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Interested committees:

Title: Draft BS ISO 14644-12 Cleanrooms and associated controlled environments —

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

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Introduction

This draft standard is based on international discussions in which the UK has taken an active part. Your comments on this draft are invited and will assist in the preparation of the consequent standard. Comments submitted will be reviewed by the relevant BSI committee before sending the consensus UK vote and comments to the international secretariat, which will then decide appropriate action on the draft and the comments received.

If the international standard is approved, it is possible the text will be published as an identical British Standard.

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Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

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- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**
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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	(7)
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/ Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

DRAFT INTERNATIONAL STANDARD

ISO/DIS 14644-12

ISO/TC 209

Secretariat: ANSI

Voting begins on:
2016-10-27

Voting terminates on:
2017-01-18

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

ICS: 13.040.35

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 209 Cleanrooms and controlled environments.

ISO 14644 consists of the following parts, under the general title Cleanrooms and associated controlled environments:

- Part 1: Classification of air cleanliness by particle concentration
- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
- Part 3: Test methods
- Part 4: Design, construction and start-up
- Part 5: Operations
- Part 7: Separative devices (clean air hoods, gloveboxes, isolators, and mini-environments)
- Part 8: Classification of airborne molecular contamination
- Part 9: Classification of surface cleanliness by particle concentration
- Part 10: Classification of surface cleanliness by chemical concentration
- Part 12: Specifications for monitoring of air cleanliness by nanoscale particle concentration

Attention is also drawn to ISO 14698, Cleanrooms and associated controlled environments — Biocontamination control:

- Part 1: General principles and methods
- Part 2: Evaluation and interpretation of biocontamination data

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.

ISO Technical Committee 209 Cleanrooms and associated controlled environments has issued standards: ISO 14644-1 and ISO 14644-3 as listed in the Foreword. The normative requirements in these standards 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 course of current Revisions, sections on ultrafine particles have been removed from ISO 14644 Parts 1 and 3 and incorporated, in modified form, in the present document ISO 14644-12. Supporting information is has also been drawn from documents developed elsewhere, e.g. by ISO Technical Committee 229 Nanotechnologies.

Nanotechnology is a recently organized field, typically dealing 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 or ultrafine particles differ from sub-micron and macro-particles in origin, chemical properties and transport behavior. 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 just like sub-micron particles dominated by air flow. However, diffusion of nanoparticles and mobility in electrical fields increases rapidly with decreasing size. As a consequence, nanoparticles have a 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 could be simply extrapolated to smaller particles than the stated lower limit.

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 will have 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 will lead to data that do not correlate to the realistic conditions.

See Bibliography references [1-8](#) for background information on particle size characteristics/properties.