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Cleanrooms and associated controlled environments —

Part 2: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1

Salles propres et environnements maîtrisés apparentés —

Partie 2: Exigences pour la surveillance et les contrôles périodiques en vue de démontrer le maintien de la conformité avec l'ISO 14644-1

[Revision of first edition (ISO 14644-2:2000)]

ICS 13.040.35

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14644-2 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

This second edition cancels and replaces in whole the first edition (1999), which has been technically revised.

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: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1:XXXX*

— *Part 3: Test methods*

— *Part 4: Design, construction and start-up*

— *Part 5: Operations*

— *Part 6: Vocabulary*

— *Part 7: Separative devices (clean air hoods, gloveboxes, isolators, and mini-environments)*

— *Part 8: Classification of airborne molecular contamination*

— *Part 9: Classification of surface cleanliness by particle concentration*

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

— *Part 1: General principles and methods*

— *Part 2: Evaluation and interpretation of biocontamination data*

Introduction

This part of ISO 14644 provides a process to prove continued compliance with ISO 14644-1:XXXX and specifies minimum requirements for testing and monitoring. In any testing plan, consideration should also be given to the particular operational requirements, risk assessment of the installation, and its use.

Cleanrooms and associated controlled environments provide for 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.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.

Cleanrooms and associated controlled environments —

Part 2:
Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1

1 Scope

This part of ISO 14644 specifies requirements for testing and monitoring of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1:XXXX for the designated classification of air cleanliness by particle concentration.

These requirements invoke the test described in ISO 14644-1:XXXX for classification of a cleanroom or clean zone.

Additional tests are also specified (see 5.2), to be carried out in accordance with the requirements of this part of ISO 14644.

This part of ISO 14644 also specifies requirements for monitoring of a cleanroom or clean zone to provide evidence of its continued compliance with ISO 14644-1:XXXX for the designated classification of airborne particulate cleanliness.

2 Normative references

The following normative documents contain provisions, which, through reference in this text, constitute provisions of this part of ISO 14644. 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.

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

ISO 14644-3:2006, *Cleanrooms and associated controlled environments — Part 3: Test methods*

3 Terms and definitions

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

3.1
test
procedure undertaken in accordance with a defined method or procedure to determine the performance of a` cleanroom or clean zone or an element thereof

3.2
monitoring
routine collection of information and data by measurement or observation of critical parameters in accordance with a defined method and plan to provide evidence of the performance or condition of an cleanroom or clean zone

NOTE 1 One example of monitoring would be the use of a fixed particle monitoring system to sample from certain selected critical locations in order to confirm compliance with or detect deviation from expected levels to achieve process control.

NOTE 2 Information derived from monitoring may be used to detect trends in operational state and to provide process support.

4 Demonstration of continued compliance

4.1 Principle

Continued compliance with air cleanliness (ISO class) requirements specified for the cleanroom or clean zone shall be demonstrated by implementing a predetermined documented “monitoring and periodic test plan.” Development of the “monitoring and periodic testing plan” requires consideration of both monitoring of parameters and the performance of specified periodic tests. Monitoring data is used as an indication of cleanroom or clean zone status and may be used to adjust the frequency with which periodic tests are carried out.

Automated systems shall be considered for monitoring of air pressure difference and concentration of airborne particles.

4.2 Monitoring and periodic testing plan

A documented “monitoring and periodic testing” plan for the cleanroom or clean zone, based on assessment of risks, shall be prepared and approved. The following shall be considered when developing the monitoring and periodic testing plan.

4.2.1 Monitoring

a) A written rationale recording the reasons and justification for the monitoring.

b) A schedule of parameters to be monitored.

c) Definitions of measurement methods, accuracy and instruments required.

d) Schedule of monitoring locations, including their location in three dimensions.

e) Frequency of sampling and measurement.

f) Requirements for storage and archiving of raw data.

g) Specification of techniques to evaluate the data, including statistical methods and preparation of reports.

h) Requirements for calibration of instruments and performance of systems.

i) Acceptance criteria, including levels and rationale for alert and action values.

j) Pre-defined action plan in event of alert-level and action-level alarms.

k) Definition of responsibility for acceptance and approval of monitoring data, alert-level alarms, action-level alarms and reports.

4.2.2 Periodic testing

a) Written rationale recording the reasons and justification for the periodic testing, including any correlation with the monitoring results.

b) Definitions of test methods, accuracy and instruments required.

c) Schedule of test locations.

d) Frequency of testing.

e) Requirements for calibration of instruments.

f) Acceptance criteria, including levels and rationale.

g) Pre-defined action plan in event of deviation from acceptance values.

h) Evidence of the competence of the tester.

i) Requirements for storage and archiving of test data.

j) Specification of techniques for evaluation of data, including preparation of test reports.

k) Definition of responsibility for acceptance and approval of test data and reports.

4.3 Records

The retention of records shall conform to quality control procedures or the requirements of applicable regulatory authorities, and be agreed upon between the customer and the supplier.

5 Testing for continued compliance

5.1 Classification of air cleanliness by particle concentration, using the test method specified in Annex A of ISO 14644-1:XXXX, shall be undertaken annually for all classes unless extended as defined in clause 5.4.

This shall be undertaken in either the “at rest” or “operational” state.

5.2 Where the application requires them, additional tests as given in Table 1 shall be carried out to demonstrate compliance. The requirement to perform each of these tests shall be determined by agreement between the customer and the supplier.

Table 1 — Schedule of additional tests for all classes

Test parameter	Frequency	Test procedure
Airflow volume [a] or airflow velocity	Annually	ISO 14644-3:2006, clause B.4.
Air pressure difference [b]	Annually	ISO 14644-3:2006, clause B.5.

[a] Airflow volume will be determined by either velocity or volume measurement techniques.

[b] This test will not apply to clean zones which are not totally enclosed.

5.3 In addition to the normative tests given in clauses 5.1 and 5.2, optional tests and their frequencies may be included by agreement between customer and supplier, as considered appropriate to the cleanroom or clean zone. Lists of optional tests that may be used can be found in ISO 14644-3. The rationale for and frequency of testing shall be defined in the monitoring and test plan.

5.4 Where the cleanroom or clean zone is provided with instrumentation for monitoring of the airborne particle concentration at an interval no greater than 60 minutes, and, where applicable, air pressure difference, the maximum time interval as stated in 5.1 may be extended, provided that the results of the monitoring remain within the specified level(s) as defined in the monitoring and testing plan.