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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

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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 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.

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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.

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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.

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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.]

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