TR 73 : Part 1 : 2020
ISO/TR 12885:2018, IDT
(ICS 07.120; 13.100)

TECHNICAL REFERENCE

Handling of engineered nanomaterials in workplaces

– Part 1 : Health and safety practices in occupational settings relevant to nanotechnologies

[ISO title: Nanotechnologies – Health and safety practices in occupational settings]

Singapore Standards Council

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Handling of engineered nanomaterials in workplaces

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The organisations in which the experts of the Working Group are involved are:

Health Sciences Authority
IOM (Institute of Occupational Medicine) Singapore Pte Ltd
Ministry of the Environment and Water Resources
Ministry of Manpower
Nanyang Technological University
National University Health System
National University of Singapore
PUB, Singapore's National Water Agency
Singapore Food Agency
TÜV SÜD PSB Pte Ltd

Contents

National Foreword

This Technical Reference (TR) was prepared by the National Mirror Committee on ISO/TC 229/WG3 for Health, Safety & Environment set up by the Technical Committee on Nanotechnology under the purview of CSC.

TR 73 consists of the following parts under the generic title "Handling of engineered nanomaterials in workplaces":

Part 1: Health and safety practices in occupational settings relevant to nanotechnologies
Part 2: Overview of available frameworks for the developmemnt of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)
Part 3: Occupational and environmental monitoring of engineered nanomaterials

This TR is identical with ISO/TR 12885:2018, "Nanotechnologies — Health and safety practices in occupational settings", published by the International Organisation for Standardisation.

NOTE 1 – Reference to International Standards/Technical Reports are replaced by applicable Singapore Standards/Technical References.

NOTE 2 – Where numerical values are expressed as decimals, the comma is read as a full point.

This TR is a provisional standard made available for application over a period of three years. The aim is to use the experience gained to update the TR so that it can be adopted as a Singapore Standard. Users of the TR are invited to provide feedback on its technical content, clarity and ease of use. Feedback can be submitted using the form provided in the TR. At the end of the three years, the TR will be reviewed, taking into account any feedback or other considerations, to further its development into a Singapore Standard if found suitable.

Attention is drawn to the possibility that some of the elements of this TR may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as "Mature Standards". Mature Standards will not be subject to further review, unless there are requests to review such standards.*

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3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

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).

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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 $MgCl_2$, 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.

Handling of engineered nanomaterials in workplaces – Part 1: Health and safety practices in occupational settings relevant to nanotechnologies

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.