INTERNATIONAL STANDARD

ISO 14644-2

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Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

Partie 2: Spécifications pour les essais et la surveilance en vue de démontrer le maintien de la confirmité avec l'ISO 14644-1

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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 3.

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 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

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 ISO 14644-1*

— *Part 3: Metrology and test methods*

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

— *Part 5: Operations*

— *Part 6: Terms and definitions*

— *Part 7: Separative enclosures (clean airhoods, gloveboxes, isolators, mini-environments)*

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.

Introduction

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

1 Scope

This part of ISO 14644 specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

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 for monitoring of a cleanroom or clean zone (hereafter referred to as an installation) to provide evidence of its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

2 Normative references

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

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

ISO 14644-3:—[1)], *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods*.

3 Terms and definitions

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

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

1) To be published.

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 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

4 Demonstration of continued compliance

4.1 Principle

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.

4.2 Testing for continued compliance

4.2.1 The reference test method and the maximum time intervals between such tests to prove continued compliance with the designated ISO class are given in Table 1.

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

Classification	Maximum time interval	Test method
⩽ ISO Class 5	6 months	Annex B in ISO 14644-1:1999
> ISO Class 5	12 months	Annex B 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.		

4.2.2 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.

Table 2 — Schedule of additional tests for all classes

Test parameter	Maximum time interval	Test procedure
Airflow volume [a] or airflow velocity	12 months	ISO 14644-3:—, clause B.4
Air pressure difference [b]	12 months	ISO 14644-3:—, clause B.5
NOTE These tests may normally be performed in either the operational or at-rest state in accordance with the designated ISO classification.		
[a] Airflow volume may be determined by either velocity or volume measurement techniques. [b] This test will not apply to clean zones which are not totally enclosed.		

4.2.3 In addition to the normative tests given in Tables 1 and 2, other tests may be included by agreement between customer and supplier as considered appropriate to the installation, such as those listed in annex A.

4.2.4 Where the installation is equipped with instrumentation for continuous or frequent monitoring of the airborne particle concentration, and air pressure difference, where applicable, the maximum time interval as stated in Table 1 may be extended, provided that the results of continuous or frequent monitoring remain within the specified limit(s).

4.2.5 In those installations that require additional tests, and where the installation is equipped with instrumentation for continuous or frequent monitoring of the test parameter applicable, the maximum time interval(s) as stated in Table 2 may be extended, provided that the results of continuous or frequent monitoring remain within the specified limit(s).

4.2.6 Where instruments are used for testing, they shall be calibrated in accordance with current industry practice.

4.2.7 If the test results are within the limits specified, then the installation is in a condition of continued compliance. If any of the test results exceeds the limits specified, the installation is not in compliance and appropriate remedial action shall be taken. Following remedial action, requalification shall be undertaken.

4.2.8 Requalification of the installation shall be undertaken after any of the following.

a) Completion of remedial action implemented to rectify an out-of-compliance condition.

b) A significant change from the current performance specification, such as a change in operational use. The significance of a change should be determined by agreement between the customer and the supplier.

c) Any significant interruption of air movement which affects the operation of the installation. The significance of an interruption should be determined by agreement between the customer and the supplier.

d) Special maintenance which significantly affects the operation of the installation, (e.g. change of final filters). The significance of an effect should be determined by agreement between the customer and the supplier.

4.3 Monitoring

4.3.1 Routine monitoring of airborne particle concentration and other parameters shall be performed according to a written plan.

NOTE Monitoring is normally performed with the installation in the operational state.

4.3.2 The airborne-particle monitoring plan shall be based on risk assessment (see annex B) related to the application of the installation. The plan shall include, as a minimum, predetermined sample locations, minimum volume of air per sample, duration of measurements, number of measurements per sample location as required, time interval between measurements, particle size or sizes to be counted, and count acceptance limits, as well as count alert, action and excursion limits, if appropriate.

NOTE 1 If continuous or frequent monitoring is specified in the plan for both airborne particle counting and air pressure difference monitoring, the schedule for the particle count test may be modified by extending the time interval between tests (see 4.2.4 and 4.2.5).

NOTE 2 Monitoring of other attributes (e.g. temperature and humidity) may also be undertaken in the same manner as above.

4.3.3 If monitoring results exceed specified action limits, the installation shall be considered non-compliant and appropriate remedial action shall be taken. Following remedial action, appropriate tests (see 4.2 and annex A) shall be performed to determine if the installation is in compliance. If compliance has been achieved, the monitoring may be resumed.

4.3.4 Instruments used for monitoring shall be calibrated in accordance with current industry practice.

4.4 Documentation

4.4.1 The results from requalification or testing of each installation to prove continued compliance shall be recorded and submitted as a comprehensive report, along with a statement of compliance or non-compliance with the specified tests.

The test report shall include the following:

a) name and address of the testing organization;

b) operator(s) identification and the date on which the test was performed;

c) reference to this part of ISO 14644, i.e. ISO 14644-2:2000;

d) clear identification of the physical location of the installation tested (including reference to adjacent areas if necessary) and specific designations for coordinates of all sampling locations;

e) specified designation criteria for the installation, including the ISO classification and considered particle size(s), relevant occupancy state(s), airflow volume or velocity, and air pressure difference;

f) measuring instruments used and proof of calibration;

g) test results, including particle concentration data for all sampling location coordinates;

h) date of the preceding test to prove continued compliance.

Where the maximum time intervals are extended in accordance with 4.2.4 and 4.2.5, the results of the continuous or frequent monitoring shall also form part of the documentation.

4.4.2 Documentation of the monitoring of each installation shall be as set out in the monitoring plan.

4.5 Records

Records retention shall conform to any quality control procedures in place for the installation. Records shall comply with regulatory requirements.