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**Cleanrooms and associated controlled environments —**

Part 2:

**Monitoring to provide evidence of  
cleanroom performance related to air  
cleanliness by particle concentration**

*Salles propres et environnements maîtrisés apparentés —*

*Partie 2: Surveillance du maintien des performances de la salle propre  
pour la propreté particulaire de l'air*



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## Introduction

This revision of ISO 14644-2 emphasizes the need to consider a monitoring strategy in addition to the initial or periodic execution of the classification of a cleanroom or clean zone in accordance with ISO 14644-1:2015, 5.1. The monitoring activity provides a continuing flow of data over time, thereby providing a more detailed view of the performance of the installation.

Potential benefits gained from monitoring are

- faster response to adverse events and conditions,
- ability to develop trends from data over time,
- integration of data from multiple instruments,
- enhanced knowledge of installation and process, which allows for more effective risk assessment, and
- improved control of operational costs and product losses.

ISO 14644-2 specifies the requirements of a monitoring plan, based on risk assessment of the intended use. The data obtained provide evidence of cleanroom or clean zone performance related to air cleanliness by particle concentration.

In some circumstances, relevant regulatory agencies may impose supplementary policies, requirements or restrictions. In such situations, appropriate adaptations of the monitoring procedures may be required. After a monitoring plan is initially established and implemented, it may be necessary to revise the plan when significant changes are made to the installation or process requirements. It is also prudent to conduct periodic reviews of a monitoring plan based on data obtained and experience in use.

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