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Cleanrooms and associated controlled environments —

Part 21: Airborne particle sampling techniques

Salles propres et environnements maîtrisés apparentés —

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

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Contents

Foreword

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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.

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).