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Izpostavljenost na delovnem mestu - Ocena izpostavljenosti pri vdihavanju nanopredmetov ter njihovih agregatov in aglomeratov

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

Exposition am Arbeitsplatz - Beurteilung der inhalativen Exposition gegenüber Nano-Objekten und deren Agglomeraten und Aggregaten

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

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

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

Exposition am Arbeitsplatz - Beurteilung der inhalativen Exposition gegenüber Nanoobjekten und deren Aggregaten und Agglomeraten

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European foreword

This document (EN 17058:2018) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2019, and conflicting national standards shall be withdrawn at the latest by May 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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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 can be appropriately addressed. ISO has published a series of documents, which focus on various aspects of exposure and risk assessment and risk mitigation, for example, ISO/TR 12885 [1], ISO/TS 12901-1 [2], ISO/TS 12901-2 [3].

The present document focuses on the assessment of occupational exposure by inhalation of nano-objects and their aggregates and agglomerates (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, existing non-nano OELs for many substances are in force and these are measured as prescribed in national regulations/EN 689. Therefore, this document concerns the elements of exposure assessment and provides guidance for various applications. In addition, CEN has published documents (EN 16897 [4], EN 16966) 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 workplace exposure by inhalation of nano-objects and their aggregates and agglomerates (NOAA). It contains guidance on the sampling and measurement strategies to adopt and methods for data evaluation.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 689:2018, *Workplace atmospheres — Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy*

EN 16966:2018, *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, EN 16966 and the following apply.

Note 1 to entry: With regard to EN 16966, in particular, the following terms are used in this document: agglomerate, aggregate, BET method, nanomaterial, nano-object, nanoscale, particle aerodynamic diameter, particle diffusive diameter, particle mobility diameter, particle and primary particle.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
appraiser
person who is sufficiently trained and experienced in occupational hygiene principles, working and measurement techniques, to conduct the part of the assessment he or she is performing according to the state of the art

Note 1 to entry: The appraiser may be supported by a team of qualified persons.

[SOURCE: EN 689:2018, 3.1.1]

3.2
background measurement
background particle measurement
measurement of the particle concentration, at a location or a time not affected by the activity/process under investigation

[SOURCE: EN 16897:2017, 3.1, modified – The preferred term and its synonym have been taken over on separate lines.] [4]

3.3
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.

3.4
exposure assessment
qualitative or quantitative determination of an employee's exposure to a chemical or biological agent performed by an appraiser

3.5
exposure monitoring
determination of exposure to airborne chemical and/or biological agents by using a sampling or monitoring device for gases, vapours or airborne particles

3.6
far field
well-mixed compartment of the workspace that remains as the near field is centered on the worker

3.7
median diameter
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, 3.47] [5]

3.8
nano-activity
activity/task related to handling or processing nanomaterial

3.9
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.

3.10
sensitivity
true positive rate
proportion of actual positives which are correctly identified as such, and is complementary to the false negative rate

3.11
source domain
generation mechanism that determines particle emission characteristics for a particular life cycle stage

Note 1 to entry: Different mechanisms determine the emission rate, particle size distribution, source location and transport of NOAA during the various life cycle stages (synthesis, downstream use, application or treatment of products and end of life)

Note 2 to entry: The source domain can comprise similar exposure situations including the vast majority of current and near future exposure situations [6].

[SOURCE: CEN ISO/TS 21623:2018-02, 3.17, modified – Note 2 to entry added] [7]

3.12
near field
well-mixed compartment consisting of a virtual cube with 2-m sides centred on the source of particles, 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.

3.13
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
APS	Aerodynamic Particle Sizer
ARIMA	AutoRegressive Integrated Moving Average
BIC	Bayesian Information Criterion
CCF	Cross Correlation Function
CMD	Count Median Diameter (the number-weighted median diameter)
CNF	Carbon NanoFiber
CNT	Carbon NanoTube
CPC	Condensation Particle Counter
d_{ae}	Particle aerodynamic equivalent diameter
d_{de}	Particle diffusive equivalent diameter

d_{me}	Particle mobility equivalent diameter
d_{opt}	Optical diameter
DC	Diffusion Charger
DEMC	Differential Electrical Mobility Classifier
DMAS	Differential Mobility Analysing System
DR	Decision Rule
DRI	Direct Reading Instrument
EDS	Energy Dispersive X-Ray Spectroscopy
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
MNO	Manufactured Nano-Object
MSDS	Material Safety Data Sheet
NECID	Nano Exposure and Contextual Information Database
NF	Near Field
NM	NanoMaterial
NOAA	Nano-Objects and their Aggregates and Agglomerates
NPV	Negative Predictive Value
NSAM	Nanoparticle Surface Area Monitor
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OPC	Optical Particle Counter
PACF	Partial Autocorrelation Function

PEROSH	Partnership for European Research in Occupational Safety and Health
PGNP	Process Generated NanoParticle
$PM_{2,5}$	Particle size fraction with the aerodynamic cut-size equal to 2,5 µm
PM_{10}	Particle size fraction with the aerodynamic cut-size equal to 10 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 Microscopy
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

5.1.1 Objectives

A measurement strategy for workplace exposure assessment might have a number of objectives to fulfil including

a) determination of the substances to which exposure may take place;

b) measurement of the existing OELs for those substances in air;

c) selection of appropriate metrics and instruments to monitor exposure;

d) analysis and interpretation of the results.

The exposure measurements are part of risk assessment and the objectives can be exposure assessment, compliance with any occupational exposure limit or benchmark level, evaluation of the effectiveness of exposure control measures or epidemiology. The design of the 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 suitable time weighted average. In contrast, studies of the efficacy of a technical 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.

5.1.2 Source domains

For exposure assessment to NOAA, the concept of the source domains (SD) was developed [6], 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 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, scooping, weighing, dispersion/ compounding in composites (SD2). However, the powders are already in agglomerated stage and high shear forces are needed for deagglomeration [8], [9]. 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 [10].

Relevant contextual information achieved during the identification of a source domain will facilitate the 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

A range of metrics and hence measurement instruments are currently used, because there are NOAA without a nanospecific OEL, and there is no agreed measurement metric to measure the exposure.

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)) and or XRF/ICP-MS for particle identification and elemental composition are given in Table 1.

Table 1 — Overview of type of monitor or sampler and associated exposure metric (see also EN 16966:2018, Table 1)

Metric	Measured or calculated metric	Size-integrated, aerosol fraction or size-resolved	Monitor or sampler	Type of device (example)
Number	measured	size-integrated	Monitor	DC
				CPC
Surface area	measured	size-integrated	Monitor	DC
Mass	measured	aerosol fraction	Sampler	Cyclone, impactor
				Diffusive collection
		size-integrated	Sampler	Sampler for EM analysis, e.g. ESP, TP, cyclone)
				Sampler for XRF – ICPMS analysis
Number	calculated	size-resolved	Monitor	DMAS, OPC, APS [a]
				ELPI
Mass	calculated	size-resolved	Sampler	Cascaded diffusion collectors
	calculated	size-resolved	Sampler	Cascade impactor
				Diffusive collection

[a] APS is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by CEN of this product.

A more comprehensive suite of real-time and off-line instruments as well as the methods to collect off-line samples that are also reported for conducting exposure measurements are summarized in Annex A.

5.3 Levels of exposure assessment

5.3.1 General

Three levels of assessment of (the potential for) exposure to NOAA will be distinguished, i.e. initial assessment, basic assessment and comprehensive assessment. They differ with respect to their objectives, methodologies and accuracy of the outcome, as well as with the information input requirements and the level of expertise needed for application. The decision rules for interpreting the outcome for all three tiers are given in Clause 6.

5.3.2 Initial assessment – Determination of the potential for release and emission of NOAA into the workplace air

The aim of the initial assessment is to determine the potential for release and emission of NOAA into the workplace air resulting from processes and handling with nanomaterials. Information shall be gathered structurally, according to established best practices in occupational hygiene on the occupational workplace under consideration, including workplace activities and the materials handled. All gathered information is then analysed and used to determine if potential for release of NOAA exists.

The initial assessment consists of a paper study, but it shall include a visit to the workplace to inspect potential locations where the NOAA of concern can be released and consequently emitted into the occupational environment. In general, air samples or air measurements are not needed for an initial assessment, however, it may include the analysis of material samples in a laboratory to verify if the material handled is a nanomaterial.

The minimum information that shall be gathered during the initial assessment is listed below. An example of a checklist is given in Annex B. The examples provided are meant to be illustrative rather than comprehensive. Therefore, the appraiser shall expand this list to be sufficiently comprehensive during the information gathering stage.

a) Information related to the **workplace**:

   1) type of workplace and its potential variability, considering e.g., the quantity of different nano-objects (nanomaterials) produced or handled, their production volumes and quantities handled, dimensions (volume) of the production zone, and the volume of the facility in general, such as a manufacturing environment in which larger volumes batches and continuous production of nano-objects are processed; versus a research environment in which smaller volumes of diverse arrays of nano-objects are processed;

   2) relevant information related to previous exposure assessment results, for example, for a given process step, information on dust exposure as part of a background assessment from other work processes, engines or welding using e.g. spatial and/or temporal information;

   3) location and type of exposure control measures;

   4) any occupational guidance already in place, such as a company's internal recommendations on exposure limits for a given workplace if such exist.

b) Information related to the **workplace activities**:

   1) identification of the source domain and activities related to handling nanomaterials; type of activities, e.g. synthesis or production. Processes and handling steps, such as weighing, packaging, pouring, and mixing of nano-objects in the open versus conveying or high temperature synthesis in a fully enclosed system; processing of nano-containing intermediates, including the machining or milling of nanocomposite, compounding using nano-enabled intermediates; or use of nanomaterials to facilitate production;

   2) identification of the presence of other processes in the workplace that can affect measurements or the measurement strategy employed, such as a docking door that opens to allow a forklift to enter the facility periodically;

   3) identification of the presence or absence of ventilation, heating, ventilating and air conditioning (HVAC), or air currents that could create positive or negative pressure possibly influencing the measurement strategy for airborne NOAA.