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Handling of engineered nanomaterials in workplaces

– Part 2 : Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)

[ISO title: Nanotechnologies — Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)]

Singapore Standards Council

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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 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)", 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.

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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 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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The committee responsible for this document is ISO/TC 229, *Nanotechnologies*.

Introduction

Nano-objects and their aggregates and agglomerates (NOAAs) represent a subset of particulate materials that 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 may 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 comprises strongly bonded or fused particles (structures). An agglomerate is a collection of weakly bound particles (structures)[1][2][3][4].

The purpose of this document is to describe a general framework for the development of occupational exposure limits (OELs) or occupational exposure bands (OEBs) for individual NOAAs or categories of NOAAs with different levels of available data. OELs and OEBs are important tools in the prevention of occupational illness. OELs have a long history in industrial hygiene and are based on observations of workers or studies of laboratory animals. OELs are established to minimize the likelihood of adverse effects from exposure to potentially hazardous substances in the workplace[5][6]. An OEL is generally substance-specific (although sometimes generically expressed, such as dust). Sufficient data to develop an OEL may not be available, especially for substances such as NOAAs used in emerging technologies. To aid in hazard communication and exposure control decisions for substances without OELs, hazard banding has been used for many years[7][8][9]. Substances are assigned to a hazard band based on limited toxicity data usually from animal studies. Hazard banding schemes typically consist of qualitative bands ranging from low to high severity of effects. Thus, a hazard band represents a range of potential toxicities for a particular substance or category of substances. Some hazard banding schemes include associated OEBs[10]. The term OEB is a general term for exposure concentration ranges used in some hazard banding schemes that are related to the ranges of hazard potentials. In contrast to an OEB, an exposure band is a range of potential concentrations of a substance (or category of substances) to which workers may be exposed in a defined occupational scenario and which is based on factors such as the amount of NOAA processed or used, the nature of the process, and the form of the NOAA including dustiness[3]. In control banding, the hazard band and the exposure band are combined to determine the control band for any particular occupational scenario (e.g. ISO/TS 12901-2).

OELs and OEBs are part of an overall occupational safety and health (OSH) program and are not intended to identify and address all safety and health risks associated with a specific process or task. OELs and OEBs are intended to provide occupational safety and health professionals with a health basis for assessing the effectiveness of exposure controls and other risk management practices. The exposure assessment of nanomaterials including carbon nanomaterials [such as fullerene, graphene, single-walled carbon nanotube (SWCNTs) and multi-walled carbon nanotube (MWCNTs)], metal oxides (TiO_2, SiO_2, zinc oxide, iron oxide), and metals (silver and gold nanoparticles) remains a challenge in the field of occupational hygiene, as there have been relatively few studies on the characterization of workplace exposures to NOAA. Sampling and analytical methods that have the capabilities to accurately measure nanomaterials are still under development. Most sampling devices that measure airborne particle count concentrations, such as condensation particle counters and optical particle counters, cannot differentiate ambient exposures to background nanoparticles from NOAA in the workplace environment. Airborne measurements of carbon nanotubes (CNTs) and carbon nanofibres (CNFs) using mobility particle sizers also sometimes could present a unique challenge due to the arcing caused by the charged airborne CNT and CNF agglomerates in the differential mobility analyser[11]. Although several groups have attempted to measure and count CNT structures using transmission electron microscopy or other microscopic methods[12][13], there

are still no standard methods for measuring and counting CNT structures. In addition, determining the mass concentration of CNTs and CNFs based on measuring the elemental carbon (EC) remains a challenge due to other sources of elemental carbon in the workplace, such as organic composite materials and air and diesel pollution that could interfere in the determination of CNT and CNF exposures.

Scientific and technical methodologies used to set exposure limits may differ from one entity to another, which can lead to disparities in worker protection from country to country[14]. Therefore, harmonizing the scientific methodologies used in developing OELs, including using the best available evidence for interspecies extrapolation and specifying the type of data and uncertainties involved in the OEL determination is necessary for a robust health and safety evaluation framework for NOAAs. This document provides a collaborative, science-based platform to describe and evaluate the state-of-the-art in such data and methods.

Current risk assessment methods are likely to apply to NOAAs[15], although the limited health hazard data for many NOAAs and the considerable variety in the types of manufactured NOAAs present a challenge to the efficient development of OELs for individual NOAAs. To date, few OELs and OEBs have been developed for specific NOAAs and none have been formally regulated by a government agency. Standard OEL and OEB methodologies for NOAAs are needed to evaluate the evidence on the hazard potential of NOAAs in the workplace to provide a health basis for risk management decisions, including selection and evaluation of engineering control options. One of the goals of this document is to identify both the similarities and differences in the methods used to develop OELs. This evaluation may lead to improvements in methods for setting exposure limits or bands.

This document presents an overview of the state-of-the-art in the development of OELs and OEBs for NOAAs. Current approaches for assigning default hazard bands in the absence of NOAA-specific toxicity data are described. These approaches build on current hazard and control banding strategies, such as those developed in ISO/TS 12901-2. The current state of the methods and data to develop OELs and OEBs for NOAAs is described in this document, along with an evaluation of those methods used in developing the current OELs for NOAAs. Categorical approaches to derive OEBs for NOAAs with limited data are also discussed, such as those based on biological mode-of-action (MOA) and physico-chemical (PC) properties. The basis for the framework described in this document is the U.S. NIOSH Current Intelligence Bulletin *Approaches to Developing Occupational Exposure Limits or Bands for Engineered Nanomaterials*[16]. This document also takes into consideration other state-of-the-science reports, including outputs of the workshop "Strategies for Setting Occupational Exposure Limits for Engineered Nanomaterials," which was held on September 10-11, 2012 in Washington, DC, USA[6] and the OECD Working Party on Manufactured Nanomaterials Expert Meeting on Categorization of Manufactured Nanomaterials, September 17-19, 2014[17].

The primary target audience of this document is occupational safety and health professionals in government, industry, and academia, who have the expertise to develop OELs or OEBs based on the guidance in this document. In addition, the evidence-based approach described in this document may be useful in the evaluation and/or verification of current hazard and control banding schemes and for identifying the key data gaps. Control banding requires information on both the applicable hazard category and exposure category. Appropriately verified control banding tools would be broadly useful, as these tools require less specialized expertise and resources (than for a comprehensive risk assessment) and are accessible to a wider group of individuals and small businesses. Therefore, this document can be considered complementary to ISO/TS 12901-2 on control banding for nanomaterials as it describes the state-of-the-art in the process of assigning nanomaterials to hazard bands/OEBs when the scientific evidence is not sufficient to develop an individual OEL.

Some of the cited methods lead to results that are not necessarily consistent and this may be due to method selection biases of the authors. In these cases, diverse results will also make it difficult to use information to confidently establish exposure and band levels. It is beyond the scope of this document to attempt to identify the methods which lead to both correct and consistent results. In the event that methods lead to diverse results, it is hoped that this report will lead to additional methods development that will lead to improvements and that these improvements can be relied on for setting exposure and banding levels.

The objectives of this document include

a) describing an evidence-based state-of-the-art framework to develop OELs or OEBs for manufactured NOAAs, and

b) examining the currently available data and other approaches and methods used (e.g. benchmark substances and benchmark exposure levels) in the occupational risk management decision-making for NOAAs.

It is anticipated that this document will contribute to the development of standard hazard and risk assessment methods and facilitate the systematic evaluation of the potential health risk of occupational exposure to NOAAs.

Handling of engineered nanomaterials in workplaces – Part 2: Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)

1 Scope

This document provides an overview of available methods and procedures for the development of occupational exposure limits (OELs) and occupational exposure bands (OEBs) for manufactured nano-objects and their aggregates and agglomerates (NOAAs) for use in occupational health risk management decision-making.

2 Normative references

There are no normative references in this document.