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Nanotechnologies — Occupational risk management applied to engineered nanomaterials —

Part 2:
Use of the control banding approach

Nanotechnologies — Gestion du risque professionnel appliquée aux nanomatériaux manufacturés — —

Partie 2: Utilisation de l'approche par bandes de dangers

Contents

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~~document 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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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.

~~The committee responsible for this~~ This document ~~is~~was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

This second edition cancels and replaces the first edition (ISO/TS 12901-2:~~2012~~2014) which has been technically revised.

The main changes are as follows:

— revision of examples in the annexes, including The Control Banding Nano Tools NaRA, GoodNanoGuide and OHB ~~were added as examples in the annexes. The Stoffenmanager Tool was removed as an annex~~, and replacement of Annex B~~added as a reference.~~;

~~— Websites that no longer are working were removed~~

— ~~Additional~~revision of links to websites;

— addition of sources for ~~sull~~all NOAA hazard characterization inventories ~~were added DANA 4.0 and OECD~~.

~~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*~~

A list of all parts in the ISO/TS 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.

Introduction

According to the current state of knowledge, nanoNano-objects, and their aggregates and agglomerates greater than 100 nm (NOAA)), can exhibit properties, including toxicological properties, which are different from those of non-nanoscale (bulk) material. Therefore, current occupational exposure limits (OELs), which are mostly established for bulk materials can be inappropriate for NOAA. In the absence of relevant regulatory specifications for NOAA, theThe control banding approach can be used as a first approach to controlling workplace exposure to NOAA.

NOTE: Regulatory specifications can apply regarding NOAA.

Control banding is a pragmatic approach which can be used for the control of workplace exposure to possibly hazardous agents with unknown or uncertain toxicological properties and for which quantitative exposure estimations are lacking. The ultimate purpose of control banding is to control exposure to prevent any possible adverse effects on workers' health. It can complement the traditional quantitative methods based on air sampling and analysis with reference to OELs when they exist. It can provide an alternative risk assessment and risk management process, by grouping occupational settings in categories presenting similarities of either hazards and/or exposure, or both, while incorporating professional judgment and monitoring. This process applies a range of control techniques (such as general ventilation or containment) to a specific chemical, considering its range (or band) of hazard and the range (or band) of exposure.

In general, control banding is based on the idea that while workers can be exposed to a diversity of chemicals, implying a diversity in risks, the number of common approaches to risk control is limited. These approaches are grouped into levels based on how much protection the approach offers (with "stringent" controls being the most protective). The greater the potential for harm, the greater the levels of protection needed for exposure control.

Control banding was originally developed by the pharmaceutical industry as a way to safely work with new chemicals that had little or no toxicity information. These new chemicals were classified into "bands" based on the toxicity of analogous and better-known chemicals and were linked to anticipated safe work practices, taking into consideration exposure assessments. Each band was then aligned with a control scheme.[1.[1]] Following this concept, the Health and Safety Executive (HSE) in the UK has developed a user-friendly scheme called COSHH Essentials[2,[2]], primarily for the benefit of small- and medium-sized enterprises that potentially do not benefit from the expertise of a resident occupational hygienist. The Department of Occupational Safety and Health Malaysia published the Nanomaterial Risk Assessment (NaRA) based on Reference [2COSHHs Essential and GoodNanoGuide[3] (see details in Annex B).]. Similar schemes are used in the practical guidance given by the German Federal Institute for Occupational Safety and Health.[4.[4]] The Stoffenmanager Tool[5]® tool[1)] represents a further development,[5,] combining a hazard banding scheme similar to that of COSHH Essentials and an exposure banding scheme based on an exposure process model, which was customized to allow non-expert users to understand and use the model.

Control banding applies to issues related to occupational health in the development, manufacturing and use of NOAA under normal or reasonably predictable conditions, including maintenance and cleaning operations but excluding incidental or accidental situations.

Control banding is not intended to apply to the fields of safety management, environment or transportation; it is considered as only one part of a comprehensive risk management process.

[1)] The Stoffenmanager® tool is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product. Equivalent products may be used if they can be shown to lead to the same results.

Control banding can be particularly useful for the risk assessment and management of nanomaterials, given the level of uncertainty in work-related potential health risks from NOAA. It maycan be used for risk management in a proactive manner and in a retroactive manner. In the proactive manner existing control measures, if any, are not used as input variables in the potential exposure banding while in a retroactive manner existing control measures are used as input variables. Both approaches are described in this document. While control banding appears, in theory, to be appropriate for nanoscale materials exposure control, very few comprehensive tools are currently available for ongoing nanotechnology operations. A conceptual control banding model was presented by Maynard[6][6] offering the same four control approaches as COSHH. A slightly different approach, called "Control Banding Nanotoolcontrol banding nanotool", was presented by Paik et al.[7.[7]] This approach takes into account existing knowledge of NOAA toxicology and uses the control banding framework proposed in earlier publications. However, the ranges of values used in the "Control Banding Nanotoolcontrol banding nanotool" correspond to those ranges that one would expect in small-scale research type operations (less than one gram) and might are possibly not seem appropriate for larger scale uses. In the meantime, several other specific control banding tools have been published to control inhalation exposure to engineered nanomaterials for larger scale uses.[8]-[11.[8, 9, 10, 11]] All these tools define hazard bands and exposure bands for inhalation exposure and combine these in a two-dimensional matrix, resulting in a score for risk control (proactive approach).

In 2009, NIOSHthe National Institute for Occupational Safety and Health (in the United States, published a review and analysis of existing toolkits for control banding without any recommendation for implementation in the United States.[12.[12]] An Occupational Exposure Bandingoccupational exposure banding process was later described as a starting point to inform risk management decisions when an Occupational Exposure LimitOEL is unavailable.[13not available.[13]] This process uses hazard-based data to identify the overall hazard potential and the associated airborne concentration range for chemical substances. It also describes special categories of aerosols, including nanoscale particles. An occupational exposure banding approach can inform risk management and control decisions. Although it is not itself a control banding approach, the use of occupational exposure bands as control ranges is consistent with common applications of control banding.

Schneider et al.[14.[14] have] developed a conceptual model for assessment of inhalation exposure to engineered nanomaterials, suggesting a general framework for future exposure models. This framework follows the same structure as the conceptual model for inhalation exposure used in the Stoffenmanager Tool® tool[2)] and the Advanced REACH Tool (ART)[5],[14]).[5, 14]]. Based on this conceptual framework, a control banding tool called "Stoffenmanager Nano" has been® was developed.[14,[14]] encompassing both the proactive approach and retroactive (risk banding) approach.

Reference [15Gridelet et. al.[15]] proposed a new approach for the handling of powders and nanomaterials. This method is very practical and has been widely used by several cosmetic manufacturers. However, industry data are limited to cosmetic ingredients.

The toxicological approach proposed by the cosmetics industry in France considers highest acute toxicity and CMRCMRS at the same level. The exposure model is applicable to powders leaning on usual descriptors that have been translated into observable data, which makes the methodology user-friendly for field operators (see details in Annex CAnnex C).).

In addition, the French agency for food, environmental and occupational health and safety (ANSES) has developed a control banding tool specifically for nanomaterials, which is described in Reference [16the report "Development of a specific control banding tool for nanomaterials" [16].].

Furthermore, the European Commission published a non-binding guidance entitled[17 'Working safely with manufactured nanomaterials'] that includes a control banding approach. The purpose of it is to assist employers, health and safety practitioners and workers in fulfilling their regulatory obligations, whenever

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exposure to manufactured nanomaterials (MNMs) or use of nanotechnology in a professional capacity ~~could~~can likely take place, with the ultimate aim of ensuring adequate protection of workers' health and safety. The ~~Guidance~~guidance provides an overview of the issues surrounding the safe use of MNMs in the workplace, sets out the broad outlines of preventive action and provides a practical tool for complying with specific aspects of ~~ensuring~~ workers' safety, such as risk assessment and risk management. This can be ~~particularly~~ valuable if an in-depth technical understanding of the issues involved is missing.[17~~, and may assist in ensuring compliance with the Occupational Safety and Health legislation when dealing with MNMs.~~[17]]

In 2021, the Organisation for Economic Co-operation and Development (OECD) embarked on a systematic review of the most representative control banding tools available for nanomaterials. The resulting inventory provided information on both regulatory and non-regulatory tools to assess occupational exposure to ~~manufactured nanomaterials~~MNMs (NOAA) and included an applicability assessment for occupational exposure to NOAA. The project was divided into occupational and consumer scopes~~. Part I involved a compilation of tools and models, part II focused on the performance of tools and models for occupational exposure, and part III presented the results for consumer exposure tools and models. Finally, 32 models and tools were assessed using a common case for each tool.~~~~[18]~~:

— part I involved a compilation of tools and models;

— part II focused on the performance of tools and models for occupational exposure;

— part III presented the results for consumer exposure tools and models;

Finally, 32 models and tools were assessed using a common case for each tool.[18]

The biggest challenge in developing any control banding approach for NOAA is to decide which parameters are to be considered~~ and~~, what criteria are relevant to assign a nano-object to a control band, and what operational control strategies ~~ought~~are to be implemented at different operational levels.

This document is focused on intentionally produced NOAA that consist of nano-objects such as nanoparticles, nanopowders, nanofibres, nanotubes, nanowires, as well as aggregates and agglomerates of the same. As used in this document, the term "NOAA" 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. However, as for many other industrial processes, nanotechnological processes can generate by-products in the form of unintentionally produced NOAA which ~~might~~can be linked to health and safety issues that ~~need to~~must be addressed as well.

This document proposes ~~guidelines~~recommendations for controlling and managing occupational risk based on a control banding approach specifically designed for NOAA. It is the responsibility of manufacturers and importers to determine whether a material of concern contains NOAA, and to provide relevant information in safety data sheets (SDS) and labels~~, in compliance with any national or international existing regulation.~~. Employers can use this information to identify hazards and implement appropriate controls. This document does not intend to give recommendations on this decision-making process.

It is emphasized that the control banding method applied to manufactured NOAA requires assumptions to be formulated on information that is desirable but unavailable. Thus, the user of the control banding tool ~~needs to~~must have proven skills in chemical risk prevention and, more specifically, in risk issues known to be related to that type of material. The successful implementation of this approach ~~requires~~involves solid expertise combined with a capacity for critical evaluation of potential occupational exposures and training to use control banding tools to ensure appropriate control measures and an adequately conservative approach.

The approach using CB Tools for NOAA includes the methodology of the sector where it is intended to be used. NOAA is used in industries where the process is frequently used and limited characterization is known but the characterization of adverse events secondary to NOAA use are well described and can be considered to implement a light approach of ~~CBTools~~CB Tools for industry, even if the hazard is not completely identified and thus not well known. If the NOAA is not frequently used but there is a possibility to characterize it physicochemical and biologically, there will be the need to use a more complex and academic CBToolCB Tool.

In parallel to the approach described in this document, a full hazard assessment is advisable to considerconsiders all substance-related hazards, including explosive risk (see NOTE 1), and environmental hazards.

Note NOTEExplosive dust clouds can be generated from most organic materials, many metals and even some non-metallic inorganic materials. The primary factor influencing the ignition sensitivity and explosive violence of a dust cloud is the particle size or specific surface area (i.e. the total surface area per unit volume or unit mass of the dust) and the particle composition. As the particle size decreases, the specific surface area increases. The general trend is for the violence of the dust explosion and the ease of ignition to increase as the particle size decreases, though for many dusts this trend begins to level out at particle sizes ofin the order of tens of micrometres (µm). However, no lower particle size limit has been established below which dust explosions cannot occur and it has to be considered that many nanoparticle types have the potential to cause explosions.

Nanotechnologies — Occupational risk management applied to engineered nanomaterials —

Part 2: Use of the control banding approach

1 Scope

This document describes the use of a control banding approach for controlling the risks associated with occupational exposures to nano-objects and their aggregates and agglomerates greater than 100 nm (NOAA), even if knowledge regarding their toxicity and quantitative exposure estimations is limited or lacking.

The ultimate purpose of control banding isThis document applies to control exposure to prevent any possible adverse effects on workers' health. Theinhalation control, for which the control banding tool described here is specifically designed for inhalation control..

NOTE Some guidance for skin and eye protection is given in ISO/TS 12901--1.[19].

This document does not apply to materials of biological origin.

This document is intended to help businesses and others, including research organizations engaged in the manufacturing, processing, or handling of NOAA, by providing an easy-to-understand, pragmatic approach to controlling occupational exposures.

2 Materials of biological originNormative references

There are outside the scope ofno normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 27687 and ISO 80004-1, *Nanotechnologies – Vocabulary – Part 1: Core vocabulary* are used throughout this document 80004-1 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/

4 Symbols and abbreviated terms

CMRS	carcinogenicity, mutagenicity, reproductive toxicity or sensitization
COSHH	control of substances hazardous to health
DLS	dynamic light scattering
EB	exposure banding
GHS	Globally Harmonized Systemglobally harmonized system of classification and labelling of chemicals
SDS	safety data sheet

MNMs	manufactured nanomaterials
NOAA	nano-objects, and their aggregates and agglomerates greater than 100 nm
OEL	occupational exposure limit
PPE	personal protective equipment
SEM	scanning electron microscopy
STOP	substitution, technical measures, organizational measures, personal protective equipment
TEM	transmission electron microscopy

5 General framework for control banding ~~applied to NOAA~~

5.1 General

The control banding tool described in this document applies to NOAA and materials containing NOAA. ~~It is important to note that this~~This control banding tool can only be considered as one part, though an integral part, of an overall system for health and safety risk management. It ~~requires~~necessitates input data, irrespective of the phase of the NOAA life cycle, such as information collected at the place of work through observation of actual work by an occupational hygienist with solid expertise and training to use control banding tools as well as the enunciation of hazards and the best toxicology data available.

The ~~foundations~~foundation of this approach ~~are~~is the hazard identification process, which is based on ~~the~~ :

— current knowledge of the specific NOAA (toxicology or health effect data; physical and chemical properties~~) and the~~);

— assessment of potential worker exposure.

The hazard and exposure information are combined to determine an appropriate level of control (such as general ventilation, local exhaust, or containment).

This approach is based on the view that the engineering control techniques for nanoparticle exposure can build on the knowledge and experience from current exposure control to aerosols. This knowledge and control have already been applied to aerosols containing ultrafine particles (e.g. welding fumes, carbon black or viruses). Effective techniques can be obtained by adapting and redesigning current technology. This applies to techniques for general ventilation, local and process ventilation, containments, enclosures and filtration.

The control banding approach allows shifting from exposure assessment to exposure control and vice versa. Thus, it can be performed either in a proactive way~~,~~ or in a retroactive way. The proactive way is based on anticipated exposures and ~~using~~uses basic factors mitigating exposure potential~~, or in a~~. The retroactive way (or risk banding approach~~),~~) is based on a risk assessment that ~~will take~~takes more exposure mitigating factors into account, including control measures actually implemented or to be implemented. In both cases, hazard banding is a common step. The general structure of the process is ~~presented~~shown in Figure 1~~Figure 1~~ and includes the following elements:

— information gathering;

— assignment of the NOAA to a hazard band: hazard banding;

— description of potential exposure characteristics: exposure banding;

— definition of recommended work environments and handling practices: control banding;

— evaluation of the control strategy or risk banding.