to prevent potential adverse health and safety consequences during the production, handling, use and disposal of manufactured Nano-Objects, and their Aggregates and Agglomerates greater than 100 nm (NOAAs). This advice is broadly applicable across a range of NOAAs and applications.

This document is based on current information about nanotechnologies, including characterization, health effects, exposure assessments, and control practices. It is expected that this document will be revised and updated and new safety standards will be developed as our knowledge increases and experience is gained in the course of technological advance.

Nanotechnology involves materials at the nanoscale. ISO/TC 229 defines the “nanoscale” to mean size range from approximately 1 nm to 100 nm (ISO/TS 80004-1:2015)^[1]. To give a sense of this scale, a human hair is of the order of 10 000 to 100 000 nm, a single red blood cell has a diameter of around 5 000 nm, viruses typically have a maximum dimension of 10 nm to 100 nm and a DNA molecule has a diameter of around 2 nm. The term “nanotechnology” can be misleading since it is not a single technology or scientific discipline. Rather it is a multidisciplinary grouping of physical, chemical, biological, engineering, and electronic processes, materials, applications and concepts in which the defining characteristic is one of size.

The distinctive and often unique properties which are observed with nanomaterials offer the promise of broad advances for a wide range of technologies in fields as diverse as computers, biomedicine, and energy. At this early stage the potential applications of nanomaterials seem to be limited only by the imagination. New companies, often spin outs from university research departments, are being formed and are finding no shortage of investors willing to back their ideas and products. New materials are being discovered or produced and for some, astonishing claims are being made concerning their properties, behaviours and applications.

While much of the current “hype” is highly speculative, there is no doubt that worldwide, governments and major industrial companies are committing significant resources for research into the development of nanometer scale processes, materials and products.

Ordinary materials such as carbon or silicon, when reduced to the nanoscale, often exhibit novel and unexpected characteristics such as extraordinary strength, chemical reactivity, electrical conductivity, or other characteristics that the same material does not possess at the micro or macro-scale. A huge range of nanomaterials have already been produced including nanotubes, nanowires, fullerene derivatives (buckyballs).

A few manufactured nanomaterials were developed already in the 19th and 20th centuries, at a time when the word “nanotechnology” was unknown. Among such nanomaterials are zeolites, catalyst supports such as MgCl₂, pigments and active fillers such as carbon black and synthetic amorphous silica. Market size of these commodity materials is well above the billion US dollars or million tons threshold.

Nanotechnologies are gaining in new commercial application. Nanomaterials are currently being used in electronic, magnetic and optoelectronic, biomedical, pharmaceutical, cosmetic, energy, catalytic and materials applications. Areas producing the greatest revenue for nanomaterials are chemical-mechanical polishing, magnetic recording tapes, sunscreens, automotive catalyst supports, electro-conductive coatings and optical fibres.

Among other factors, due to the great variability of physical and chemical properties of nanomaterials, our abilities to accurately predict the impact of some nanomaterials exposures on worker health are

limited at this time. Similarly, there might be insufficient information about human exposures during work and our abilities to measure nanomaterials in the workplace (or more generally) are limited by current technologies. Overall, there is currently limited knowledge on chronic health effects of nanomaterials. In the case of some nanostructured materials, such as carbon black and synthetic amorphous silica, toxicological and epidemiological data are available.

A subset of nanomaterials, NOAAs are of particular concern in the workplace as they can be dispersed in the air and can represent health risks via inhalation exposures. NOAAs include structures with one, two or three external dimensions in the nanoscale from approximately 1 nm to 100 nm, 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. An aggregate is comprised of strongly bonded or fused particles (structures). An agglomerate is a collection of weakly bound particles and/or aggregates.

There are many gaps in current science about identifying, characterizing, and evaluating potential occupational exposures in the nanotechnology context. These gaps in our knowledge are best addressed at a multidisciplinary level. Occupational health practitioners and scientists and practitioners in the toxicology field including medical scientists and environmental scientists have vital roles to play in safeguarding health in this fast-moving field. Collaborative studies — ideally with international coordination — are essential in order to provide the critical information required within a reasonable time frame.

Nanotechnologies — Health and safety practices in occupational settings

1 Scope

This document describes health and safety practices in occupational settings relevant to nanotechnologies. This document focuses on the occupational manufacture and use of manufactured nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAAs). It does not address health and safety issues or practices associated with NOAAs generated by natural processes, hot processes and other standard operations which unintentionally generate NOAAs, or potential consumer exposures or uses, though some of the information in this document can be relevant to those areas.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the ISO/TS 80004 series apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp/ui>
- IEC Electropedia: available at <http://www.electropedia.org/>

4 Symbols and abbreviated terms

ACGIH	American Conference of Governmental Industrial Hygienists
AIDS	acquired immune deficiency syndrome
APF	assigned protection factor
APR	air-purifying respirator
BEI	biological exposure index
BET	Brunauer-Emmett-Teller
BMD	benchmark dose
BSC	biological safety cabinet
CNF	carbon nanofibre
CNT	carbon nanotube
COSHH	control of substances hazardous to health
CPC	condensation particle counter
DC	diffusion charger