International Standard

ISO 14644-5

Cleanrooms and associated controlled environments —

Part 5: Operations

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation

Second edition
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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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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*, in collaboration with the European Committee for Standardisation (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14644-5:2004), which has been technically revised.

The main changes are as follows:

— new normative content for development of an impact assessment, development of an Operations Control Programme and the associated programmes that support cleanroom operation, and updated information concerning the movement of goods and materials into and out of the cleanrooms;

— informative sections have been condensed so as not to duplicate information available in books and papers.

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 provide for the control of contamination to air and surface cleanliness levels appropriate for accomplishing contamination-sensitive activities.

Consistent quality depends, in part, on cleanliness. Specified cleanliness levels for all contaminants addressed in the ISO 14644 series can be attained and maintained through a deliberate programme to establish and implement adequate design and operational procedures. Regulatory agencies that have authority over processes and products produced in the cleanroom can require additional procedures and measures.

Processes and products that benefit from the control of contamination include those in industries such as aerospace, automotive, assorted consumer products, defence, microelectronics, optics, nuclear, scientific research and life sciences (pharmaceuticals, biotechnology, medical devices, food, healthcare).

This document specifies basic requirements for cleanroom operations. It is intended for those who design, construct, start up or operate a cleanroom. For guidance about consumables and equipment used in cleanrooms refer to the ISO 14644 series.

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Cleanrooms and associated controlled environments —

Part 5: Operations

1 Scope

This document specifies requirements for the establishment of an operations control programme (OCP) to ensure efficient cleanroom operation within specified cleanliness levels. The OCP includes management of personnel, entry and exit of personnel and materials, cleaning, maintenance and monitoring.

This document specifies operational requirements that relate to:

— providing a system that specifies policies and operational procedures for maintaining cleanliness levels;

— training of personnel;

— transferring, installing and maintaining stationary equipment;

— transferring material and portable equipment into and out of the cleanroom;

— maintaining a personnel management programme that includes a gowning programme;

— maintaining a cleaning programme that addresses special cleaning;

— maintaining a cleanroom maintenance programme;

— establishing an appropriate monitoring programme.

This document gives additional information in annexes for:

— personnel management;

— gowning;

— training;

— cleaning.

This document does not specifically address biocontamination control. For details on this topic, see ISO 14698-1 and ISO 14698-2.

This document does not apply to the following topics:

— aspects of health and safety management that have no direct bearing on contamination control;

— specific requirements for individual industries;

— specific requirements for equipment and materials used or associated with processes and products;

— design details of equipment;

— cleaning agent compatibility with cleanroom materials.

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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 14644-9, *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 14644-18, *Cleanrooms and associated controlled environments — Part 18: Assessment of suitability of consumables*

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
cleaning efficiency
fraction of specific contaminants removed from a surface by a cleaning process

Note 1 to entry: The fraction is determined by the accomplished surface cleanliness in respect to the initial surface cleanliness.

[SOURCE: ISO 14644-13:2017, 3.3]

3.2
cleanliness
condition not exceeding a specified level of contamination

[SOURCE: ISO 14644-15:2017, 3.5]

3.3
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]

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