
Cleanrooms and associated controlled environments —

Part 9:
**Classification of surface cleanliness by
particle concentration**

Salles propres et environnements maîtrisés apparentés —

*Partie 9: Classification de la propreté des surfaces par la concentration
de particules*





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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14644-9 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

- *Part 1: Classification of air cleanliness*
- *Part 2: Specifications for monitoring to prove continued compliance with ISO 14644-1*
- *Part 3: Test methods*
- *Part 4: Design, construction and start-up*
- *Part 5: Operations*
- *Part 6: Vocabulary*
- *Part 7: Separative devices (clean air hoods, gloveboxes, isolators, and mini-environments)*
- *Part 8: Classification of air cleanliness by chemical concentration*
- *Part 9: Classification of surface cleanliness by particle concentration*
- *Part 10: Classification of surface cleanliness by chemical concentration*

Attention is also drawn to ISO 14698, *Cleanrooms and associated controlled environments — Biocontamination control*:

- *Part 1: General principles and methods*
- *Part 2: Evaluation and interpretation of biocontamination data*

Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare).

ISO 14644-1 to ISO 14644-8 and ISO 14698-1 and ISO 14698-2 (biological contamination) deal exclusively with airborne particle and chemical contamination. Many factors, besides the classification of surface cleanliness, should be considered in the design, specification, operation and control of cleanrooms and other controlled environments. These factors are covered in some detail in other parts of ISO 14644 and ISO 14698.

This part of ISO 14644 provides a classification for the determination and designation of surface cleanliness levels based on particle concentrations. This part of ISO 14644 also lists some methods of testing, as well as procedure(s) for determining the concentration of particles on surfaces.

Where regulatory agencies impose supplementary guidelines or restrictions, appropriate adaptations of the testing procedures might be required.

Cleanrooms and associated controlled environments —

Part 9:

Classification of surface cleanliness by particle concentration

1 Scope

This part of ISO 14644 establishes the classification of cleanliness levels on solid surfaces by particle concentration in cleanrooms and associated controlled environment applications. Recommendations on testing and measuring methods, as well as information about surface characteristics, are given in Annexes A to D.

This part of ISO 14644 applies to all solid surfaces in cleanrooms and associated controlled environments, such as walls, ceilings, floors, working environments, tools, equipment and products. The classification of surface cleanliness by particle concentration (SCP) is limited to particles between 0,05 µm and 500 µm.

The following issues are not considered in this part of ISO 14644:

- requirements for the cleanliness and suitability of surfaces for specific processes;
- procedures for the cleaning of surfaces;
- material characteristics;
- references to interactive bonding forces or generation processes that are usually time-dependent and process-dependent;
- selection and use of statistical methods for classification and testing;
- other characteristics of particles, such as electrostatic charge, ionic charges, microbiological state, etc.

2 Normative references

The following referenced documents are indispensable for the application 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 14644-6:2007, *Cleanrooms and associated controlled environments — Part 6: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-6:2007 and the following apply.

3.1

descriptor for specific particle size ranges

differential descriptor that expresses SCP level within specific particle size ranges