Z12885-12

Nanotechnologies — Exposure control program for engineered nanomaterials in occupational settings

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S. Yick	National Research Council Innovation Centre, Vancouver, British Columbia	
B. Haydon	CSA Group, Mississauga, Ontario	*Project Manager*
R. Meyers	CSA Group, Mississauga, Ontario	*Project Manager*

Preface

This is the first edition of CSA Z12885, *Nanotechnologies — Exposure control program for engineered nanomaterials in occupational setting*s. It is based on ISO (International Organization for Standardization) Technical Report 12885 (first edition, 2008-10-01) entitled *Nanotechnologies — Health and safety practices in occupational settings relevant to nanotechnologies* and contains revisions and additional guidance to reflect Canadian practices and safety considerations. This Standard is the first in a series of Standards on nanotechnologies resulting from international and Canadian contributions to the continued activity of ISO/TC 229, the ISO Technical Committee on nanotechnologies.

At the time of publication, health and safety legislation for the safe handling and use of engineered nanomaterials differs from jurisdiction to jurisdiction in Canada. It is the user's responsibility to determine how the applicable legislative requirements in any of these jurisdictions relate to this Standard.

This Standard was prepared by the Technical Committee on Nanotechnology — Occupational Health and Safety, under the jurisdiction of the CSA Strategic Steering Committee on Occupational Health and Safety, and has been formally approved by the Technical Committee.

Notes:

(1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*

(2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*

(3) *This Standard was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*

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(a) define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;
(b) provide an explanation of circumstances surrounding the actual field condition; and
(c) where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.
Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at* ***standardsactivities.csa.ca****.*

(5) *This Standard is subject to periodic review, and suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to* ***inquiries@csagroup.org*** *and include "Proposal for change" in the subject line:*
(a) Standard designation (number);
(b) relevant clause, table, and/or figure number;
(c) wording of the proposed change; and
(d) rationale for the change.

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0 Introduction

The field of nanotechnologies is advancing rapidly and is expected to impact virtually every facet of global industry and society. Use of new engineered nanomaterials will likely be introduced into workplaces in the future, and questions concerning occupational health and safety should be addressed by Standards. The purpose of this Standard is to assemble and make available to users knowledge on occupational safety and health practices in the context of nanotechnologies. Nanotechnology involves materials at the nanoscale. As a working definition, the term “nanoscale” means the size range from approximately 1 nm to 100 nm. A nanometre is 1×10^{-9} m or one millionth of a millimetre. It is difficult to fully appreciate these remarkably small scales. To give a sense of this scale, in comparison a human hair is of the order of 10 000 to 100 000 nm, a single red blood cell has a diameter of around 5000 nm, viruses typically have a maximum dimension of 10 to 100 nm, and a DNA molecule has a diameter of around 2 nm. The term “nanotechnology” is a multidisciplinary grouping of physical, chemical, biological, engineering, and electronic processes, materials, applications, and concepts in which the defining characteristic is size.

The unique properties of nanomaterials are utilized in fields as diverse as computers, biomedicine, and energy. At this early stage the potential applications of nanomaterials seem to be limitless. New materials are being discovered or produced yearly, and astonishing claims are being made concerning their properties, behaviours, and applications.

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 range of nanomaterials have already been produced, including nanotubes, nanowires, and fullerene derivatives (bucky balls).

A few engineered nanomaterials were developed in the 19^{th} and 20^{th} centuries, at a time when the word “nanotechnology” was unknown. Among such nanomaterials are zeolites, catalyst supports, pigments, and active fillers such as carbon black and synthetic amorphous silica. Market size of these commodity materials is well above the billion U.S. dollars or million tons threshold. Nanomaterials are currently being used in electronic, magnetic, optoelectronic, biomedical, pharmaceutical, cosmetic, energy, catalytic, and materials applications.

The occupational health and safety effects of new nanomaterials are mostly unknown. This can be attributed to the relatively recent development of the nanotechnology sector and, as a result, the lack of available information on human exposures and working conditions. There is uncertainty regarding routes of exposure, and some nanomaterials are suspected of passing through the dermal barrier. Also there is concern that within the body a small percentage of some nanomaterials might be able to cross or circumvent barriers that larger particles cannot (e.g., the blood-brain barrier, circumventing this barrier by travelling along nerve paths from the nose to the brain). Thus, these nanomaterials might accumulate in organs that otherwise would not be impacted. As a consequence the ability to accurately predict the impact of some nanomaterials exposures on worker health is limited at this time. In particular the ability to measure nanomaterials in the workplace is limited by current technologies. Nanotechnology presents new challenges as the properties of nanomaterials relevant to worker health include size and shape as much as the more conventional factors of chemical structure and composition. The greater surface area per mass of nanoparticles compared to larger particles is a fundamental contributor to the greater chemical reactivity and utility of nanomaterials for industrial, commercial, and medical applications, but it also raises concerns about the potential for adverse health effects in workers exposed to nanomaterials. Measuring these additional attributes will be necessary to accurately assess the health impacts of nanomaterials in the workplace.

In summary, there are many gaps in current science about identifying, characterizing, and evaluating potential occupational exposures and their impacts on workers. Because there are many unknowns about the hazardous nature of nanomaterials, it is currently considered that

- the toxicological properties of nanomaterials cannot always be predicted from the known toxicity of the substance in bulk form alone;
- for the same substance, the nanomaterials are often more toxic than their larger counterparts; and
- fire and explosion hazards posed by nanomaterials could be greater than those for larger particles or bulk materials, and, therefore, additional tests could be necessary to evaluate flammability, explosivity, and reactivity of nanomaterials.

Within this realm of unknowns, employers are still responsible for

- ensuring the health and safety of persons at or near the workplace through the implementation of the hierarchy of controls;
- providing safety instruction and training;
- making sure that employees are aware of hazards in the workplace; and
- ensuring that employees have the right safety and personal protective equipment (PPE) to do their jobs safely, and that they know how to use it.

It is within this context that this Standard provides

- an overview of the steps an organization needs to take to establish and maintain an effective program for the prevention of harmful exposure to nanomaterials; and
- information for workers handling or using nanomaterials and for persons responsible for ensuring the safety of such workers. This includes information on characterization, health effects, exposure assessments, and control practices.

This Standard outlines the requirements necessary to establish and implement a comprehensive, managed program to control exposure to nanomaterials in the workplace. Clause 4 is organized into clauses based on the Plan-Do-Check-Act (PDCA) model and is designed to be consistent with CAN/CSA-Z1000. This approach is intended to help users integrate their nanomaterial exposure control management program into an organization's existing occupational health and safety management system (OHSMS). However, use of this Standard is not contingent on an organization having an OHSMS.

Further details and guidance information to assist with the implementation of an effective program to control exposure to nanomaterials is provided in the Annexes.

Annex A contains information on the description and common manufacturing processes of nanomaterials.

Annex B provides the principles for characterization and identification of hazards related to nanomaterials.

Annex C provides the framework for methodologies currently available for conducting exposure assessments.

Annex D outlines some of the common hazard and risk assessment methodologies.

Annex E describes preventive and protective measures to control exposure to nanomaterials in the workplace.

See also OECD (Organisation for Economic Co-operation and Development) Series on the Safety of Manufactured Nanomaterials — No. 11, *Emission Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance.* http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2009)16&doclanguage=en

1 Scope

1.1

This Standard specifies requirements for establishing and maintaining an exposure control program for engineered nanomaterials in the workplace in accordance with occupational health and safety management system (OHSMS) principles (see CAN/CSA-Z1000 and Clause 4).

1.2

This Standard provides guidance on health and safety practices in occupational settings relevant to nanotechnologies (see Annexes A to E).

1.3

The information in this Standard reflects current information about nanotechnologies, including characterization, health effects, exposure assessments, and control practices. The terms and definitions used in this Standard are consistent with those developed under ISO TC 229, the ISO Technical Committee on nanotechnologies.

1.4

This Standard focuses on the manufacture and use of engineered nanomaterials in workplaces. It does not address health and safety issues or practices associated with nanomaterials generated by natural processes, hot processes, and other standard operations that unintentionally generate nanomaterials or with potential consumer exposures or uses, although some of the information in this Standard could be relevant to those areas. The information in this Standard can help companies, researchers, workers, and others to prevent adverse health and safety consequences during the production, handling, use, and disposal of engineered nanomaterials. This advice is broadly applicable across a range of nanomaterials and applications. For the purposes of this Standard

(a) the term "nanomaterials" refers to engineered nanomaterials; and

(b) the term "nanoparticle" is understood to refer more broadly to a nanomaterial with one, two, or three dimensions in the nanoscale.

1.5

In this Standard, "shall" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard; "should" is used to express a recommendation or that which is advised but not required; and "may" is used to express an option or that which is permissible within the limits of the standard.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (nonmandatory) to define their application.

2 Reference publications

Note: *Reference publications for Annexes A to E are included in a bibliography at the end of each Annex.*

This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below. Such reference shall include all amendments published up to the time this referencing Standard was approved.

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Z94.4-11
Selection, use, and care of respirators