INTERNATIONAL STANDARD

ISO 14644-14

First edition
2016-09-15

Cleanrooms and associated controlled environments —

Part 14: Assessment of suitability for use of equipment by airborne particle concentration

Salles propres et environnements maîtrisés apparentés — Partie 14: Évaluation de l'aptitude à l'emploi des équipements par la détermination de la concentration de particules en suspension dans l'air

Reference number
ISO 14644-14:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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).

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).

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

A list of all part in the ISO 14644 series, published under the general title *Cleanrooms and associated controlled environments*, can be found on the ISO website.

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear and life sciences (pharmaceuticals, medical devices, food and healthcare).

This part of ISO 14644 links the cleanroom classification of air cleanliness by particle concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

Cleanrooms and associated controlled environments —

Part 14: Assessment of suitability for use of equipment by airborne particle concentration

1 Scope

This part of ISO 14644 specifies a methodology to assess the suitability of equipment (e.g. machinery, measuring equipment, process equipment, components and tools) for use in cleanrooms and associated controlled environments, with respect to airborne particle cleanliness as specified in ISO 14644-1. Particle sizes range from 0,1 µm to equal to or larger than 5 µm (given in ISO 14644-1).

NOTE Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptation of the assessment methodology can be required.

The following items are not covered by this part of ISO 14644:

— assessment of suitability with respect to biocontamination;

— testing for suitability of decontamination agents and techniques;

— cleanability of equipment and materials;

— requirements on design of equipment and selection of materials;

— physical properties of materials (e.g. electrostatic, thermal properties);

— optimizing performance of equipment for specific process applications;

— selection and use of statistical methods for testing;

— protocols and requirements for local safety regulations.

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
cleanliness
condition not exceeding a specified level of contamination

3.2
cleanroom
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.1]

3.3
cleanroom suitability
ability to maintain the critical control attributes or condition of any clean zone when used as intended

Note 1 to entry: For the purposes of this part of ISO 14644, the assessment is based on airborne particle concentration.

3.4
clean zone
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.2]

3.5
decontamination
reduction of unwanted matter to a defined level

[SOURCE: ISO 14644-7:2004, 3.7]

3.6
equipment
system designed for specific function(s), integrating materials, components and/or controls

EXAMPLE Testing and manufacturing equipment and machinery, equipment for transport and handling, storage units, tools, furniture, doors, ceilings, Information Technology (IT) hardware and handling robots.

3.7
test environment
space in which the test is carried out, described by a set of parameters

4 General outline of the assessment

Cleanroom suitability assessment has the following outline.

a) Before the assessment can be executed, the customer and supplier shall agree upon the particle size range(s), with reference to air cleanliness by particle concentration, designated by ISO Class *N* as given in ISO 14644-1 and item to be tested including the modes of operation(s). Each selected mode of operation shall be assessed separately.

b) A short description regarding how the equipment will be used in routine operation (with operating parameters) shall be given to promote setting the appropriate testing condition and parameters.

c) Visual inspection (see Clause 5).

d) The procedure described in Clause 6 shall be used in order to establish a link to the ISO 14644-1 classification system.

e) Execution of measurements (see 6.2).

f) The data gathered will be processed and the results linked to the ISO classification system (see 6.2.9 and 6.2.10).

g) The results obtained shall conclude the equipment's cleanroom suitability; the statement shall follow the defined designation (see Clause 8).

Additional optional tests (not linked to ISO class *N*), such as total emission of particles or operational life cycle test, are described in Annex B.

The method described in B.4 may be used to determine the average total emission of equipment and provides data that may be used to determine the particle load on a cleanroom.

5 Visual inspection

Visual inspection of the equipment shall be carried out before and after any measurement-based assessment.

The visual inspection shall ensure that all packaging has been removed and that the equipment is undamaged and that it is correctly assembled and appropriately connected to its required utilities.

Visual surface cleanliness shall be qualitatively assessed such that any subsequent quantifiable tests shall not be compromised. This part of the visual inspection can include assessment for particles, surface films or inappropriately located lubricants.

The objectives of this inspection are the following:

— identify contamination, such as particles and films originated from manufacturing, packaging, transportation or initial assembly;

— identify contamination that has withstood any prior decontamination process.

It is not intended that this inspection will provide a measurement of surface cleanliness.

Depending on the location of the contamination, the results from visual inspection shall be

— recorded and available for comparison with the post-test visual inspection of surface cleanliness, and

— used as basis to direct a repeat or improved decontamination process.

Detection efficiency of visible contamination on equipment will depend upon the following factors:

— the accessibility and orientation of the surface to be inspected;

— the materials used for equipment construction, their surface condition and treatment;

— the viewing parameters (e.g. illumination, field of view, vision magnification, viewing distance).

6 Assessment of suitability by airborne particle concentration measurements

6.1 General

The objective of Clause 6 is to describe a suitability methodology using measurement of airborne particle emissions at critical locations. By including measurement locations at, or close to, the locations of high particle concentration (HPC), the intended use of the application is reflected.

This assessment methodology enables a link to the classification system of ISO 14644-1, in one or more particle size ranges to be established.

In order to assess the cleanroom suitability of equipment, it is intended that the location(s) with HPC emitted by the equipment be identified and included in the final suitability measurement. Since the size distribution of the emitted particles is not known in advance, it is required that more than one particle size range is measured. Ideally, three widely spread particle size ranges should be selected.

Subsequently, the particle concentrations thus determined from equipment assessment are compared with the air cleanliness by particle concentration limits for ISO Class *N* as specified in ISO 14644-1.

For the equipment to be tested, it shall be ensured that cleanroom compliant design principles have been incorporated. These principles include, but are not limited to, the following:

— selection of appropriate materials and surface finishes;

— avoidance of static air zones;

— design principles for cleanability;

— considerations for maintenance.

This measurement methodology is not intended to determine overall emission rates for the equipment under test.

6.2 Assessment procedure

6.2.1 Overview

The flowchart in Figure 1 gives an overview of the necessary assessment steps.

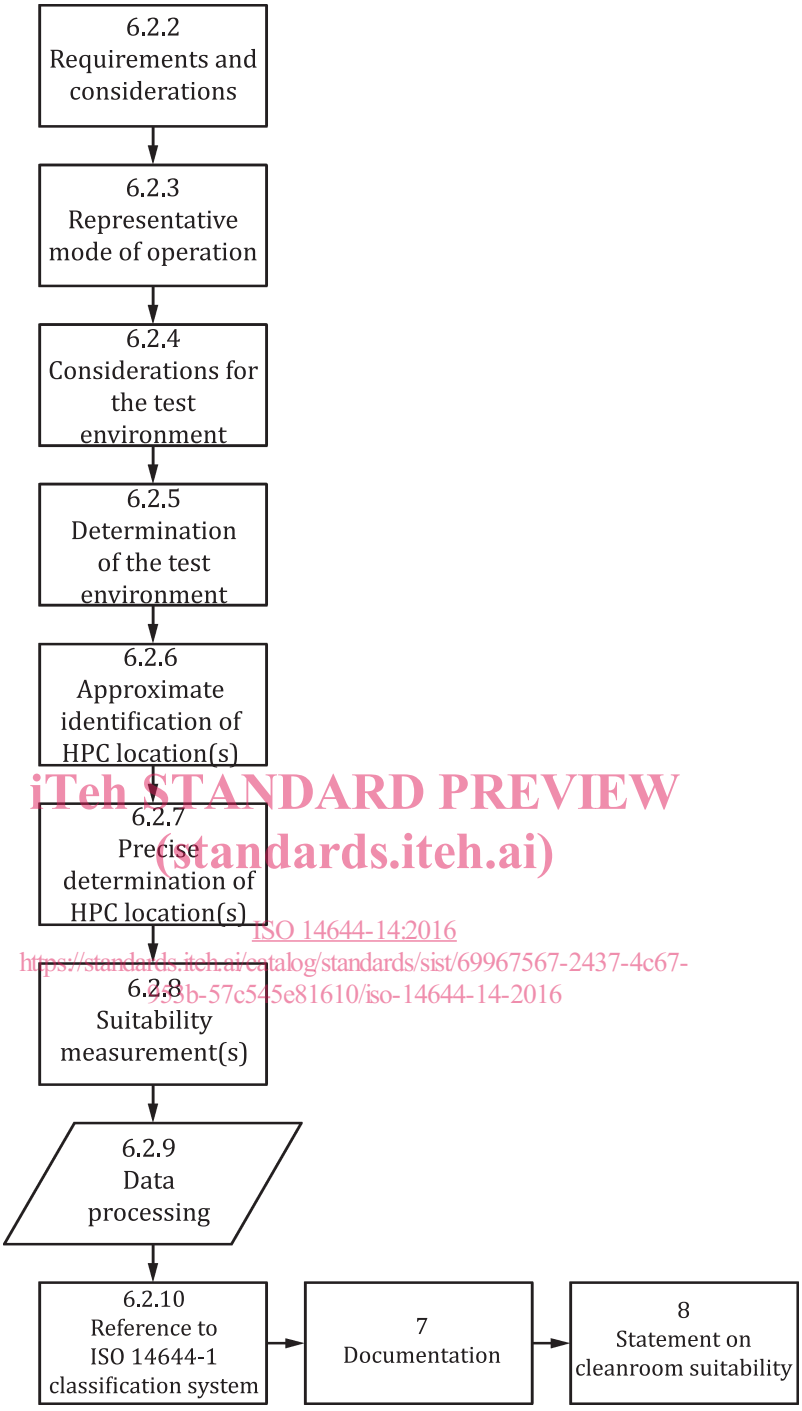

Figure 1 — Overview of the assessment procedure

6.2.2 Requirements and considerations

When defining the scope of the suitability assessment, aspects that could influence the assessment results shall be considered, for example (but not limited to):

— variability between the same type of equipment;

— pre-conditioning of the equipment to be tested (accumulated operating hours);

— running-in of equipment.