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Cleanrooms and associated controlled environments - Part 18: Assessment of suitability of consumables (ISO/DIS 14644-18:2022)

Reinräume und zugehörige Reinraumbereiche - Teil 18: Bewertung der Reinraumtauglichkeit von Verbrauchsmaterialien (ISO/DIS 14644-18:2022)

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Cleanrooms and associated controlled environments —

Part 18:
Assessment of suitability of consumables

ICS: 13.040.35

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IMPORTANT — Please use this updated version dated 2022-08-11, and discard any previous version of this DIS because Figure 1 was missing.

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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.

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 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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, and by Technical Committee CEN/TC 243, *Cleanroom technology* in collaboration.

For biocontamination control, see EN 17141.

A list of all parts in the ISO 14644 and ISO 14698 series can be found on the ISO website.

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 (pharmaceuticals, medical devices, food). Contamination control in healthcare-related industries (pharmaceutical, medical devices …) benefit 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 may 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 assessment of suitability of consumables for being used in cleanrooms, clean zones or controlled zones in respect to contamination in air and on surfaces by:

— particles,

— chemicals or;

— microorganisms.

Customers or users need to have the possibility to assess a given consumable by matching their intended use requirements with the designed use data of the supplier. This might 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 suitability of consumables for their use in cleanrooms.

The cleanroom suitability assessment always has to be accompanied with 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 consumable 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) 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 candidate consumable by the customer with respect to functional performance, cleanliness attributes and special properties;

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

— assessment of a candidate 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 as well as the potential impact of consumables on a cleanroom.

Cleaning agents, disinfectants and lubricants are considered as cleanroom consumables with respect to their packaging, as their packaging is likely to have cleanliness requirements in common with all cleanroom 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 documents of a specific country shall be considered;

— cleanability;

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

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

ISO 14644-15, *Cleanrooms and associated controlled environments — Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration*

ISO 14644-17, *Cleanrooms and associated controlled environments — Part 17: Particle deposition rate applications*

3 Terms and definitions

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

ISO and IEC maintain terminological 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: Unit: 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: Moved unit to Note to entry]

3.2
appropriate use
application matching designed use and intended use within acceptable limits

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

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

[SOURCE: ISO 14644-8:2013, 3.1.1]

3.4
cleanliness
condition not exceeding a specified level of contamination

[SOURCE: ISO 14644-14:2016, 3.1]

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

3.6
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]

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

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

3.8
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]

3.9
compatibility
state of which at least two things are able to exist without adverse effect

Note 1 to entry: All types of contamination, being emitted from the consumables under consideration that might have an impact on the quality of the product or process shall be taken into account.

3.10
consumable
item selected for a prescribed use and disposal, if applicable, within cleanrooms and controlled environments

3.11
contamination
unwanted matter in an undesirable location

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

3.12
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 by class(es).

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 or may be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

[SOURCE: ISO 14644-15:2016, 3.9]

3.13
designed use
application as foreseen for a specified purpose and shelf-life

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

3.14
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.

3.15
limited use
application within a defined period of time

Note 1 to entry: In this document, this is applicable for intended use, designed use or appropriate use.

Note 2 to entry: In this document, the period of time has to be justified and verified by test results.

3.16
material
single substance or composite

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

[SOURCE: ISO 14644-15, 3.13]

3.17
multiple use
sequence of several times application after reprocessing to achieve agreed upon attributes

Note 1 to entry: In this document, this is applicable for intended use, designed use or appropriate use.

3.18
personal consumable
Consumable that is worn by a person

3.19
service life
length of time or number of cycles an item is suitable for use

Note 1 to entry: In this document, items are considered as consumable.

Note 2 to entry: Service life is depending on appropriate use.

3.20
single use
applied only once

Note 1 to entry: In this document, this is applicable for intended use, designed use or appropriate use.

3.21
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, modified: Cross-references to other terms deleted]

4 Description and Suitability Properties of Consumables

4.1 Types of Consumables

Consumables consist of 2 types:

a) Personal consumables: Items 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.

4.2 Properties of Consumables

4.2.1 General

Cleanroom consumables are items that 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 nearness 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 endotoxins. Depending on the type, consumables can be either disposed of after a single use or can be reprocessed to the required quality for multiple use within a cleanroom.

In principle, cleanroom consumables can be selected for three main properties (see Figure 1):

a) functional performance properties;

b) cleanliness attributes;

c) special properties.