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International Standard

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Cleanrooms and associated controlled environments —

Part 5: Operations

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation

ISO/TC **209**

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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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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.

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.

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.

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]

3.4
clean zone
defined space which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space below a maximum concentration of airborne particles based on its designation

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(s) can be a defined space within a cleanroom or can 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 can also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

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

3.5
consumable
item selected for a prescribed, limited use and subsequent disposal, if applicable, within cleanrooms and controlled environments

Note 1 to entry: Consumables can be garments, gloves, (see 3.11) and wipes, swabs, paper.

Note 2 to entry: Items for use and disposal, if applicable within cleanrooms and controlled environments.

[SOURCE: ISO 14644-18: 2023, 3.9]

3.6
contamination
unwanted matter in an undesirable location

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

3.7
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities

[SOURCE: ISO 14644-1:2015, 3.1.3]

3.8
operational
agreed condition where the cleanroom or clean zone is functioning in the specified manner, with equipment operating and with the specified number of personnel present

[SOURCE: ISO 14644-1:2015, 3.3.3]

3.9
particle
minute piece of matter with defined physical boundaries

[SOURCE: ISO 14644-1:2015, 3.2.1]

3.10
personnel
persons entering the cleanroom for any purpose

3.11
personal consumable
consumable (3.5) that is worn by a person

[SOURCE: ISO 14644-18:2023, 3.15]

3.12
service life
length of time or number of cycles a consumable is suitable for use

Note 1 to entry: In this document, items are considered as *consumable* (3.5).

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

[SOURCE: ISO 14644-18:2023, 3.16, modified — added Note 1 to entry.]

3.13
shutdown
action of turning off or taking out of operation

Note 1 to entry: It can be applied to equipment within the installation

3.14
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 Abbreviations

OCP Operations control programme

5 General

A cleanroom or associated controlled environment is designed to protect processes or products from contamination. The operations within the cleanroom impact air cleanliness, deposition rates and surface cleanliness. The specifications of the product and process determine the required cleanliness levels and operational requirements.

An impact assessment is intended to identify factors that can prevent the cleanroom from attaining or maintaining the required cleanliness concerning contaminants of interest (particles, macro-particles, microorganisms, chemicals and/or nanoparticles). The cleanroom shall have adequate ancillary areas, such as utilities, equipment storage and equipment preparation to support its operations. An impact assessment, as discussed in Clause 6, is the basis for the operations control programme, which is discussed in 7.2.

A cleanroom or clean zone that operates successfully within specified limits requires a systematic approach, starting with design and continuing throughout construction, commissioning, selecting equipment, and operating the process. Cleaning of surfaces, equipment, and transferred items shall be accomplished in a manner that will not impact operations. The systematic approach includes operational aspects, such as the control and limiting of emissions and the effects of potential cross-contamination, electrostatic discharge, maintenance and personnel.

Trained individuals are critical for cleanroom operation. Personnel executing operations in cleanrooms shall be managed as discussed in 7.4.

Operations shall be documented in procedures and monitored, as discussed in Clause 8.

An overview of cleanroom operational aspects is shown in Figure 1. The desired limits for air cleanliness, contamination deposition rate, and product and process specifications with the intended operations control programme are the input for the establishment of contamination control. Potentially applicable cleanroom standards that can be used to fulfil these specifications and limits are shown in Figure 1; corresponding paragraphs from Clauses 7 and 8 of this document are shown in parentheses.

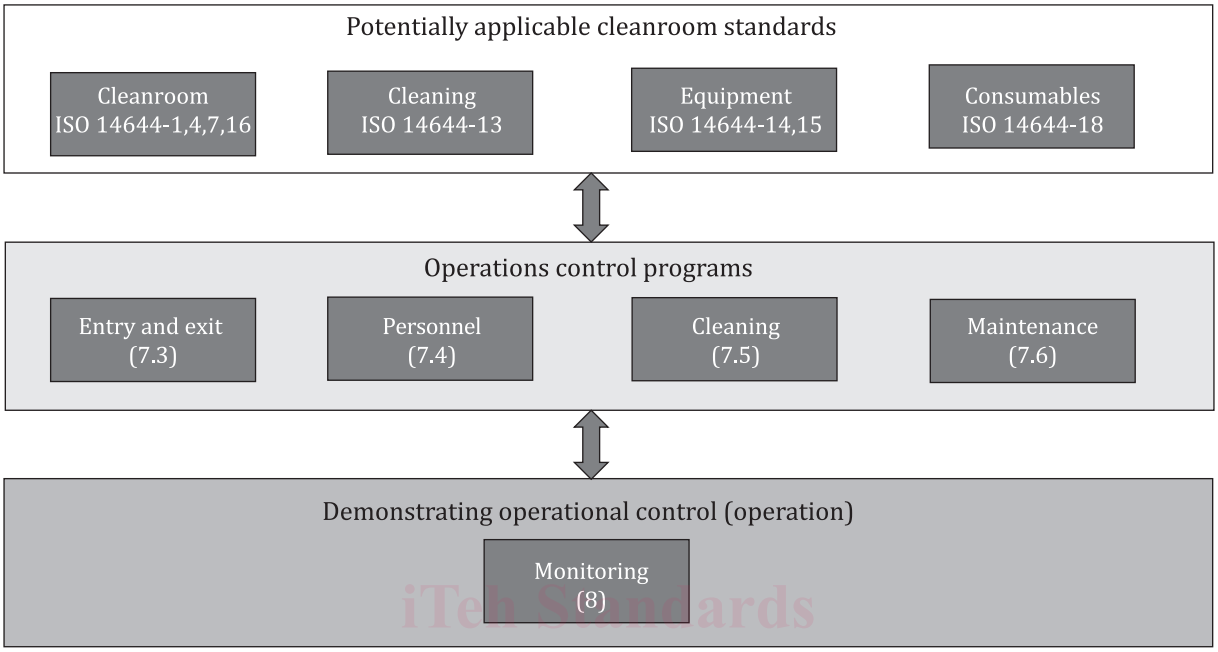

Figure 1 — Overview of operational aspects of a cleanroom

6 Impact assessment

The goal of the impact assessment is to understand factors that may affect the cleanroom from operating within specified limits. An impact assessment shall be performed for the start of the routine cleanroom operation and shall be revisited or revised as part of planning major modifications, including an exchange of stationary equipment.

The impact assessment is based on design data or as-built data for the cleanroom installation and the specified cleanroom environment with its operations. It shall include the impact on products or processes to aide in determining the operations in the environment.

The following aspects shall be assessed for their impact on achieving and maintaining specified cleanliness levels:

— operations programme, including an assessment that necessary procedures are available and adequate;

— cleaning programme execution and control of surface cleanliness;

— gowning programme;

— selection of personal and non-personal consumables (ISO 14644-18, if applicable);

— maintenance programme for the installation;

— maintenance programme for the stationary equipment including considerations for repair during operation;

— transfer of material, mobile equipment and tools in and out and within the cleanroom or clean zone;