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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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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 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.

This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

This second edition cancels and replaces the first edition (ISO/TS 12901-2:2014) 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, and replacement of Annex B;

— revision of links to websites;

— addition of sources for all NOAA hazard characterization inventories.

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

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 can be inappropriate for NOAA. The 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 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] Following this concept, the Health and Safety Executive in the UK has developed a user-friendly scheme called COSHH Essentials[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 [2]. Similar schemes are used in the practical guidance given by the German Federal Institute for Occupational Safety and Health.[4] The Stoffenmanager® 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.

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 can 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] offering the same four control approaches as COSHH. A slightly different approach, called "control banding nanotool", was presented by Paik et al.[7] This approach takes into account existing knowledge of NOAA toxicology and uses the control banding framework proposed in

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.

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 are possibly not 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] 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, the 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] An occupational exposure banding process was later described as a starting point to inform risk management decisions when an OEL is unavailable.[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] 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[2)] and the Advanced REACH Tool (ART)[5],[14]. Based on this conceptual framework, a control banding tool called Stoffenmanager Nano® was developed,[14] encompassing both the proactive approach and retroactive (risk banding) approach.

Reference [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 CMRS 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 C).

In addition, the French agency for food, environmental and occupational health and safety has developed a control banding tool specifically for nanomaterials, which is described in Reference [16].

Furthermore, the European Commission published non-binding guidance entitled[17] 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 exposure to manufactured nanomaterials (MNMs) or use of nanotechnology in a professional capacity can likely take place, with the ultimate aim of ensuring adequate protection of workers' health and safety. The 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 workers' safety, such as risk assessment and risk management. This can be valuable if an in-depth technical understanding of the issues involved is missing.[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 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;

— 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]

2) 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.

The biggest challenge in developing any control banding approach for NOAA is to decide which parameters are to be considered, what criteria are relevant to assign a nano-object to a control band, and what operational control strategies 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 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 can be linked to health and safety issues that must be addressed as well.

This document proposes 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. 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 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 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 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 CB Tool.

In parallel to the approach described in this document, a full hazard assessment considers all substance-related hazards, including explosive risk and environmental hazards.

NOTE 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 in the order of tens of micrometres (μm). However, no lower particle size limit has been established below which dust explosions cannot occur and 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.

This document applies to inhalation control, for which the control banding tool is specifically designed.

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

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 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 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 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

5.1 General

The control banding tool described in this document applies to NOAA and materials containing NOAA. 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 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 foundation of this approach is the hazard identification process, which is based on:

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

— 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 uses basic factors mitigating exposure potential. The retroactive way (or risk banding approach) is based on a risk assessment that 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 shown 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.

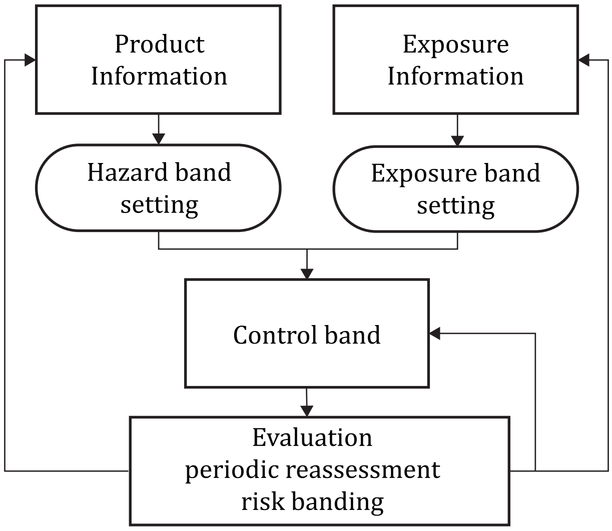

Figure 1 — Control banding process

5.2 Information gathering and data recording

The methodology presented in this document 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 must be obtained prior to implementing 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 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, and 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 of assigning an exposure scenario (a set of conditions under which exposure can 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 must 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.

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.

Such an approach may be used to determine the actual risk level using the existing control measures as an input variable. In this respect, the retroactive approach can be considered as a means for periodic re-evaluation of the proactive approach.

5.6 Review and data recording

In the review and adapt step, a system of periodic and as-needed reviews should be implemented to ensure that the information, evaluations, decisions and actions of the previous steps are kept up-to-date. Reviews should be performed when new information has been generated or has emerged. The adequacy of the risk management process for the material or the application at hand should be re-assessed. It should be questioned whether the current risk evaluation must be revised in light of the new information and, if so, whether the current risk management practices must be changed as well.

6 Information gathering

6.1 Characterization

6.1.1 General

The lists of characteristics and endpoints given in 6.1.2 to 6.1.4 should be taken into account when assessing the human health hazards of NOAA. Addressing this data set should lead to the development of dossiers describing basic characterization parameters and available mammalian toxicity information. These endpoints are based upon the list proposed by the OECD testing program for a set of MNMs for human health and environmental safety.[20] It can be considered as a starting point when assessing the human health hazards of NOAA. Epidemiological data, when available, should also be taken into account.

6.1.2 Information and identification

The following information should be taken into consideration:

— NOAA name;