



**International
Standard**

ISO 14644-5

**Cleanrooms and associated
controlled environments —**

**Part 5:
Operations**

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation

**Second edition
2025-05**

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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 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.

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