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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

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Contents

Page

Foreword

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

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*

Introduction

According to the current state of knowledge, nano-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 might not be appropriate for NOAA. In the absence of relevant regulatory specifications for NOAA, the control banding approach can be used as a first approach to controlling workplace exposure to NOAA.

NOTE 1 Aggregates and agglomerates smaller than 100 nm are to be considered as nano-objects.

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. It may 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 hazards and/or exposure, 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] Following this concept, the Health and Safety Executive (HSE) in the UK has developed a user-friendly scheme called COSHH Essentials,[2][3][4] primarily for the benefit of small- and medium-sized enterprises that might not benefit from the expertise of a resident occupational hygienist. Similar schemes are used in the practical guidance given by the German Federal Institute for Occupational Safety and Health.[5] The Stoffenmanager Tool[6] represents a further development, 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 in order to allow non-expert users to understand and use the model.

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 may 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 part of ISO/TS 12901. 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[7] offering the same four control approaches as COSHH. A slightly different approach, called “Control Banding Nanotool”, was presented by Paik et al.[8][9] 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 Nanotool” correspond to those ranges that one would expect in small-scale research type operations (less than one gram) and might 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.[10][11][12][13][14] All these tools define hazard bands and exposure bands for inhalatory exposure and combine these in a two-dimensional matrix, resulting in a score for risk control (proactive approach).

Schneider et al.[15] 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 and the Advanced REACH Tool (ART).[6][16][17] Based on this conceptual framework, a control banding tool called "Stoffenmanager Nano" has been developed,[18] encompassing both proactive approach and retroactive (risk banding) approach.

In addition, the French agency for food, environmental and occupational health and safety (ANSES) have developed a control banding tool specifically for nanomaterials which is described in the report "Development of a specific control banding tool for nanomaterials" [31].

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 to be implemented at different operational levels.

This part of ISO/TS 12901 proposes guidelines 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 part of ISO/TS 12901 does not intend to give recommendations on this decision-making process. It cannot replace regulation and employers are expected to comply with the existing regulations.

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 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 a 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.

In parallel to the approach described in this part of ISO/TS 12901, a full hazard assessment is advisable to consider all substance-related hazards, including explosive risk (see NOTE 2), and environmental hazards.

NOTE 2 Explosive 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 of 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

The purpose of this part of ISO/TS 12901 is to describe 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 is to control exposure in order to prevent any possible adverse effects on workers' health. The control banding tool described here is specifically designed for inhalation control. Some guidance for skin and eye protection is given in ISO/TS 12901-1.[19]

This part of ISO/TS 12901 is focused on intentionally produced NOAA that consist of nano-objects such as nanoparticles, nanopowders, nanofibres, nanotubes, nanowires, as well as of aggregates and agglomerates of the same. As used in this part of ISO/TS 12901, the term "NOAA" applies to such components, whether in their original form or incorporated in materials or preparations from which they could 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 be linked to health and safety issues that need to be addressed as well.

This part of ISO/TS 12901 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 for the control of occupational exposures.

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.

Materials of biological origin are outside the scope of this part of ISO/TS 12901.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 27687, *Nanotechnologies — Terminology and definitions for nano-objects — Nanoparticle, nanofibre and nanoplate*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 27687 and the following apply.

3.1
agglomerate
collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces, or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO/TS 27687:2008, definition 3.2]

3.2
aggregate
particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components

Note 1 to entry: The forces holding an aggregate together are strong forces, for example covalent bonds, or those resulting from sintering or complex physical entanglement.

Note 2 to entry: Aggregates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO/TS 27687:2008, definition 3.3]

3.3
analogous material
material of the same chemical category, with a similar composition and/or crystalline phase and documented similar physicochemical properties (metal oxides, graphite, ceramics, etc.)

3.4
bulk material
material of the same chemical composition as the NOAA, at a scale greater than the nanoscale

3.5
classification and labelling
system to communicate hazard information about a specific substance based on the principles of the GHS (Globally Harmonized System of classification and labelling of chemicals), or equivalent, and GHS' transposition into national legislation (e.g.: Regulation (EC) No 1272/2008 for the European Union)

3.6
chemical category
group of chemicals whose physicochemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity

3.7
dustiness
tendency of particles to separate from the main bulk of powder and then to be dispersed into the atmosphere

3.8
exposure
contact with a chemical, physical or biological agent by swallowing, breathing, or touching the skin or eyes

Note 1 to entry: Exposure can be short-term (acute exposure), of intermediate duration, or long term (chronic).

3.9
health hazard
potential source of harm to health

[SOURCE: ISO 10993-17:2002, definition 3.7]

3.10
health risk
combination of the likelihood of occurrence of harm to health and the severity of that harm

[SOURCE: ISO 10993-17:2002, definition 3.8]

3.11
nanofibre
nano-object with two similar external dimensions in the nanoscale and the third dimension being significantly larger

Note 1 to entry: A nanofibre can be flexible or rigid.

Note 2 to entry: The two similar external dimensions are considered to differ in size by less than three times and the significantly larger external dimension is considered to differ from the other two by more than three times.

Note 3 to entry: The largest external dimension is not necessarily in the nanoscale.

[SOURCE: ISO/TS 27687:2008, definition 4.3]

3.12
nano-object
material with one, two or three external dimensions in the nanoscale

Note 1 to entry: Generic term for all discrete nanoscale objects.

[SOURCE: ISO/TS 27687:2008, definition 2.2]

3.13
nanoparticle
nano-object with all three dimensions in the nanoscale

Note 1 to entry: If the lengths of the longest to the shortest axes of the nano-object differ significantly (typically by more than three times), the terms nanorod or nanoplate are intended to be used instead of the term nanoparticle.

[SOURCE: ISO/TS 27687:2008, definition 4.1]

3.14
nanoplate
nano-object with one external dimension in the nanoscale and the two other external dimensions significantly larger

Note 1 to entry: The smallest external dimension is the thickness of the nanoplate.

Note 2 to entry: The two significantly larger dimensions are considered to differ from the nanoscale dimension by more than three times.

Note 3 to entry: The larger external dimensions are not necessarily in the nanoscale.

[SOURCE: ISO/TS 27687:2008, definition 4.2]

3.15
nanoscale
size range from approximately 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.

Note 2 to entry: The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.

[SOURCE: ISO/TS 27687:2008, definition 2.1]

3.16
particle
minute piece of matter with defined physical boundaries

Note 1 to entry: A physical boundary can also be described as an interface.

Note 2 to entry: A particle can move as a unit.

Note 3 to entry: This general particle definition applies to nano-objects.

[SOURCE: ISO/TS 27687:2008, definition 3.1]

3.17
solubility
maximum mass of a nanomaterial that is soluble in a given volume of a particular solvent under specified conditions

Note 1 to entry: Solubility is expressed in grams per litre of solvent.

[SOURCE: ISO/TR 13014, definition 2.27]

4 Symbols and abbreviated terms

CMRS carcinogenicity, mutagenicity, reprotoxicity or sensitization

COSHH control of substances hazardous to health

GHS Globally Harmonized System of classification and labelling of chemicals

SDS safety data sheet

NOAA nano-objects, and their aggregates and agglomerates greater than 100 nm

OEL occupational exposure limit

PPE personal protective equipment

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 part of ISO/TS 12901 applies to NOAA and materials containing NOAA. It is important to note that 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 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 a solid expertise and training to use control banding tools as well as the enunciation of hazards and the best toxicology data available.

The foundations of this approach are 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 is combined to determine an appropriate level of control (such as general ventilation, local exhaust, or containment).

This approach is based on the opinion of experts developing this part of ISO/TS 12901 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 has 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, based on anticipated exposures and using basic factors mitigating exposure potential, or in a retroactive way (or risk banding approach), based on a risk assessment that will take 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 in 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.

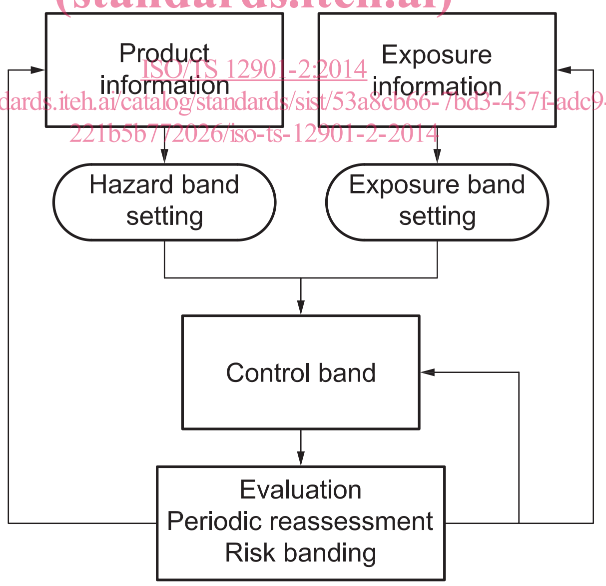

Figure 1 — Control banding process

5.2 Information gathering and data recording

The methodology presented in this part of ISO/TS 12901 is information driven; it does not implicitly assume the presence of risk or hazard in any material. Where there is little or no information to guide decisions on the potential for a particular hazard or exposure, “reasonable worst-case assumptions” should be used along with management practices appropriate for those options. The methodology is also designed to encourage replacing assumptions with real information and refining management practices accordingly.

Input data are pre-required in order to implement control banding. Especially considering NOAA for which no health-based limit values can be established, it is important to document substances being used, control measures taken, working conditions and possibly exposure measurements, given that these factors are not always easy to determine with complete certainty, and that they depend on the extent to which the hazard is known and on the accuracy of the methods used for exposure assessment.

All input data should be documented and be traceable through an appropriate documentation management system.

5.3 Hazard banding

Hazard banding consists in assigning a hazard band to NOAA on the basis of a comprehensive evaluation of all available data on this material, taking into account parameters such as toxicity, *in vivo* biopersistence and factors influencing the ability of particles to reach the respiratory tract, their ability to deposit in various regions of the respiratory tract, their ability to elicit biological responses. These factors can be related to physical and chemical properties such as surface area, surface chemistry, shape, particle size, etc.

5.4 Exposure banding

Exposure banding consists in assigning an exposure scenario (a set of conditions under which exposure may occur) at a workplace or a workstation to an exposure band on the basis of a comprehensive evaluation of all available data of the exposure scenario under consideration, e.g. physical form of NOAA, amount of NOAA, dust generation potential of processes and actual exposure measurement data.

5.5 Control banding

5.5.1 Proactive implementation of control banding

Control banding can be used for risk control management in a proactive manner. In that case, recommended work environments and handling practices may be defined on the basis of hazard banding as well as of fundamental factors mitigating anticipated exposure potential, e.g. propensity of the material to become airborne, the type of process and amounts of material being handled.

Such an approach is used to determine the control measures appropriate for the operation being assessed but not to determine an actual level of risk, as the existing control measures, if any, are not used as an input variable in the exposure banding process.

5.5.2 Retroactive implementation approach: evaluation of control banding and risk banding

In a retroactive approach, control banding may be used either to evaluate the controls recommended as outputs of the proactive approach, or for risk assessment on its own.

In that case, both hazard and actual exposure need to be characterized in order to define a risk level. The major difference with the proactive use of control banding is that exposure mitigating factors (such as implemented control measures) are taken into account using an exposure algorithm (see Annex A).

The approach then includes the following elements:

— assignment of the NOAA to a hazard band;

— exposure banding;

— overview of risks based on risk banding as a result of hazard and exposure banding;

— iterative examination of control measures until the risk is reduced to an acceptable level;

— design of an action plan based on the chosen specific control scenario.

