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BSI Standards Publication

Cleanrooms and associated controlled environments

Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration

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National foreword

This British Standard is the UK implementation of ISO 14644-12:2018.

The UK participation in its preparation was entrusted to Technical Committee LBI/30, Cleanroom technology.

A list of organizations represented on this committee can be obtained on request to its secretary.

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INTERNATIONAL STANDARD

ISO 14644-12

First edition
2018-08-27

Cleanrooms and associated controlled environments —

Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 12: Spécification de la propreté de l'air en fonction de la concentration des nanoparticules

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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 documents 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 209, *Cleanrooms and associated controlled environments*.

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.

A list of all parts in the ISO 14644 series can be found on the ISO website.

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Introduction

Cleanrooms and associated controlled environments provide the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare and food.

The normative requirements in the first editions of ISO 14644-1 and ISO 14644-3 were limited to classification of particles greater than 100 nm. However, informative material was included in both documents for airborne particles smaller than 100 nm. At the time these documents were written; particles smaller than 100 nm were called ultrafine particles rather than the more recent term, nanoparticles.

In the second editions of ISO 14644-1 and ISO 14644-3[1)], sections on ultrafine particles have been removed and these are incorporated, in modified form, in this document. Supporting information has also been drawn from documents developed elsewhere, for example by ISO/TC 229, *Nanotechnologies*.

Nanotechnology typically deals with material in the size range of approximately 1 nm to 100 nm. As part of the long-term trend of manufacturing products with ever smaller feature size to improve performance, many industries utilizing cleanrooms (such as microelectronics and those related to health) now have products in the nanoscale.

Nanoparticles are man-made. Other particles in the nanoscale size range can originate as incidental by-product emissions from industrial process or additionally as naturally occurring particles. A cleanroom with a nanotechnology-based process can contain nanoscale particles from all three sources.

Nanoparticles or ultrafine particles differ from sub-micron and macro-particles in origin, chemical properties and transport behaviour. Most sub-micron and macro particles in cleanrooms can be related to human activity. Nanoparticles are generated by electrostatic discharge, chemical reactions, such as oxidation, and gas phase nucleation. Material properties of nanoparticles are expected to differ from bulk properties with potentially greater reactivity and sometimes enhanced toxicity. Transport of nanoparticles is dominated by air flow, just like sub-micron particles. However, diffusion of nanoparticles and mobility in electrical fields increases rapidly with decreasing size. As a consequence, nanoparticles have higher coagulation rates in the air and deposition rates on surfaces are higher than larger sized particles. Therefore, it is not expected that the classification curves as described in ISO 14644-1 can be simply extrapolated to smaller particles than the stated lower limit.

Ultra Low Particulate Air (ULPA) filters remove nanoparticles with high efficiency, preventing penetration from the atmosphere and recirculated air. Therefore, the majority of the nanoparticles in cleanrooms are process related. For many cleanrooms, the composition of sub-micron and macro particles is comparable. For nanoparticles, each cleanroom has nanoparticles corresponding to the specific process. Therefore, measurement of the nanoparticle concentration is only suitable when the cleanroom is in an “operational” state. In the “as-built” or “at-rest” state, the lack of process related particles leads to data that do not correlate to the realistic conditions.

See Bibliography references [1] to [18] for background information on particle size characteristics/properties.

1) Under preparation. (Stage at the time of publication: ISO/DIS 14644-3.)

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INTERNATIONAL STANDARD ISO 14644-12:2018

Cleanrooms and associated controlled environments —

Part 12:
Specifications for monitoring air cleanliness by nanoscale particle concentration

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1 Scope

This document covers the monitoring of air cleanliness by particles in terms of concentration of airborne nanoscale particles.

For monitoring purposes, only populations of particles with a lower size limit of 0.1 microns (100 nm) or less – "nanoscale" – are considered.

The monitoring given in this document is for use mainly in "operational" states.

NOTE 1 For the purposes of this document, reference is made to "nanoscale particles", which means all nano-objects having one (nanoplate), two (nanofibre) or three (nanoparticle) dimensions in the nanoscale.

NOTE 2 As a consequence, the specifications for monitoring air cleanliness by nanoscale particle concentration of the cleanroom in operational state also considers process specifics, e.g., used equipment, personnel behaviour, etc.

NOTE 3 Health and safety considerations are excluded from this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 https://www.electropedia.org/

3.1 General

3.1.1
cleanroom
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or *nanoscale* (3.2.1) concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

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Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.1]

3.1.2
clean zone
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or *nanoscale* (3.2.1) concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: A clean zone(s) can be a defined space within a *cleanroom* (3.1.1) or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.2]

3.2 Size

3.2.1
nanoscale
length range approximately from 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from a larger size are predominantly exhibited in this length range.

[SOURCE: ISO/TS 80004-2:2015, 2.1]

3.2.2
particle size cutoff
D_{50}
particle size at which the counting efficiency is 50 %

Note 1 to entry: See Annex B for an explanation of counting efficiency.

3.3 Airborne particles

3.3.1
nanoparticle
nano-object (3.2.2) with all external dimensions in the *nanoscale* (3.2.1) where the lengths of the longest and the shortest axes of the nano-object do not differ significantly

Note 1 to entry: If the dimensions differ significantly (typically by more than 3 times), terms such as nanofibre or nanoplate may be preferred to the term nanoparticle

[SOURCE: ISO/TS 80004-2:2015, 4.4]

3.3.2
particle size distribution
cumulative distribution of particle concentration as a function of particle size

[SOURCE: ISO 14644-1:2015, 3.2.4]

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3.3.3
aerosol
system of solid or liquid particles suspended in gas

[SOURCE: ISO 15900:2009, 2.1]

3.4 Occupancy states

3.4.1
operational
agreed condition where the *cleanroom* (3.1.1) or *clean zone* (3.1.2) is functioning in the specified manner, with equipment operating and with the specified number of personnel present

[SOURCE: ISO 14644-1:2015, 3.3.3]

3.5 Measuring apparatus

3.5.1
condensation particle counter
CPC
instrument that measures the particle number concentration of an *aerosol* (3.3.3)

Note 1 to entry: The sizes of particles detected are usually smaller than several hundred nanometres and larger than a few nanometres.

Note 2 to entry: A CPC is one possible detector for use with a DEMC.

Note 3 to entry: In some cases, a condensation particle counter may be called a condensation nucleus counter (CNC).

[SOURCE: ISO 15900:2009, 2.5]

3.5.2
counting efficiency
ratio of the reported concentration of particles in a given size range to the actual concentration of such particles

[SOURCE: ISO 14644-3:2005, 3.6.5]

4 Monitoring

4.1 General

For measurement purposes, the only important particle characteristic is its “equivalent diameter”.

4.2 Principle

The monitoring limits and requirements specified by the customer are verified by performing specified testing procedures and by providing documentation of the results and conditions of testing, as agreed upon by the customer and the supplier. See ISO 14644-2:2015, Annex A which specifies the requirements of a monitoring plan based on the risk assessment of the intended use. The data obtained provide evidence of cleanroom performance related to the nano-particle concentration.

4.3 Methods

For the purposes of monitoring, airborne nanoscale particle counting can be carried out most effectively by CPC. The reference test method for CPC monitoring is given in Annex A. The method for performing the monitoring of air cleanliness by nanoscale particle concentration should give a systematic plan, well-defined procedure and identify how the assessment should be performed. In general, the establishment

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of alert and action limits is based on a risk assessment. If there is a requirement for buyer and seller, the limits may be established per agreement.

Criteria for determining the counting method shall include:

— nanoscale particle size to be measured;

— time dependence of sampling and analysis;

— sample volume;

— location of sampling;

— number of samples;

— criticality of process/product;

— design/layout of clean zone.

Alternative methods and/or instrumentation, having at least comparable performance to CPC measurement may be specified. If no alternative is specified or agreed upon, the reference method shall be used.

Tests performed to demonstrate compliance shall be conducted using calibrated instruments.

5 Test report

The results from testing each clean zone shall be recorded and submitted as a comprehensive report. The data summary should include a review of the monitoring data for adverse trends, operational levels, and any investigational requirements consistent with the monitoring plan specified in 4.2.

The test report shall include:

a) the name and address of the testing organization, and the date on which the test was performed;

b) a reference to this document, i.e. ISO 14644-12;

c) a clear identification of the physical location of the clean zone tested (including reference to adjacent areas if necessary), and specific designations for coordinates of all sampling locations;

d) the specified designation criteria for the clean zone, the relevant occupancy state(s), and the considered particle size(s);

e) details of the test method used, with any special conditions relating to the test, or departures from the test method, and identification of the test instrument and its current calibration:

   1) identification of the CPC and particle size cutoff device, if used, and the calibration status;

   2) lower particle size limit for the nanoscale particle concentration being reported ;

   3) zero count rate for the CPC, when used;

   4) particle size cutoff device performance data, as required;

   5) type of measurement: nanoscale particle concentration measurement or monitoring;

   6) nanoscale particle measurement system inlet and sensing volume flow rates;

f) the test results, including particle concentration data for all sampling locations.

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Annex A
(informative)

Reference method for monitoring by condensation particle counting

A.1 Principle

A CPC instrument is used to determine the concentration of airborne nanoscale particles, equal to and greater than the specified sizes, at designated sampling locations.

A.2 Apparatus requirements

A.2.1 CPC instrument

The instrument shall have a means of displaying or recording the count of airborne nanoscale particles with a size discrimination capability to detect the total nanoscale particle concentration in the appropriate particle size ranges for the class under consideration.

A.2.2 Condensation particle counter (CPC)

The instrument counts all droplets formed by condensation of supersaturated vapour on sampled nuclei particles. Cumulative particle concentrations are produced for particles larger than or equal to the lower size limit of the CPC. Example specifications for the condensation particle counter are given in Table A.1. The specifications of any instrument shall be provided by the vendor and accepted by the user.

Table A.1 — Specifications for condensation particle counter

Item	Specification
Upper concentration limit	$>3{,}5 \times 10^8/m^3$
Particle size cutoff (D_{50})	Application specific, e.g. D_{50} = 0,01 µm
Accuracy of count measurement	±10 % at below the upper concentration limit
Ambient conditions for stability of reading	Temp. range: 10 °C to 35 °C Relative Hum.: 0 to 90 % non-condensing Ambient pressure: 75 kPa to 105 kPa (0,75 atm. to 1,1 atm.)
Flow rate stability	±10 % of specified flow at T/RH/P (temperature/ relative humidity/pressure)that tests will be conducted
Calibration interval	12 months maximum
False count error	False counts shall be less than a 1/3 of the maximum permitted concentration as agreed by customer
Counting efficiency	50 % ± 10 % at the lower size limit, and >85 % at 5× the lower size limit, and <25 % at 0,5× the lower size limit (see Figure B.1) using sucrose or silver nanoparticles

A.2.3 Instrument calibration

The instrument shall have a valid calibration certificate; the frequency and method of calibration should be based on current accepted practice (see ISO 27891).

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A.3 Particle counting efficiency and particle size cut-off

For a discussion of particle counting efficiency and particle size cut-off, please refer to Annex B.

A.4 Pretest conditions

A.4.1 Preparation for testing

Prior to testing, verify that all aspects of the clean zone or the associated controlled environment that contribute to its integrity are complete and functioning in accordance with its performance specification. Such verification methods are referenced in ISO 14644-3, and include, for example, data on the following:

a) airflow tests (e.g. air volume, air velocity, or uniformity of unidirectional airflow);

b) air pressure differential test;

c) containment leak test;

d) installed filter system leakage test.

A.4.2 Pretest equipment setup

Perform equipment setup in accordance with the manufacturer's instructions. Verify flow rate and zero count of the CPC meet specifications in Table A.1 prior to any cleanliness classification test.

A.5 Sampling

A.5.1 Establishment of sampling locations

The sampling location(s) shall be agreed upon between customer and supplier.

A.5.2 Sampling procedure for CPC

A.5.2.1 Set up the particle counter (A.2) in accordance with the manufacturer's instructions and in compliance with the manufacturer's acceptable operating conditions. Personnel carrying out this procedure should be appropriately trained in the use of the instrumentation.

A.5.2.2 Position the sampling probe pointing into the airflow. If the direction of the airflow being sampled is not controlled or predictable (e.g., non-unidirectional airflow), the inlet of the sampling probe shall be directed vertically upward.

A.5.2.3 If necessary, allow stable conditions to be established before sampling. Sample the volume of air determined in A.4.2, as a minimum, at each sampling location. Select tubing that is known to transport charged particles effectively and minimize tubing length.

A.5.3.4 If, during testing at multiple locations, an unusually high result is found at a particular location in the single sample volume, further testing may be undertaken at the location to investigate the problem and determine if the location meets user requirements. Where information on stability of nanoscale particle concentration is required, make three or more measurements at selected locations at time intervals, as agreed upon between customer and supplier.

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A.6 Recording of results: Average concentration of particles at each sampling location

A.6.1 Record the result of each sample measurement as the number of particles in each single sample volume at each of the considered particle size(s) appropriate to the relevant user specifications.

A.6.2 When two or more single sample volumes are taken at a location, calculate and record the average number of particles per location at each considered particle size from the individual sample particle concentrations (A.6.1), according to Formula (A.1).

$$x_i = [x_{i,1} + x_{i,2} + \ldots . x_{i,n}] \; / \; n \qquad \text{(A.1)}$$

where

x_i is the average number of particles at location i, representing any location;
$x_{i,1}$ to $x_{i,n}$ are the number of particles in individual samples;
n is the number of samples taken at location i.

A.6.3 Calculate the concentration, C_i, per m^3 using Formula (A.2).

$$C_i = x_i \times 1\,000 \; / \; V_t \qquad \text{(A.2)}$$

where

x_i is the average number of particles at location i, representing each location;
V_t is the adopted single sample volume in litres.

A.7 Interpretation of results — requirements

The clean zone is deemed to have met the specified monitoring requirements if the average of the particle concentrations expressed as number of particles per m^3 measured at each of the sampling locations does not exceed the concentration limits as established by the user or by agreement of buyer and seller.

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Annex B
(informative)

Particle counting efficiency and particle size cutoff

B.1 Counting efficiency

Counting efficiency of a condensation particle counter is affected mainly by particle size and to some extent by particle composition. In rare circumstances, the composition can cause the counting efficiency to decrease for very hydrophobic materials, when water is the condensing fluid.

The counting efficiency of the system used to measure nanoscale particle concentration should fall within the shaded envelope region shown in Figure B.1. This region of acceptable performance centres on a counting efficiency of 50 % at the defined nanoscale particle size (D_{50}). X is the ratio of D divided by D_{50} (D/ D_{50}). The region includes a tolerance band of ±10 % of the normalized nanoscale particle size, X, shown as X = 1,1 and X = 0,9 in Figure B.1. The acceptable minimum and maximum counting efficiencies for particles above and below the ±10 % normalized size tolerance band are shown, and indicate that at X = 5, the counting efficiency should be at least 85 %, and at X = 0,5 the counting efficiency should be at <25 %. The counting efficiency should be performed with sucrose or silver as the particle standard.

If the CPC has a counting efficiency curve that falls to the right of the shaded envelope of Figure B.1, the CPC should not be used to measure or verify the nanoscale particle concentration. If the curve falls to the left of the shaded envelope, the counting efficiency can be decreased by modifying it with a particle size cutoff device as described in B.2. In this case, the counting efficiency of the modified CPC becomes the product of the counting efficiency of the unmodified CPC and the fractional penetration of the particle size cutoff device.

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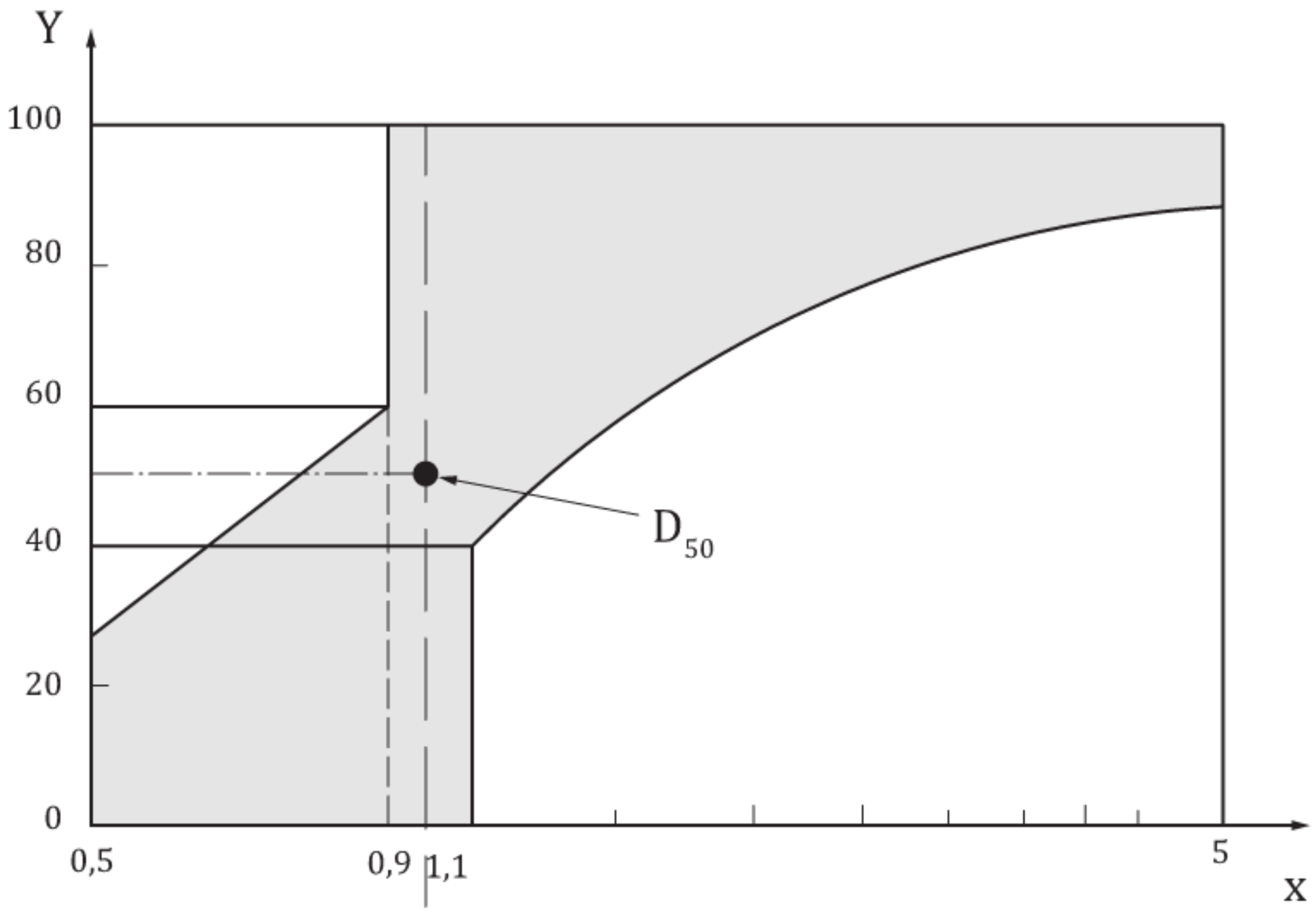

Example D_{50} = 5 nm

X	0,5	0,9	1	1,1	5
D, nm	2,5	4,5	5	5,5	25

Example D_{50} = 10 nm

X	0,5	0,9	1	1,1	5
D, nm	5	9	10	11	50

Example D_{50} = 50 nm

X	0,5	0,9	1	1,1	5
D, nm	25	45	50	55	250

Key

X normalized particle diameter, D/ D_{50}

Y counting efficiency, %

Figure B.1 — Acceptability envelope for the counting efficiency of selected apparatus

Particle size cut off (D_{50}) is instrument-specific.

B.2 Particle size cutoff device

Particle size cutoff devices remove particles smaller than a defined size, reducing penetration in a well-defined and reproducible manner. A wide variety of sizes and configurations of particle size cutoff devices are available and acceptable, provided that they produce the required penetration characteristics. Diffusion battery elements and virtual impactors can be used as suitable particle size cutoff devices.

Penetration is a function of particle physical properties, device configuration and volumetric flow rate. Care is required with all particle size cutoff devices to ensure that they are used only at the flow rates

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for which they were designed and that they are installed so as to avoid accumulation of electrostatic charge. Charge accumulation can be minimized by ensuring that the particle size cutoff device is suitably electrically grounded. A particle size cutoff device, is typically used at the inlet of the nanoscale particle counting device.

Examples of a particle size cutoff device include a diffusion battery element, and a virtual impactor.

The specifications for the particle size cutoff device are given in Table B.1.

Table B.1 — Specifications for particle size cutoff device

Item	Specification
Uncertainty of measurement	(50 ± 10) % removals of particles at defined size
Calibration interval	Varies with device type; typically 12 months
Sample flow rate	Flow rate through the particle size cutoff device should be constant, ±10 %, with flow rate greater than or equal to that required by counting device

B.3 Nanoscale particle size distribution

A DEMC and CPC can be used in conjunction to create a DMAS (Differential Mobility Analyzing System) for nanoscale particle size distribution measurement. The DEMC classifies charged aerosol particles into different size bins, letting only one narrow size range through at a time. Particles sized by the DEMC are subsequently counted by a CPC. For cleanroom applications, due to the scanning nature of the instrument and the limited efficiency of imparting charge onto the particles, there needs to be a constant source of particles and sufficient sampling time to make a valid and meaningful nanoscale particle size distribution measurement using a DMAS. A DMAS is not intended for use in monitoring the cleanliness of a cleanroom. However, it can provide a nanoscale particle size distribution for diagnostic applications if the particle concentration is sufficiently high and constant, and the sampling time is sufficiently long.

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