

Redline version  
compares Second edition to  
First edition



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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*



Reference number  
ISO 14644-2:redline:2015(E)

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All changes in this document have yet to reach concensus by vote and as such should only be used internally for review purposes.

**DISCLAIMER**

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.



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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.

~~International Standards are~~ 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 ~~rules given in~~ editorial rules of the ISO/IEC Directives, Part 32 (see [www.iso.org/directives](http://www.iso.org/directives)).

~~Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.~~

Attention is drawn to the possibility that some of the elements of this ~~part of ISO 14644~~ 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](#)

~~International Standard ISO 14644-2 was prepared by Technical Committee~~ 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~~

- ~~Part 2: Specifications for testing and monitoring to prove continued compliance with~~ **1: ISO 14644-1 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: Metrology and test~~ **Test methods**
- ~~Part 4: Design, construction and start-up~~
- ~~Part 5: Operations~~
- ~~Part 6: Terms and definitions~~ **7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)**
- ~~Part 7: Separative enclosures (clean airhoods, gloveboxes, isolators, mini environments)~~ **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*

~~Users should note that the titles listed for parts 3 to 7 are working titles at the time of the release of part 2. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.~~

~~Annexes A and B of this part of ISO 14644 are for information only.~~ 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*

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<https://standards.iteh.ai/catalog/standards/sist/dea7ce4d-af4f-49fd-a164-e3eb372eddfa/iso-14644-2-2015>

## Introduction

This part revision of ISO 14644-2 provides a process to prove continued compliance 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 and specifies minimum requirements for testing and monitoring. In any testing plan, consideration should also be given to the particular operational requirements, risk assessment. The monitoring activity provides a continuing flow of data over time, thereby providing a more detailed view of the performance of the installation, and its use.

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.

Cleanrooms and associated controlled environments provide for ISO 14644-2 specifies the control of airborne particulate contamination to levels appropriate for accomplishing contamination sensitive activities. Products and processes that benefit from the control of airborne contamination include aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, food and others. Many factors besides airborne particulate cleanliness should be considered in the design, specification, operation and control of cleanrooms and other controlled environments 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 standard testing 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.

# 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 ~~requirements for periodic testing of a~~ minimum requirements for a monitoring plan for cleanroom or clean zone to prove its continued compliance with performance related to ISO 14644-1 for the designated classification of airborne particulate cleanliness air cleanliness by particle concentration, based upon parameters that measure or affect airborne particle concentration.

~~These requirements invoke the test described in ISO 14644-1 for classification of a cleanroom or clean zone. Additional tests are also specified, to be carried out in accordance with the requirements of this part of ISO 14644. Optional tests, to be applied at the user's discretion, are also identified.~~

This part of ISO 14644 ~~also specifies requirements~~ does not address condition monitoring of aspects such as vibration or general maintenance of the engineering systems. It does not provide for monitoring of a cleanroom or clean zone (hereafter referred to as an installation) to provide evidence of its continued compliance with particle populations that are outside the specified lower threshold particle-size range, 0,1 µm to 5 µm. Concentrations of ISO 14644-1 for the designated classification of airborne particulate cleanliness ultrafine particles (particles smaller than 0,1 µm) will be addressed in a separate standard.

## 2 Normative references

The following ~~normative document contains provisions which, through reference in this text, constitute provisions of this part of documents, in whole or in part, are normatively referenced in this ISO 14644 document and are indispensable for its application. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below only the edition cited applies. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.~~ referenced document (including any amendments) applies.

ISO 14644-1:1999/2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*.

~~ISO 14644-3:1999/2015, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods*.~~

## 3 Terms and definitions

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

1) ~~To be published.~~

### ~~3.1 General terms~~

#### ~~3.1.1~~

##### ~~requalification~~

~~execution of the test sequence specified for the installation to demonstrate compliance with ISO 14644-1 according to the classification of the installation, including the verification of the selected pre-test conditions~~

#### ~~3.1.2~~

##### ~~test~~

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

#### ~~3.1.3~~

##### ~~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: This information may be used to detect trends in operational state and to provide process support.~~

### ~~3.2 Terms concerning frequency intervals~~

#### ~~3.2.1~~

##### ~~continuous~~

~~updating that occurs constantly~~

#### ~~3.2.2~~

##### ~~frequent~~

~~updating that occurs at specified intervals not exceeding 60 minutes during operation~~

#### ~~3.2.3~~

##### ~~6 months~~

~~updating that occurs at an average interval not exceeding 183 days throughout periods of operational use, subject to no interval exceeding 190 days~~

#### ~~3.2.4~~

##### ~~12 months~~

~~updating that occurs at an average interval not exceeding 366 days throughout periods of operational use, subject to no interval exceeding 400 days~~

#### ~~3.2.5~~

##### ~~24 months~~

~~updating that occurs at an average interval not exceeding 731 days throughout periods of operational use, subject to no interval exceeding 800 days~~

### ~~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 ~~Demonstration of continued compliance~~ 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.

~~Continued compliance with air cleanliness (ISO class) requirements specified for the installation is verified by performing specified tests and by documenting the results. Monitoring data is used as an indication of installation status and may determine the frequency with which tests are carried out.~~ 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](#).

~~4.2~~ **4.3 Testing for continued compliance** **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.

~~4.2.1~~ **4.3.6** The reference test method and the maximum time intervals between such tests to prove continued compliance with the designated ISO class are given in [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 [Table 1](#) [Annex B](#).

~~Table 1 — Schedule of testing to demonstrate compliance with particle concentration limits~~

Classification	Maximum time interval	Test method
≤ ISO Class 5	6 months	<a href="#">Annex B</a> in ISO 14644-1:1999
> ISO Class 5	12 months	<a href="#">Annex B</a> in ISO 14644-1:1999

~~NOTE Particle count tests will normally be performed in the operational state, but may also be performed in the at-rest state in accordance with the designated ISO classification.~~

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

~~4.2.2~~ **4.3.8** Where the application requires them, tests as given in [Table 2](#) shall be carried out to demonstrate compliance. The requirement for each of these tests shall be determined by agreement between the customer and supplier. 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.