
Cleanrooms and associated controlled environments —

Part 4:
Design, construction and start-up

Salles propres et environnements maîtrisés apparentés —

Partie 4: Conception, construction et mise en service



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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/or 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*, 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).

This second edition cancels and replaces the first edition (ISO 14644-4:2001), which has been technically revised.

The main changes are as follows:

- normative content has been extended;
- the process of gathering and defining requirements has been added;
- the scope has been extended from classified cleanrooms to include additional cleanliness attributes;
- the entire text has been revised or clarified to aid its application.

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 airborne particulate contamination and, if relevant, other forms of contamination, to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food and research and development laboratories and some applications in healthcare.

Cleanrooms and associated controlled environments are classified for air cleanliness by particle concentration (ISO 14644-1). Cleanliness attributes relating to chemicals, nanoscale particles and viable particles (microorganisms), as well as cleanliness of surfaces, can also be considered.

This document is one of the series of International Standards concerned with cleanrooms and associated controlled environments prepared by ISO/TC 209.

This document provides guidance for the design, construction and start-up of cleanrooms, both new and those undergoing modification or refurbishment. In this edition, a more structured approach is provided with separate normative sections on requirements, design, construction and start-up, supported by four corresponding informative annexes.

For this edition, key recommendations and considerations include:

- a) A structured approach with a logical sequential flow through the design, construction and start-up stages. There will normally be reviews and iterations of the requirements, contamination control concepts, layouts and other considerations. The final design should be reviewed against the requirements before construction commences and when construction is complete. The operation and performance are verified against the requirements during start-up.
- b) Inclusion of other cleanliness attributes. The ISO 14644 series has parts that deal with other cleanliness attributes, namely chemicals, nanoscale particles, macro-particles and, in ISO 14698, viable particles (microorganisms), as well as cleanliness of surfaces. These other attributes should be considered if relevant, bearing in mind that the primary requirement for a cleanroom or clean zone is that it meets a classification by airborne particle concentration according to ISO 14644-1.
- c) Importance of a contamination risk assessment. Assessments should be carried out to better understand the contamination risk and its impact on the process and product and to identify the critical control points (locations) in the cleanroom or clean zone.
- d) A clear statement of requirements, namely everything needed for input into the design, including the purpose of the cleanroom and the acceptance criteria for performance parameters. This is critical and should be documented prior to the start of the design process.
- e) Ventilation effectiveness. This revision focuses on the importance of ventilation effectiveness through control of air-flow patterns and clean-up recovery rates. Two measures are identified: air change effectiveness (ACE) and contaminant removal effectiveness (CRE).
- f) Using air supply rate for calculations of contaminant dilution and removal. This will make it possible to achieve energy-efficient cleanrooms while achieving the required level of air cleanliness.
- g) Energy efficiency and life cycle considerations. Energy efficiency in cleanrooms is very important and is covered by ISO 14644-16.
- h) A clean build protocol. This is included to minimize contamination during construction of the cleanroom.

Information directly relevant to cleanrooms and associated controlled environments is included in the informative annexes. Supporting information is given in the Bibliography.

Cleanrooms and associated controlled environments —

Part 4: Design, construction and start-up

1 Scope

This document specifies the process for creating a cleanroom from requirements through to its design, construction and start-up. It applies to new, refurbished and modified cleanroom installations. It does not prescribe specific technological or contractual means of achieving these requirements. It is intended for use by users, specifiers, designers, purchasers, suppliers, builders and performance verifiers of cleanroom installations. The primary cleanliness consideration is airborne particle concentration. Detailed checklists are provided for the requirements, design, construction and start-up, which include important performance parameters to be considered. Energy management design approaches are identified to support an energy-efficient cleanroom design. Construction guidance is provided, including requirements for start-up and verification. A basic element of this document is consideration of aspects, including maintenance, that will help to ensure continued satisfactory operation for the entire life cycle of the cleanroom.

NOTE Further guidance is given in [Annexes A to D](#). ISO 14644-1, ISO 14644-2, ISO 14644-8, ISO 14644-9, ISO 14644-10, ISO 14644-12 and ISO 14644-17 provide complementary information. ISO 14644-7 offers guidance on design, construction and requirements for separative devices (clean air hoods, glove boxes, isolators and mini-environments).

The following subjects are mentioned but not addressed in this document:

- specific operational activities, processes to be accommodated and process equipment in the cleanroom installation;
- fire and safety regulations;
- ongoing operation, cleaning and maintenance activities, which are covered by ISO 14644-5.

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 14644-16, *Cleanrooms and associated controlled environments — Part 16: Energy efficiency in cleanrooms and separative devices*

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/>