SLOVENSKI STANDARD
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Izpostavljenost na delovnem mestu - Ocena izpostavljenosti vdihavanju nano delcev

Workplace exposure - Assessment of inhalation exposure to nano-objects and their agglomerates and aggregates

Exposition am Arbeitsplatz - Leitfaden zu Messtechniken für durch Einatmung expositionsrelevante Nanopartikel

Exposition sur les lieux de travail - Évaluation de l'exposition par inhalation aux nano-objets et à leurs agglomérats ou à leurs agrégats

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Workplace exposure - Assessment of inhalation exposure to nano-objects and their agglomerates and aggregates

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Contents

Page

European foreword

This document (prEN 17058:2016) has been prepared by Technical Committee CEN/TC 137 “Assessment of workplace exposure to chemical and biological agents”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

Introduction

The rapidly advancing field of nanotechnologies and concern on its potential impact on occupational health and safety has initiated efforts by Standardization bodies to provide guidance how health and safety issues should appropriately be address. ISO has published a series of documents, which focus on various aspects of exposure and risk assessment and risk mitigation, e. g. ISO/TR 12885 [32], ISO/TS 12901-1 [33], ISO/TS 12901-2 [34].

The present document focuses on the assessment of occupational exposure to nano-objects and their agglomerates and aggregates (NOAA). In general the objectives of an exposure assessment can vary widely and can include exposure exploration and determination, evaluation of the effectiveness of exposure control measures, check for compliance with any occupational exposure limit or other benchmark level, and can contribute to risk assessment and epidemiological studies. The measurement strategy used for the assessment will depend amongst other factors on the objective of the assessment. ISO/TS 12901-1 for example, provides guidance for the measurement strategy for evaluation controls. No EU legal workplace exposure limits for NOAA are established at the time of the publication of this European Standard. However, in case they would be published and are similar to existing OELs, compliance measurements should meet the conditions as prescribed in EN 689. Therefore, this document concerns the elements of exposure assessment and provides guidance for various applications. In addition, CEN has published documents (prEN 16897:2015 [26], prEN 16966:2016) that provide guidance of the use of commonly used devices for detection of nano-sized and submicron-sized aerosols using different metrics in the workplace air.

1 Scope

This European Standard provides guidelines to assess inhalation exposure to nano-objects and their agglomerates and aggregates (NOAA) as well as to evaluate the results of the assessment either as stand-alone assessment or embedded in a tiered approach framework.

While the focus of this European Standard is on the assessment of nano-objects, the approach is also applicable for exposure to the associated agglomerates and aggregates, i.e. NOAA, and particles released from nano composites and nano-enabled products.

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.

EN 1540, *Workplace exposure – Terminology*

EN 689, *Workplace atmospheres – Guidance for the assessment of exposure to inhalation to chemical agents for comparison with limit values and measurement strategy*

prEN 16966:2016, *Workplace exposure – Metrics to be used for the measurements of exposure to inhaled nanoparticles (nano-objects and nanostructured materials) such as mass concentration, number concentration and surface area concentration*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 1540, prEN 16966:2016 and the following apply.

3.1
particle aerodynamic (equivalent) diameter
diameter of a sphere of 1 g/cm³ density with the same terminal settling velocity in calm air as the particle, under the prevailing conditions of temperature, pressure and relative humidity

Note 1 to entry: The particle aerodynamic diameter depends on the size, density and shape of the particle.

Note 2 to entry: In the human respiratory tract, the separation of particles with an aerodynamic diameter smaller than approximately 0,4 µm is better characterized by the particle diffusion equivalent diameter.

[SOURCE: EN 1540, definition 2.3.2, modified]

3.2
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: CEN ISO/TS 27687:2009, definition 3.2]

3.3
aggregate
particle comprising strongly bonded or fused particles where the resulting external surface area can 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: CEN ISO/TS 27687:2009, definition 3.3]

3.4
Brunauer, Emmett and Teller method
BET method
method for the determination of the total specific external and internal surface area of disperse powders and/or porous solids per unit of mass by measuring the amount of physically adsorbed gas utilizing the model developed by Brunauer, Emmett and Teller for interpreting gas adsorption isotherms

Note 1 to entry: Method originates from Brunauer, Emmett and Teller [1].

Note 2 to entry: Inaccessible pores are not detected. The BET method cannot reliably be applied to solids that absorb the measuring gas.

[SOURCE ISO 9277, modified]

3.5
emission
transfer process of liberated nanomaterial or other material to the workplace air

Note 1 to entry: The emission is usually expressed as a flow, e.g. quantity as mass or number of particles per unit time or unit area, or particle per mass of product.

3.6
exposure monitoring
determination of exposure to chemical and/or biological agents by using a sampling or monitoring device for gases, vapours or airborne particles

3.7
exposure assessment
qualitative or quantitative determination of an employee's exposure to a chemical or biological agent performed by an industrial hygienist or other appropriately trained individual

3.8
far field
well-mixed compartment of the indoor space that remains as the near field is centered on the worker

3.9
median (particle) diameter
particle size of a particle distribution for which one-half the total number of particles are larger and one-half are smaller

[SOURCE: ISO 16972:2010, definition 3.47]

3.10
nano-activity
activity/task related to handling or processing nanomaterial

3.11
nanomaterial
material with any external dimensions in the nanoscale or having internal structure or surface structure in the nanoscale

[SOURCE: CEN ISO/TS 80004-1:2015, definition 2.4]

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 CEN ISO/TS 27687:2009, definition 2.2]

3.13
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: CEN ISO/TS 27687:2009, definition 2.1]

3.14
near field
well-mixed compartment consisting of a virtual cube with 2-m sides centred on the workers head, with volume of 8 m^3

Note 1 to entry: This near field space is a nominal definition and no sharp decline in concentration is envisaged to occur at the boundary between the near field and the far field.

3.15
primary particle
particle (usually spherical) not formed from a collection of smaller un-coalesced particles

Note 1 to entry: The term typically refers to particles formed through nucleation from the vapour phase before coagulation occurs.

Note 2 to entry: These particles are generally the original source particles of agglomerates or aggregates, or mixtures of the two.

[SOURCE: ISO/TR 27628:2007, definition 2.16, modified]

3.16
release
liberation of nanomaterial during a natural or technical process at any given lifecycle stage

Note 1 to entry: Liberation can occur in three main release forms, i.e. air dispersed (aerosols), liquid dispersed (suspensions) and undispersed material, e.g. debris. Release can be expressed without a specific metric, as a dispersion-specific fraction or percentage (in relation to air dispersed, liquid dispersed and undispersed) of the total release, or as a mass per unit area or unit quantity of the matrix. Release will be dependent on the physical-chemical properties of the nanomaterial and operational and environmental conditions.

3.17
sensitivity
true positive rate
proportion of actual positives which are correctly identified as such, and is complementary to the false negative rate

3.18
specificity
true negative rate
proportion of negatives which are correctly identified as such, and is complementary to the false positive rate

4 Symbols and abbreviations

For the purposes of this document, the following symbols and abbreviations apply.

ACF	Autocorrelation Function
AIC	Aikaike Information Criterion
AR	AutoRegressive
ARIMA	AutoRegressive Integrated Moving Average
BIC	Bayesian Information Criterion
CCF	Cross Correlation Function
CMD	Count Median Diameter (the number-weighted median diameter)
CNF	Carbon Nanofibres
CNT	Carbon Nanotubes
CPC	Condensation Particle Counter
d_{ae}	Particle aerodynamic equivalent diameter
d_{me}	Mobility equivalent diameter
DC	Diffusion charger
DEMC	Differential Electrical Mobility Classifier
DMAS	Differential Electrical Mobility Analysing System
DR	Decision Rule
DRI	Direct reading instrument
EC	Elemental Carbon
EDS	Energy Dispersive X-Ray Spectroscopy

EDX	Energy Dispersive X-Ray
ELPI	Electrical Low Pressure Impactor
EM	Electron Microscopy
EoL	End of Life
ESP	Electrostatic Precipitator
FF	Far Field
FMPS	Fast Mobility Particle Sizer
HVAC	Heating, Ventilation and Air Conditioning
ICP-AES	Inductively Coupled Plasma – Atomic Emission Spectroscopy
ICP-MS	Inductively Coupled Plasma – Mass Spectroscopy
LSL	Lower Size Limit
MA	Moving Average
MCMC	Markov chain Monte Carlo
MMAD	Mass Median Aerodynamic Diameter
MNO	Manufactured Nano-Object
MOUDI	Micro-Orifice Uniform Deposit Impactor
MPPD	Multiple-Path Particle Dosimetry
MSDS	Material Safety Data Sheet
NF	Near Field
NM	Nanomaterial
NOAA	Nano-Objects and their Aggregates and Agglomerates
NPV	Negative Predictive Value
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OPC	Optical Particle Counter
PACF	Partial Autocorrelation Function
PGNP	Process generated nanoparticle
PM1	Particle size fraction with the aerodynamic cut-size equal to 1 µm
PSD	Particle Size Distribution
QA	Quality Assurance
QC	Quality Control
R&D	Research & Development
REL	Recommended Exposure Limit (by NIOSH)
SD	Source Domain
SEM	Scanning Electron Microscope
SMPS	Scanning Mobility Particle Sizer

SOP	Standard Operating Procedure
TEM	Transmission Electron Microscopy
TEOM	Tapered Element Oscillating Microbalance
TP	Thermal Precipitator
TWA	Time Weighted Average
XRD	X-Ray Diffraction
XRF	X-ray Fluorescence

5 Measurement Strategy

5.1 General

In general, a measurement strategy for workplace exposure assessment can be described as a framework for the selection of relevant considerations associated with a measurement campaign, e.g. what substance will be measured, at which location, when, for how long, how many individuals to sample, how many samples per individual to collect, and by what methods, in particular, which exposure metrics will be measured.

The objectives of a measurement campaign can vary widely and may include exposure assessment, risk assessment, epidemiology, evaluation of the effectiveness of exposure control measures, and compliance with any occupational exposure limit or benchmark level. The design of actual measurement strategy shall be consistent with the study objectives. Exposure measurement studies that attempt to identify exposure pathways (transport processes of the contaminant from source to the receptor (the worker)) and exposure-modifying factors/determinants shall include both measurements at the source as well as at the receptor, i.e. the breathing zone. Exposure assessments for use in compliance assessment, epidemiologic studies, or risk assessment shall focus on the individual worker using breathing zone samples collected over a full work shift, or a surrogate that enables numerical calculation of shift exposure. In contrast, studies of the efficacy of a control measure may for example be carried out using static measurements at or near the workstation or the location where the task is performed.

Depending on the objective of the assessment, the resources and the expertise, the assessment can be performed at a specific level. The levels of exposure assessment are addressed in 5.3.

For modelling inhalation exposure to NOAA, the concept of the source domains (SD) was developed (Schneider et al. [2]), which describes different processes during the lifecycle of a nanomaterial:

— During the production phase (synthesis) prior to harvesting the bulk material, point source or fugitive emission, e.g. emissions from the reactor, leaks through seals and connections, and incidental releases, can take place (SD1). In these cases, discrete nanoparticles and homogeneous and inhomogeneous agglomerates will be formed;

— During the manufacturing of products, the handling and transfer of bulk manufactured nanomaterial powders with relatively low energy can release nanoparticles, e.g. collection, harvesting, bagging/ bag dumping bag-emptying- dumping, scooping, weighing, dispersion/ compounding in composites (SD2). However, the powders are already in agglomerated stage and high shear forces are needed for deagglomeration. Therefore, the majority of the released particles will be agglomerates;

— During further processing or in the use phase of a ready-to-use nanoproduct, release can be expected during the relatively high energy dispersion of either a) solid, powdery or (liquid) intermediates containing highly concentrated (> 25 %) nanoparticles or b) application of (relatively low concentrated < 5 %) ready-to-use products (SD3). Examples of SD3a are pouring/ injection molding, (jet) milling, stirring/ mixing. As higher shear forces can occur during high energy dispersion de-agglomeration can occur. Examples of SD3b are application of coatings or spraying of solutions that can form nanosized aerosols after evaporation of the liquid phase component, usually of mixed composition;

— During the use phase of a product or its end-of-life (EoL) phase, activities resulting in fracturing and abrasion of manufactured nanoparticles-enabled end-products at work sites, e.g.

  — low energy abrasion, manual sanding, or,

  — high energy machining, e.g., sanding, grinding, drilling cutting, shredding.

  High temperature processes like incineration which can occur during the EoL of a material or product are included (SD4). Most likely it will be multi-composed aerosols, and in case of machining also matrix-bound nanoparticles, whereas during thermal processes nanoparticles can also be formed following nucleation and condensation of vapours (Brouwer et al. [3]).

Identification of source domain for the situation under consideration will provide relevant contextual information for considerations concerning selection of an appropriate measurement strategy, since the source domain concept reflects different mechanisms of release and consequently possible different nature of released aerosols, e.g. state of agglomeration and composition.

5.2 Measuring devices and measurement methods

Because there is currently no single commercially available measuring device capable of meeting all desired requirements of exposure measurement of airborne NOAA, a suite of instruments is typically used to conduct an exposure measurement of an occupational environment. Hence exposure assessment methodologies and measurement strategies often rely on multiple metrics and instruments, including real-time monitors and sampling devices to enable off-line analysis, in order to conduct an adequate exposure assessment. The most commonly reported combination of real-time and off-line instruments include direct-reading, handheld instruments (Condensation Particle Counter (CPC), Diffusion Charger (DC) and Optical Particle Counter (OPC)) to detect releases of airborne nano-objects accompanied by sampling (Electrostatic Precipitator (ESP), Thermal Precipitator (TP) or filter) and subsequent chemical and electron microscopic (EM) analyses (SEM or TEM with Energy Dispersive X-Ray Spectroscopy (EDS)) for particle identification and elemental composition.

Table 1 gives an overview of type of monitor or sampler and associated exposure metric.