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**Renhetsteknik – Renrum och tillhörande renhetskontrollerade miljöer –
Del 12: Renhetsteknik – Renrum och tillhörande renhetskontrollerade miljöer – Specifikationer för övervakning av nanopartiklar (ISO 14644-12:2018, IDT)**

**Cleanrooms and associated controlled environments –
Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration (ISO 14644-12:2018, IDT)**

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Den internationella standarden ISO 14644-12:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av ISO 14644-12:2018.

The International Standard ISO 14644-12:2018 has the status of a Swedish Standard. This document contains the official English version of ISO 14644-12:2018.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Renhetsteknik, SIS/TK 108.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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.

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.)

Cleanrooms and associated controlled environments —

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

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.

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]

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 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.

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 × $10^8/m^3$
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).