FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/FDIS
14644-18**

ISO/TC **209**

Secretariat: **ANSI**

Voting begins on:
2023-06-21

Voting terminates on:
2023-08-16

Cleanrooms and associated controlled environments —

Part 18:
Assessment of suitability of consumables

Salles propres et environnements maîtrisés apparentés —

Partie 18: Évaluation de l'aptitude à l'emploi des consommables

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/FDIS 14644-18:2023(E)

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Published in Switzerland

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Foreword

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 14644 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Cleanrooms and associated controlled environments are used for the control of contamination to levels appropriate for performing contamination-sensitive activities.

Products and processes that benefit from the control of contamination include those in industries such as aerospace, microelectronics, optics, displays, nuclear, micro-mechanical devices, consumer goods, cosmetics and life sciences (e.g. pharmaceuticals, medical devices, food). Contamination control in the healthcare sector benefits the patients by enabling access to products free of potentially harmful particles.

Consumables are widely used during preparation and operations in cleanrooms, clean zones or controlled zones to maintain the air or surface cleanliness level in the cleanroom by shielding a contamination source or a vulnerable object or by removing contamination from a surface. For monitoring and testing purposes, consumables can be used for sampling contamination. Consumables need to be carefully selected and appropriately used in order to maintain cleanliness levels and mitigate risk for processes and products.

Consumables are used for a limited time only. They do not constitute a part of the final product.

This document addresses the suitability assessment of consumables for use in cleanrooms, clean zones or controlled zones in respect to contamination in air and on surfaces by:

— particles;

— chemicals;

— microorganisms.

Customers or users need to have the opportunity to assess a given consumable by matching their intended use requirements with the designed use data of the supplier. This can be supplemented by additional tests. This match of intended use and designed use is addressed as appropriate use.

Depending on the use case, an impact assessment to determine the kind and acceptable quantity of contamination from consumables can be derived by benchmarking the requirements with respect to emission of contaminants.

This document is written for suppliers (manufacturers of consumables or distributors) and customers (as users of consumables) to assess the cleanroom suitability of consumables.

The cleanroom suitability assessment always has to be accompanied with a description of use, technical data as required by the nature of the consumable and test results. A sole statement such as “suitable for cleanroom of classification ISO 5” is not foreseen, due to the variety and complexity of use cases and the likelihood that a cleanroom suitability assessment would not rely on test data relating solely to airborne particle emissions.

Cleanrooms and associated controlled environments —

Part 18: Assessment of suitability of consumables

1 Scope

This document gives guidance for assessing personal and non-personal consumables for their appropriate use in cleanrooms, clean zones or controlled zones, based on product and process requirements, cleanliness attributes and functional performance properties. The cleanliness attributes addressed are particles or chemicals in air or on surfaces. Biocontamination (viable particles, microorganisms or pyrogens) is considered as a special property of consumables. Identification of associated risks are considered.

This document complements cleanroom operation as outlined in ISO 14644-5.

This document gives guidance concerning:

— determination of cleanroom suitability of consumables in general;

— specification of requirements for an intended use of a consumable by the customer with respect to functional performance, cleanliness attributes and special properties;

— specification of properties for a designed use of a consumable by supplier;

— assessment of a consumable for an appropriate use;

— documentation.

Informative annexes are used to list examples for personal and non-personal consumables, verification methods for cleanliness attributes testing and the potential impact of consumables on a cleanroom.

Cleaning agents, disinfectants and lubricants are considered as consumables with respect to their packaging, as their packaging is likely to have cleanliness requirements in common with all consumables.

This document does not apply to:

— design details of consumables;

— testing of functional performance of materials, e.g. barrier properties of gloves, wear and slip resistance of flooring;

— health and safety requirements; legal requirements can apply in specific countries;

— cleanability;

— (raw) materials which are added within the production process as ingredients;

— performance or function testing;

— transport containers;

— process media such as gases or liquids;

— the functional performance of cleaning agents, disinfectants and lubricants.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 14644-8:2022, *Cleanrooms and associated controlled environments — Part 8: Assessment of air cleanliness by chemical concentration (ACC)*

ISO 14644-9, *Cleanrooms and associated controlled environments — Part 9: Assessment of surface cleanliness for particle concentration*

ISO 14644-10:2022, *Cleanrooms and associated controlled environments — Part 10: Assessment of surface cleanliness for chemical contamination*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
air cleanliness by chemical concentration
ACC
quantity of chemical detected in the air, expressed in terms of an ISO-ACC level N, which represents the maximum allowable concentration of a given chemical species or a group of chemical species

Note 1 to entry: Units: g/m^3.

Note 2 to entry: This definition does not include macromolecules of biological origin, which are judged to be particles.

[SOURCE: ISO 14644-8:2022, 3.1.2, modified — Units moved to note to entry.]

3.2
appropriate use
application matching *designed use* (3.12) and *intended use* (3.13) within acceptable limits

Note 1 to entry: This use is typically stated by the customer of the *consumable* (3.9).

3.3
chemical contamination
non-particulate substances that can have a deleterious effect on the product, process or equipment

[SOURCE: ISO 14644-8:2022, 3.1.1]

3.4
cleanliness
condition not exceeding a specified level of *contamination* (3.10)

Note 1 to entry: In this document, *contamination* (3.10) refers to particles, chemicals or viables.

[SOURCE: ISO 14644-14:2016, 3.1, modified — Note to entry added.]

3.5
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 can also be specified and controlled.

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

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

3.6
cleanroom suitability
ability to maintain the critical control attributes or condition of any *clean zone* (3.7) when used as intended

[SOURCE: ISO 14644-14:2016, 3.3, modified — Note 1 to entry deleted.]

3.7
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 can also be specified and controlled.

Note 3 to entry: A clean zone can be a defined space within a *cleanroom* (3.5) or can be achieved by a separative device. Such a device can be located inside or outside a *cleanroom* (3.5).

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

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

3.8
compatibility
state of which at least two things are able to exist without adverse effect

Note 1 to entry: All types of *contamination* (3.10) emitted from the consumables under consideration that could have an impact on the quality of the product or process shall be taken into account.

3.9
consumable
item for use and disposal, if applicable, within *cleanrooms* (3.5) and controlled environments

3.10
contamination
unwanted matter in an undesirable location

[SOURCE: ISO 14644-13:2017, 3.4]

3.11
controlled zone
designated space in which the concentration of at least one contamination category (particles, chemical, biocontamination) in air and on surfaces is controlled and specified and which is constructed and used in a manner to minimize the introduction and impact of contamination

Note 1 to entry: Levels of cleanliness attributes such as chemical and viable concentrations in the air or cleanliness in terms of particle, chemical and viable concentrations on surfaces should be specified.

Note 2 to entry: Other relevant parameters may also be controlled as necessary, e.g. temperature, humidity and pressure, vibration and electrostatic.

Note 3 to entry: A controlled zone can be a defined space within a *cleanroom* (3.5) or may be achieved by a separative device. Such a device can be located inside or outside a *cleanroom* (3.5).

[SOURCE: ISO 14644-15:2017, 3.9, modified — deleted "by class(es)" in Note 1 to entry]

3.12
designed use
application as foreseen for a specified purpose and *shelf-life* (3.17)

Note 1 to entry: This is typically stated by the manufacturer or supplier of the *consumable* (3.9).

3.13
intended use
application in accordance with a specified purpose

Note 1 to entry: This is typically stated by a user, customer or third party of the *consumable* (3.9).

3.14
material
single substance or composite

Note 1 to entry: It can be necessary to provide material in a representative form to enable testing.

[SOURCE: ISO 14644-15:2017, 3.13]

3.15
personal consumable
consumable (3.9) that is worn by a person

3.16
service life
period of time or number of cycles a consumable is suitable for use

Note 1 to entry: Service life is dependent on *appropriate use* (3.2).

3.17
shelf-life
specified period of time from the date of manufacture of a product to its labelled expiration date

[SOURCE: ISO 18369-1:2017, 3.1.9.10]

3.18
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

4 Description and cleanroom suitability properties of consumables

4.1 Types of consumables

Consumables consist of 2 types:

a) Personal consumables: consumables worn by personnel, primarily to protect the product and process from contamination emitted by the wearers, see A.2. Personal consumables can also have a special function to protect the person wearing them. Fit, function and comfort are important aspects for personal consumables.

b) Non-personal consumables, see A.3.

In Annex A, examples of typical consumables are described.

4.2 Properties of consumables

4.2.1 General

Consumables are used operationally in a clean controlled environment to both maintain the cleanliness of this environment and facilitate the product realization process. However, due to their high use rate, and their proximity to the process and product, consumables can also pose a considerable risk of contamination with particles, chemicals or material of biological nature, such as microorganisms or pyrogens. Depending on the type, consumables can be either disposed of after a single use or reprocessed to the required quality for multiple use within a cleanroom.

In principle, consumables can be selected for three main properties:

a) functional performance properties;

b) cleanliness attributes;

c) special properties.

These properties and attributes can be generic or specific and apply to both types of consumables, personal or non-personal.

4.2.2 Functional performance properties

Functional properties are the starting point for consumable selection for use in a cleanroom, clean zone or controlled zone. All necessary functional performance properties for a consumable shall be considered. The following list can be used as an input for the consideration:

a) cleaning properties;

b) sorption;

c) physical properties;

d) chemical compatibility;

e) breathability, if applicable;

f) barrier protecting the cleanroom or controlled environment or process;

g) barrier protecting personnel;

h) application of liquids to surfaces;

i) surface protection;

j) abrasion resistance.

4.2.3 Cleanliness attributes

Cleanliness attributes address the contaminant of concern and how the implementation of a personal or non-personal consumable affects the overall cleanliness level when being used in a cleanroom or controlled environment. In order to be able to assess the cleanroom suitability of a consumable, it has to be specified which contaminants, such as particles, fibres, chemicals and microorganisms, are of interest. Therefore, the cleanliness attributes shall be captured at least by:

a) contaminant of concern (see Clause 5);

b) maximum concentration of contaminant(s) of concern at observed airflow conditions;

c) transfer of contamination (direct or indirect).

Biocontamination can be addressed as a special property, either as sterility or bioburden (number of contaminants and species). In addition, pyrogens can be assessed as applicable.

4.2.4 Special properties

Examples of special properties related to cleanroom suitability are:

a) antistatic or static dissipative properties;

b) supply chain management and logistics:

   1) quality management systems;

   2) batch or lot information or certification(s);

c) biocontamination sensitive processes:

   1) specific sterilization methods, packaging marking, etc.;

   2) material compatibility with sterilization processes;

   3) bioburden or sterility;

   4) pyrogens;

   5) cleaning or disinfecting consumables;

      i) particle filtration;

      ii) residue requirements;

d) appearance and texture (e.g. woven or non-woven);

e) dry or wet used;

f) recycling.

4.3 Intended use

The intended use shall be documented by the customer along with the consumable description. It shall take into consideration functional performance properties, cleanliness attributes and special properties, if applicable. A clear description of the intended use enables selection of the most suitable consumable(s)