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Cleanrooms and associated controlled environments

Part 21: Airborne particle sampling techniques

bsi.

National foreword

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Partie 21: Techniques de prélèvement des particules en suspension dans l'air

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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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 document 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 ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

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.

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Introduction

This document provides clarification on the application of sound airborne particle sampling techniques in support of ISO 14644-1:2015 for classification of cleanrooms and clean zones, and ISO 14644-2:2015 for airborne particle monitoring, to provide evidence of cleanroom performance related to air cleanliness by particle concentration. It provides information on how to gather appropriate, accurate and repeatable data, and how to interpret this information for the purpose of improving process protection. This also includes information on the choice of measurement methods and apparatus configuration, calibration, repeatability/reproducibility and the uncertainty associated with measurement. In short, what can be reasonably attained with the current technology.

This document addresses potential misinterpretation of the use of ISO 14644-1:2015, C.4.1.2 in informative Annex C, which suggests the use of limited tubing length for sampling macroparticles. The phrase in question has been applied beyond the context intended in ISO 14644-1, to other applications. This document also provides extra clarity on the use of the M Descriptor in ISO 14644-1:2015,Annex C, specifically in relation to consideration of ≥5,0 µm alongside ISO Class 5 (EU-PIC/S GMP Grade A and B at rest).

It provides information on the uncertainty associated with sampling particles ≥5,0 µm and macro-particles, and measures that can be taken to reduce that uncertainty.

It addresses the importance of understanding that:

— for classification, the quality of the sample is the most important factor;

— for monitoring, the quality of the data is the most important factor;

— direct sampling without tubing is preferred. However, sample tubing is sometimes necessary to get a representative sample at a significant or critical location;

— to reduce sampling loss in tubing, this tubing is as short and straight as possible;

— a sampling system is evaluated to assess the impact of any compromises in its set up.

An evaluation of existing sampling systems can deem them suitable for continued use even if the system is assessed as less than optimal.

The scientific basis for airborne particle counting, and the performance characteristics of airborne particle counters, particularly LSAPC, is amply documented in established technical publications (see Bibliography).

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TECHNICAL REPORT **ISO/TR 14644-21:2023**

Cleanrooms and associated controlled environments —

Part 21:
Airborne particle sampling techniques

1 Scope

This document discusses the physical limitations of probe and particle counter placement, and any tubing that connects the two, particularly in providing representative samples where particles 5 micrometres and greater are of interest.

The document further identifies the key factors of sampling performance when classifying and monitoring, and good practice to determine and maintain an acceptable compromise between attainable accuracy in counting and feasibility of counting in real-life situations.

This document includes a decision tree, used to identify key considerations when sampling airborne particles, and whether the system requires further assessment. There are also examples provided to illustrate typical application challenges and show how the decision tree can be used.

It is assumed that this document is read in conjunction with ISO 14644-1 and ISO 14644-2. This document is not a manual, but an explanatory document. It does not describe measurement methods, which is handled in ISO 14644-1 and ISO 14644-2, but provides information to help make effective choices of sampling configuration, when evaluating a new or existing system.

2 Normative documents

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 terminology 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
classification
method of assessing level of cleanliness against a specification for a cleanroom or clean zone

Note 1 to entry: Levels should be expressed in terms of an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air.

[SOURCE: ISO 14644-1:2015, 3.1.4]

3.2
monitoring
observations made by measurement in accordance with a defined method and plan to provide evidence of the performance of an installation

Note 1 to entry: Monitoring may be continuous, sequential or periodic; and if periodic, the frequency shall be specified.

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