

Second edition
2022-05

Cleanrooms and associated controlled environments —

Part 9: Assessment of surface cleanliness for particle concentration

Salles propres et environnements maîtrisés apparentés —

*Partie 9: Évaluation de la propreté des surfaces en fonction de la
concentration de particules*



Reference number
ISO 14644-9:2022(E)

© ISO 2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 14644-9:2022". Click here to purchase the full version from the ANSI store.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	2
5 The surface cleanliness level assessment system	3
5.1 ISO-SCP grading level format.....	3
5.2 Designation.....	6
5.3 General information on surface cleanliness levels of particle concentration.....	6
6 Demonstration of conformity	6
6.1 Principle.....	6
6.2 Testing.....	6
6.3 Test report.....	7
Annex A (informative) Surface characteristics	9
Annex B (informative) Descriptor for specific particle size ranges	12
Annex C (informative) Parameters influencing the SCP grading level assessments	15
Annex D (informative) Measurement methods for determining surface cleanliness by particle concentration	17
Bibliography	26

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 14644-9:2012), of which it constitutes a minor revision. The changes are as follows:

- "Class" (classification, classified) has been changed to grade or assessment where appropriate;
- ISO 14644-6 has been removed from the opening text of [Clause 3](#) and, as a result, [Clause 2](#);
- entry 3.8 removed from [Clause 3](#);
- ISO 4287 and ISO 4288 replaced by ISO 21920-2 and ISO 21920-3, respectively;
- ISO 16232-2, ISO 16232-3, ISO 16232-4 and ISO 16232-5 replaced by ISO 16232;
- minor editorial changes.

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.

This is a preview of "ISO 14644-9:2022". [Click here to purchase the full version from the ANSI store.](#)

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, ISO 14698-1 and ISO 14698-2 deal exclusively with airborne particle and chemical contamination. Many factors, besides the assessment 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 document provides an analytical process for the determination and designation of surface cleanliness levels based on particle concentration. This document 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.

NOTE When assessment of surface cleanliness by particle concentration (SCP) at critical control point(s) is used as an additional cleanliness attribute to classification of air cleanliness by airborne particle concentration in accordance with ISO 14644-1, then the space can be described as a cleanroom or clean-zone. If SCP is used alone, then the space is described as a controlled zone.