

Workplace atmospheres — Volumetric bioaerosol sampling devices — Requirements and test methods

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National foreword

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Foreword

This document (EN 14583:2004) 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of an identical text or by endorsement, at the latest by March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.

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Introduction

A European Standard is needed to promote the development of new equipment for measurement of micro-organisms 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 European Standard can involve hazardous materials, operations and equipment. This European Standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this European Standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This document specifies requirements and test methods to determine the performance of volumetric sampling devices used to assess bioaerosols in the workplace.

For clean room measurements EN ISO 14698-1 is applicable.

2 Normative references

The following referenced documents are indispensable for the application 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 1232, *Workplace atmospheres — Pumps for personal sampling of chemical agents — Requirements and test methods*

EN 12919, *Workplace atmospheres — Pumps for the sampling of chemical agents with a volume flow rate of over 5 l/min — Requirements and test methods*

EN 13205, *Workplace atmosphere — Assessment of performance of instruments for measurement of airborne particle concentrations*

EN 50015, *Electrical apparatus for potentially explosive atmospheres — Oil immersion ‘o’*

EN 50016, *Electrical apparatus for potentially explosive atmospheres — Pressurised apparatus ‘p’*

EN 50017, *Electrical apparatus for potentially explosive atmospheres — Powder filling ‘q’*

EN 50020, *Electrical apparatus for potentially explosive atmospheres — Intrinsic safety ‘i’*

EN 60079-0, *Electrical apparatus for potentially explosive atmospheres — Part 0: General requirements (IEC 60079-0: 2004)*

EN 60079-1, *Electrical apparatus for potentially explosive atmospheres — Part 1: Flameproof enclosure ‘d’ (IEC 60079-1:2003)*

EN 60079-7, *Electrical apparatus for explosive gas atmospheres — Part 7: Increased safety ‘e’ (IEC 60079-7: 2001)*

EN 60079-18, *Electrical apparatus for explosive gas atmospheres — Part 18: Construction, test and marking of type of protection encapsulation “m” electrical apparatus (IEC 60079-18:2004)*

EN 60079-25, *Electrical apparatus for explosive gas atmospheres — Part 25: Intrinsically safe systems (IEC 60079-25:2003)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

accuracy

closeness of agreement between a test result and the accepted reference value

[ISO 3534-1:1993]

NOTE 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 %.

3.2 bias
consistent deviation of the results of a measurement process from the true value of the air quality characteristic itself

[EN 482:1994]

3.3 culturable number
number of micro-organisms, single cells or aggregates able to form colonies on a solid nutrient medium

[EN 13098:2000]

3.4 total number of micro-organisms
number of micro-organisms determined as single organisms (or a corresponding measure)

[EN 13098:2000]

3.5 personal sampler
device, which samples air in the breathing zone of a person to determine exposure to biological agents

NOTE 1 Some sampling devices have integral pumps, and some do not. Where the instrument requires the use of an external pump, the pump is not subject to the requirements of this document.

NOTE 2 Adapted from EN 1540.

3.6 particle aerodynamic diameter
diameter of a sphere of density 1 g cm^{-3} with the same terminal velocity due to gravitational force in calm air, as the particle, under the prevailing conditions of temperature, pressure and relative humidity

[EN 1540:1998]

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

4 Abbreviated terms

ATCC	American Type Culture Collection
BTC	bioaerosol test chamber
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

5.1 General

Performance requirements for volumetric sampling pumps shall comply with EN 1232 for low flow rate pumps or EN 12919 for high flow rate pumps. This shall apply both to integral and separate pumps.

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 50015 to EN 50017, EN 50020, EN 60079-0, EN 60079-1, EN 60079-7, 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.

NOTE 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 involuntary action during sampling. The operational settings should be displayed.

5.6 Battery powered sampling devices

Sampling devices powered with integral batteries shall be provided with an early indication of low battery condition. Short recharge time, light-weight and low noise levels are recommended.

5.7 Airflow-control

During the sampling deviation from the required airflow should not exceed $\pm 5\%$.

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 source and the manufacturer of the sampling device shall be clearly identified to ensure traceability to published performance characteristics.

5.10 Instruction manual

The instruction manual shall be written in a language, which is understandable in the country of the operator. It shall be easily understood and every function explained. It shall illustrate all operation knobs and their handling by figures. It shall give the environmental and other conditions under which the instrument 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 manual shall also give the address for service of the instrument.

5.11 Fraction to be sampled

To measure personal exposure to bioaerosols the sampling device should follow the criteria for size fractions of airborne particles according to EN 481.

5.12 Physical sampling efficiency

Physical sampling efficiency is defined in EN 13098 and EN 13205. It shall be measured as a function of particle aerodynamic diameter and other influent parameters.

NOTE 1 Annex A gives some information about the physical behaviour of a sampling device and the experimental assessment of its physical sampling efficiency in the laboratory.

Physical sampling efficiency can be interpreted as the percentage of ambient particles of specific size that are sampled and collected by the sampling device. As airborne micro-organisms often adhere to non-biological particles of various sizes, the measurement of micro-organism concentration implies an accurate knowledge of this parameter.

Sampling devices shall collect a representative sample of the required health related fraction of the bioaerosol (see EN 481).

When assessing the performance of any bioaerosol sampling device, the overall sampling efficiency shall be determined. The performance of a personal sampler will be affected by the proximity of the operator's body when worn within the breathing zone, and therefore personal inhalable sampling devices need to be assessed whilst attached to a torso or other well characterised equivalents.

NOTE 2 Personal sampling is performed when assessing the exposure to evaluate a suspected disease. Many biological tests are more effectively carried out with a personal sampler used as a free standing device. A free-standing sampler can be used to scan the environment for high emissions of micro-organisms.

5.13 Preservation efficiency

Preservation efficiency is defined in EN 13098 as the capacity of the sampling device to maintain the culturability of the airborne micro-organisms during collection and also to keep the microbial products intact. The loss of culturability of micro-organisms due to sampling stress shall be tested on relevant model organisms.

5.14 Concentration range

The manufacturer shall give the operational range and its limitations. An ideal sampling device should be able to sample concentrations of culturable micro-organisms and/or total number of micro-organisms up to 10^{10} m^{-3} air.

5.15 Duration of sampling

The collected bioaerosol samples should refer to a time period representative of that corresponding to the exposure pattern. The manufacturer shall give the operational range of duration.

NOTE The sampling time can vary from a few minutes up to an 8 h workshift. Overloading can affect the analysis negatively.

5.16 Loading of the sampling device

The sampling device shall be easy to aseptically load, empty and reload with new sampling substrates at the work place with a minimum loss of collected bioaerosol.

5.17 Cleaning of the sampling device

The sampling device shall be constructed to allow easy cleaning and decontamination in the field and to allow disinfection in the laboratory.

5.18 Accuracy

Bias and accuracy shall be determined according to EN 13205. For personal samplers the target conventional fraction of the bioaerosol is generally the inhalable fraction, but it may be other subfractions (thoracic or respirable). The bias shall refer to one of these conventional fractions. For static sampling devices the reference fraction for the calculation of bias can be any of the conventional fractions.

6 Test conditions

6.1 General

The conditions applied during the test shall be within the range specified by the manufacturer. For test of sampling device EN 13205 can give additional information.

For the purpose of sampling device performance testing, the tests shall be carried out on at least two specimen of the sampling device and compared to the performance of a reference sampling device.

6.2 Reference sampling device

The reference sampling device used shall be well characterised and the samples shall be taken to allow analysis of both viable and total number of micro-organisms (see EN 13098). If appropriate, two different reference sampling devices may be used.

6.3 Stabilisation time

For the purposes of the tests in each instance where the sampling device is subjected to different test conditions, the sampling device shall be allowed to stabilise.

Maximum time for stabilisation should not exceed 30 min.

6.4 Test environment

6.4.1 General

The test environment shall consist of single particles as well as aggregates of particles in an atmosphere with controllable humidity and temperature. The concentration range of particles within which the sampling device is suitable shall be given. The temperature and humidity of the test environment shall be stated.

Limitations in temperature and humidity shall be given by the manufacturer.

6.4.2 Test facilities for assessing physical performance of bioaerosol sampling devices

The experimental conditions for measuring the physical sampling efficiency of bioaerosol sampling devices shall be the same as those that are described in EN 13205. However, when bioaerosol sampling devices are only designed to measure micro-organisms and not their microbial products, the calculation of bias and accuracy relative to mass concentration is not required.

6.4.3 Test facilities for assessing biological performance of bioaerosol sampling devices

The biological performance of the bioaerosol sampling devices shall be studied in a test chamber into which specified aerosols of micro-organisms can be generated in suitable conditions. Annex B describes such a test facility. The ratio between the measured concentration of micro-organisms and the concentration assessed by some reference equipment shall be calculated for each micro-organism species to be studied.

6.5 Production of test bioaerosols and recommended strains

Microbial cell suspensions shall be controllably aerosolised and homogeneously mixed in a test chamber at selected temperature and relative humidity. The particle size shall be specified.

The test organisms and used media shall be specified and should be appropriate to the end use of the sampling device. The test strains shall be available from a standard culture collection (i.e. ATCC, CCUG, NCTC, CBS, DSMZ).

NOTE Test bioaerosols can be produced from cultivations in liquid or semisolid culture media, water, or from selected buffer solutions. This can change the surface characteristics of the bioaerosol particles. Spore aerosols can also be generated from dust or powder.

6.6 Orientation

The manufacturer shall state in which orientations the sampling devices have been tested relative to the bioaerosol air-stream. The personal samplers shall be tested on a mannequin.

The sampling device should be tested in the test environment within the orientation limits stated in the manufacturers instruction manual but in no case less than 15 ° from the normal orientation. Rotate the inlet or the whole sampling device if relevant, in the test environment, through 360 ° in steps of 90 ° around each of its mutually perpendicular axis. Record the indication in each position (see EN 13205).

6.7 Calibration

The manufacturer shall state the way in which the sampling device has been calibrated.

6.8 Air flow velocity

The manufacturer shall state the airflow velocity in which the sampling device has been tested.

7 Environmental conditions for test methods

7.1 General

The tests shall be carried out to determine the impact of variable air temperature, barometric pressure, and relative humidity conditions on flow rate and sampled air volume, the sampling device being initially calibrated for referenced ambient conditions. The measurements shall be performed inside a laboratory chamber, with controlled temperature (T) and relative humidity (RH). A separate enclosure can be used for the tests with a variable pressure. The measurements shall be repeated at least five times for any series of (T, RH). The sampled air volume or representative values of sampling time shall be measured for all predetermined values. The average value of each measured variable and its standard deviation shall be estimated. The results of the tests shall be given in the test report and the operating conditions shall be documented.

7.2 Temperature

The tests shall be carried out at specified temperatures. At least two temperatures shall be used to cover the range as expected to be used by the sampling device.

7.3 Humidity

The tests shall be carried out at two humidity conditions for each temperature used in 7.2.

8 Test report

A test report describing the results of all the tests shall be provided with the sampling device.

The test report shall contain at least the following information:

- a) reference to this document
- b) description of the test environment;
- c) method of flow rate measurement;
- d) physical conditions used;
- e) reference sampling device used;
- f) sampling duration;
- g) test chamber used;
- h) test strain used;
- i) warm up time to achieve stable conditions.

Annex A (informative)

Bioaerosol sampling

A.1 General

The behaviour and potential hazard of bioaerosols can only be accurately described once the principles of aerosol sampling, micro-organism viability, culture preparation and biological assay are understood. It is important that sampling devices collect a representative sample of the required fraction of the bioaerosol with the minimum of stress, so that the biological activity of the aerosol is not significantly impaired. It is possible, that these two requirements will not be compatible, particularly with vegetative micro-organisms. Ideally, the total number concentration, size distribution and viable number concentration of the airborne micro-organisms need to be known in order to assess possible hazards.

A.2 Aerodynamic behaviour of bioaerosol sampling devices

The performance of a sampling device designed to collect airborne particles can be described in terms of a number of parameters (see [14]): the aspiration efficiency is the efficiency with which particles enter the sampling device directly through the aspiration orifice or slot, the apparent aspiration efficiency is the efficiency with which particles enter the sampling device directly and from external surfaces by rebound or blow-off, and the overall sampling efficiency is the efficiency by which the particles reach the collection surface. When assessing the performance of any bioaerosol sampling device, the aspiration, apparent aspiration and sampling efficiencies have to be determined over a range of wind speeds with a series of particles of different size. These studies can be carried out experimentally in test chambers (calm air conditions) or in wind tunnels (see [13]). The performance of a personal sampler will be generally affected by the proximity of the operator's body when worn within the breathing zone, and therefore need to be assessed whilst mounted on a life-size mannequin or under circumstances shown to give equivalent results when wind speed exceeds 1 m s^{-1} . EN 13205 describes methods which can be used for laboratory testing of sampling devices with respect to sampling conventions defined in EN 481, and laboratory comparison of instruments.

A.3 Biological activity of micro-organisms after sampling

Sampling devices that are used to collect airborne liquid or solid particles are often unsuitable for bioaerosols, which often are collected with minimal damage to establish their viability in the airborne state. Shear forces, static forces and dehydration can damage bioaerosols (see [4]). Sampling devices, which operate with low shear forces cause least damage to micro-organisms, although these sampling devices usually have low physical sampling efficiencies (see [4]). Birch and Griffiths (see [3]) showed that the viability of some bioaerosols was affected by different degrees using a number of different personal samplers.

Annex B (informative)

Example of test facility usable for assessing biological performance of bioaerosol sampling devices

A possible bioaerosol test chamber (BTC) consists of a vertical, rectangular structure over 4 m high with approximately 1 m × 1 m internal working section. The chamber is constructed from stove enamelled aluminium angle, sheet and toughened glass, and consists of five sections, with square pyramid upper and lower sections.

High efficiency particulate aerosol HEPA-filtered air enters the BTC through the top section, which contains arrangement of stainless steel wire meshes of different porosity designed to reduce the funnelling effect of the airflow through the pyramidal section into the main section of the BTC. This arrangement minimises the uniformity of flow across the working area. Aerosols are generated in the second section and are forced vertically downwards into the third section by the flow of air and gravity where mixing occurs. The airflow contains large and small swirls and eddies moving slowly downwards towards the fourth section, which houses the bioaerosol sampling devices. Turbulent components of the airflow are reduced by passage through a flow laminator mounted between the third and fourth sections to maximise the uniformity of aerosol concentration across the fourth section.

Each bioaerosol sampling device can be mounted on a reciprocating carousel so that they are challenged with the same aerosol concentration. The carousel is constructed from perforated stainless steel sheet to facilitate the flow of air. Air from the fifth and lowest section of the BTC passes through a HEPA filter to remove aerosol particles. The airflow rate through the BTC is $2,7 \text{ m}^3 \text{ min}^{-1}$, giving an airflow velocity of $0,045 \text{ m s}^{-1}$ in the $1 \text{ m} \times 1 \text{ m}$ cross section of the sampling section. A specially designed air conditioning system is used to support the flow of air and aerosol through the BTC. This air conditioning system and ducting were fitted with thermal insulation to help ensure that air supplied to the BTC was controllable in the temperature range from $20 \text{ }^\circ\text{C}$ to $40 \text{ }^\circ\text{C}$ and relative humidity range from 30 % to 80 %.

In the actual work environment the temperature where the sampling device is used can vary between $-20 \text{ }^\circ\text{C}$ and $+40 \text{ }^\circ\text{C}$. Also the relative humidity can vary within the range from 0 % to 100 %.

NOTE Another possible test facility especially for determination of low concentrations of bioaerosols is described in EN ISO 14698-1 particularly aimed at evaluating sampling devices for use in clean rooms.

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