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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**

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*Salles propres et environnements maîtrisés apparentés —*

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

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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](http://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](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 \(standards.iteh.ai\)](http://Foreword - Supplementary information (standards.iteh.ai))

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

This second edition cancels and replaces the first edition (ISO 14644-2:2000), which has been technically revised throughout.

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 air cleanliness by chemical concentration (ACC)*
- *Part 9: Classification of surface cleanliness by particle concentration*
- *Part 10: Classification of surface cleanliness by chemical concentration*

Attention is also drawn to ISO 14698, *Cleanrooms and associated controlled environments — Bio-contamination control*:

- *Part 1: General principles and methods*
- *Part 2: Evaluation and interpretation of bio-contamination data*

## 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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# Cleanrooms and associated controlled environments —

## Part 2:

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

### 1 Scope

This part of ISO 14644 specifies minimum requirements for a monitoring plan for cleanroom or clean zone performance related to air cleanliness by particle concentration, based upon parameters that measure or affect airborne particle concentration.

This part of ISO 14644 does not address condition monitoring of aspects such as vibration or general maintenance of the engineering systems. It does not provide for monitoring of particle populations that are outside the specified lower threshold particle-size range, 0,1 µm to 5 µm. Concentrations of ultrafine particles (particles smaller than 0,1µm) will be addressed in a separate standard.

### 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration* <https://standards.iso.org/standards-store/catalog/iso-14644-1-2015>

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-1 and the following apply:

#### 3.1

##### test

procedure undertaken in accordance with a defined method to determine the performance of an installation or an element thereof

#### 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.

Note 2 to entry: This information may be used to detect trends in operational state and to provide process support.

#### 3.3

##### action level

level of a parameter set by the user which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

### 3.4 alert level

level of a parameter set by the user giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention or corrective action

## 4 Creating, implementing and maintaining a monitoring plan

### 4.1 Principle

In order to gain assurance that a cleanroom or clean zone is performing adequately by delivering the required control of air cleanliness by particle concentration, a monitoring plan shall be created, implemented and maintained.

A monitoring plan shall take into account the level of air cleanliness required, critical locations and performance attributes of the cleanroom or clean zone that affect the performance of the installation. The following steps shall be included in the creation, implementation and maintenance of the monitoring plan:

- use appropriate risk assessment tools to understand, evaluate and document the risk of adverse contamination events;
- develop a written monitoring plan;
- review and approve the plan;
- implement the plan by performing the monitoring;
- analyse the data derived from the monitoring activity, undertake trend analysis where appropriate and report performance;
- implement and document actions or corrective actions required;
- undertake periodic review of the monitoring plan.

The concentration of airborne particles measured under a monitoring plan may be higher than the concentration observed during at-rest classification. The observed values may fluctuate considerably due to factors such as, but not limited to, the number of personnel present, the airflow rate, ventilation effectiveness, the operation of instruments or machinery, and activities in adjacent spaces.

For processes that inherently produce particles as part of the process and where these particles are not a threat to the process or product, it may be appropriate to rely on periodic at-rest classification, or operational classification of simulated operations, rather than monitoring of airborne particles in operation. Other performance and cleanliness attributes may still be required to be monitored.

### 4.2 Risk assessment

Risk assessment is a systematic process of identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

A risk assessment shall be undertaken in order to

- develop a monitoring plan by determining factors that may affect the ability to maintain the agreed air cleanliness by particle concentration of the cleanroom or clean zone, and
- determine the monitoring requirements to provide evidence of performance.

For guidance on what to consider when undertaking a risk assessment, see informative [Annex A](#).



### 4.3 Monitoring plan

**4.3.1** The monitoring plan shall take into account the output from the risk assessment.

When developing the monitoring plan, the factors described in [4.3.2](#) to [4.3.13](#) shall be included as a minimum.

**4.3.2** Listing and justification of all the parameters to be monitored, including those that may affect the airborne particle concentration.

**4.3.3** Description and justification of measurement methods. For further guidance on considerations when developing a monitoring plan, see informative [Annex A](#).

**4.3.4** Accuracy, maintenance and calibration of monitoring instrumentation.

**4.3.5** Identification and justification of selected monitoring locations. Monitoring locations shall be defined in three dimensions.

**4.3.6** Identification and justification of monitoring acceptance criteria or limits, including establishment of a single alarm level, or a dual alarm approach of alert and action levels. The minimum requirement is that a single alarm action level is established. Additionally, an alarm alert level can be established to provide early warning of performance deviation. For further guidance on setting alert and action levels, see informative [Annex B](#).

**4.3.7** Specification of the response required should the data fall outside the specified limits.

**4.3.8** The need for and frequency of periodic cleanroom or clean zone air cleanliness classification by particle concentration in accordance with ISO 14644-1:2015, 5.1.

**4.3.9** The format for recording data.

**4.3.10** The methods, including statistical methods to be used for data trending or other appropriate analysis.

**4.3.11** The reporting requirements.

**4.3.12** The policy and media to be used for record retention.

**4.3.13** The frequency of review of the monitoring plan.

**NOTE** Monitoring plans are reviewed periodically; and based on the knowledge gained about the cleanroom or clean zone, the monitoring programme is revised.

### 4.4 Calibration

Instrumentation used for monitoring shall be adequate to perform the monitoring operations required, shall have a valid calibration certificate, and shall meet current accepted practices for the frequency and method of calibration.

In particular for airborne particle counters, the frequency and method of calibration should be based upon current accepted practice as specified in ISO 21501-4.

**NOTE** Some particle counters cannot be calibrated to all of the required tests in ISO 21501-4. If this is the case, record the decision to use the counter in the monitoring plan.

#### 4.5 Review and approval

The completed plan shall be reviewed and approved.

#### 4.6 Response to a deviation during monitoring

If monitoring results exceed the specified limit(s), an investigation shall be conducted to determine cause, and remedial action taken as required.

If the remedial action requires significant changes to the installation and/or its operation, then the classification test according to ISO 14644-1 shall be undertaken. The monitoring plan shall also be reviewed as a result of the changes to the installation and/or its operation.

When the desired classification has been achieved, monitoring may be resumed.

### 5 Periodic classification of air cleanliness by particle concentration

Periodic classification testing shall be undertaken annually in accordance with ISO 14644-1. This frequency can be extended based on risk assessment, the extent of the monitoring system, and data that are consistently in compliance with acceptance limits or levels defined in the monitoring plan.

NOTE ISO 14644-3 specifies ancillary tests related to other aspects of cleanroom performance such as pressure difference, airflow, etc.

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## Annex A (informative)

### Matters to consider when developing a monitoring plan

#### A.1 Risk assessment considerations

##### A.1.1 Selection of an appropriate risk assessment tool

Risk assessment can be undertaken using a number of tools – separately or in combination – including but not limited to

- HACCP,
- FMEA / FMECA,
- PHA,
- FTA, and
- HAZOP.

##### A.1.2 Definition of required performance and operating conditions that may need to be monitored

These can be factors such as <https://standards.iteh.ai/catalog/standards/sist/dea7ce4d-af4f-49fd-a164-e3eb372edd6f/iso-14644-2-2015>

- understanding the contamination sources and their impact on the activity in the cleanroom or clean zone at critical locations or at locations representative of the general air cleanliness in a cleanroom or clean zone,
- performance of the installation that might affect the cleanliness levels such as pressure differential, airflow uniformity, airflow volume, ventilation effectiveness, temperature, relative humidity,
- normal and energy-saving set-back mode,
- at-rest or operational states, and
- occupancy and level of activity, such as change of shift.

#### A.2 General considerations

**A.2.1** The general matters described in [A.2.2](#) to [A.2.21](#) should be considered when developing a monitoring plan.

**A.2.2** The measurement technique, including the selection of manual and/or automated monitoring.

**A.2.3** The resolution, accuracy and calibration requirements of the measurement system including, in the case of airborne particle counters, the efficiency and limitations of the collection system.

**A.2.4** The location of monitoring system components, including requirements for access for maintenance and calibration.