SLOVENSKI STANDARD
oSIST prEN 14583:2020

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Izpostavljenost na delovnem mestu - Naprave za volumetrijsko vzorčenje bioaerosolov - Splošne zahteve za uporabo in vrednotenje lastnosti

Workplace exposure - Volumetric bioaerosol sampling devices - General requirements for use and evaluation of performance

Exposition am Arbeitsplatz - Volumetrische Probenahmeeinrichtungen für Bioaerosole - Allgemeine Anforderungen an die Verwendung und Evaluierung der Leistungsfähigkeit

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Workplace exposure - Volumetric bioaerosol sampling devices - General requirements for use and evaluation of performance

Exposition am Arbeitsplatz - Volumetrische Probenahmeeinrichtungen für Bioaerosole - Allgemeine Anforderungen an die Verwendung und Evaluierung der Leistungsfähigkeit

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 137.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 14583:2020) 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 will supersede EN 14583:2004.

The major technical changes between this document and the previous edition are as follows:

a) document title changed;

b) Scope rewritten and given more detailed;

c) Terms and definitions already referred to in EN 1540 or EN 13098 deleted;

d) Annex B revised by replacing the former content by general requirements on test facilities and an overview on different types and examples of test facilities;

e) new Annex C on microbial surrogates used for bioaerosol studies added;

f) Bibliography updated;

g) whole document restructured and editorially and technically revised.

Introduction

This document is needed to promote the development of new equipment for measurement of microorganisms in the work environment. This document can also apply to existing equipment. It is intended to specify requirements and methods to determine performance characteristics of sampling devices used to collect bioaerosols from the workplace atmosphere. Examples of test environments and methods will be described and test methods will be provided.

WARNING — The use of this document can involve hazardous materials, operations and equipment. This document does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This document specifies general requirements for the use and evaluation of physical and biological performance of volumetric sampling devices applied for assessing bioaerosols in the workplace.

This document lists the criteria for the selection of microbial strains that can be used for the evaluation of biological performance of samplers.

This document also describes a bioaerosol test facility suited for assessing the biological performance of bioaerosol sampling devices.

This document is not applicable for clean room measurements.

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 13098, *Workplace exposure - Measurement of airborne microorganisms and microbial compounds - General requirements*

EN 13205 (all parts), *Workplace exposure - Assessment of sampler performance for measurement of airborne particle concentrations*

EN 60079-1, *Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"*

EN 60079-2, *Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"*

EN 60079-5, *Explosive atmospheres - Part 5: Equipment protection by powder filling "q"*

EN 60079-6, *Explosive atmospheres - Part 6: Equipment protection by liquid immersion "o"*

EN 60079-7, *Explosive atmospheres - Part 7: Equipment protection by increased safety "e"*

EN 60079-11, *Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"*

EN 60079-18, *Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"*

EN 60079-25, *Explosive atmospheres - Part 25: Intrinsically safe electrical systems*

EN ISO 13137, *Workplace atmospheres - Pumps for personal sampling of chemical and biological agents - Requirements and test methods (ISO 13137)*

EN IEC 60079-0, *Explosive atmospheres - Part 0: Equipment - General requirements (IEC 60079-0)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 1540, EN 13098 and the following apply.

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

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

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

3.1
accuracy
closeness of agreement between a test result or measurement result and the true value

Note 1 to entry: In practise, the accepted reference value is substituted for the true value.

Note 2 to entry: The term “accuracy”, when applied to a set of test or measurement results, involves a combination of random components and a common systematic error or bias component.

Note 3 to entry: Accuracy refers to a combination of trueness and precision.

Note 4 to entry: The quantity referred to in this document as accuracy provides an estimation of the range around the measured value in which can be found the accepted reference value with the confidence of 95 %.

[SOURCE: ISO 3534-2:2006, 3.3.1, modified – All cross references have been removed and Note 4 to entry has been added.]

3.2
bias
measurement bias

difference between the expectation of a test result or measurement result and a true value

Note 1 to entry: Bias is the total non-random error as contrasted to random error. There can be one or more non-random error components contributing to the bias. A larger systematic difference from the true value is reflected by a larger bias value.

Note 2 to entry: In practice, the accepted reference value is substituted for the true value. The accepted reference value (for definition see ISO 3534-2) can be, for example, the certified value of a reference material, the concentration of a standard test atmosphere or the target value of an interlaboratory comparison.

[SOURCE: ISO 3534-2:2006, 3.3.2, modified – Synonymous term “measurement bias” has been added.]

3.3
personal sampler
sampler, attached to a person, that collects gases, vapours or airborne particles in the breathing zone for the purpose of measuring exposure to chemical agents and/or biological agents

Note 1 to entry: Some sampling devices have integral pumps, and some do not. Where the personal sampler requires the use of an external pump, the pump is not subject to the requirements of this document.

[SOURCE: ISO 18158:2016, 2.2.2.2, modified – Note 1 to entry has been added.]

3.4
particle aerodynamic diameter
diameter of a sphere of 1 g/cm^3 density with the same terminal settling velocity in calm air as the particle, under the prevailing conditions of temperature, pressure and relative humidity

[SOURCE ISO 18158:2016, 2.1.4.8]

3.5
sampling device
total equipment used for sampling, e. g. pump, sampling head and sampling substrate

4 Abbreviated terms

ATCC	American Type Culture Collection
CBS	Centraalbureau voor Schimmelcultures
CCUG	Culture Collection University of Göteborg
DSMZ	Deutsche Stammsammlung für Mikroorganismen und Zellkulturen
HEPA	high efficiency particulate aerosol
NCTC	National Collection of Type Cultures
RH	relative humidity
T	temperature

5 Requirements for sampling devices

5.1 General

The pumps used for personal sampling shall fulfil the requirements specified in EN ISO 13137.

5.2 Use in potentially explosive atmospheres

When the sampling device covered by this document is to be used in potentially explosive atmospheres, it shall comply with EN IEC 60079-0, EN 60079-1, EN 60079-2, EN 60079-5, EN 60079-6, EN 60079-7, EN 60079-11, EN 60079-18 and EN 60079-25.

5.3 Mechanical construction

Every sampling device shall be constructed in such a manner that it is easily accessible for regular function checks and that airflow can easily be measured and calibrated. The sampling pump shall maintain the required airflow rate throughout the sampling period.

Material used in the sampling head should be chosen to avoid moisture uptake and electrostatic charges.

5.4 Indicator devices

An indicator device shall be provided to show that the sampling device is switched on. If the sampling device has more than one measuring range, the selected range shall be clearly identified.

NOTE It is an advantage if elapsed time indicators, low flow rate indicators, flow interrupted indicators are given.

5.5 Adjustments

Any equipment (switch, knob, etc.) used for modifying the operating parameters (sampling time, flow rate, etc.) of the sampling device shall be protected against inadvertent or purposeful adjustment during sampling. The operational settings should be displayed.

5.6 Battery powered sampling devices

Sampling devices powered with integrated batteries shall be provided with an early indication of low battery condition.

5.7 Airflow control

During the sampling deviation from the required airflow should not exceed ± 5 %.

5.8 Airflow meter

A device to measure the airflow through the sampling device before and after sampling in the field should be supplied if required.

NOTE This device can be different from that used for calibration.

Sampling devices with integral airflow meters shall be calibrated against a traceable external airflow meter before use.

5.9 Labelling and marking

The manufacturer of the sampling device shall be clearly identified to ensure traceability to specified performance characteristics.

5.10 Instruction handbook

The instruction handbook shall be written in a language, which is understandable in the country of the operator. It shall be easily understood and every function explained.

The instruction handbook shall illustrate all components and their handling by figures.

The instruction handbook shall give the environmental conditions and other conditions under which the sampling device shall be operated including limitations to its use. It shall give exact calibration instructions and recommended equipment (e.g. flow meters) to be used. The instruction handbook shall also give instructions for troubleshooting and maintenance of the sampling device.

5.11 Fraction to be sampled

The sampling device should be able to collect a representative sample of the required health-related fraction of the bioaerosol according to EN 481.

NOTE Most personal samplers collect the inhalable fraction of bioaerosol, but other samplers might be used to collect the thoracic or respirable fraction as well.

For static sampling the health-related fraction to be used shall be specified by the manufacturer.