

---

---

**Cleanrooms and associated controlled environments —**

**Part 1:**  
Classification of air cleanliness

*Salles propres et environnements maîtrisés apparentés —*

*Partie 1: Classification de la propreté de l'air*



## Contents

	Page
Foreword .....	iii
Introduction .....	iv
1 Scope .....	1
2 Definitions .....	1
3 Classification .....	3
4 Demonstration of compliance .....	4
<b>Annexes</b>	
Annex A (informative) Graphical illustration of the classes of Table 1 .....	5
Annex B (normative) Determination of particulate cleanliness classification using a discrete-particle-counting, light-scattering instrument .....	6
Annex C (normative) Statistical treatment of particle concentration data .....	9
Annex D (informative) Worked examples of classification calculations .....	10
Annex E (informative) Considerations for the counting and sizing of particles outside the size range applicable for classification .....	13
Annex F (informative) Sequential sampling procedure .....	15
Bibliography .....	18
<b>Figures</b>	
Figure A.1 Graphical representation of ISO-class concentration limits for selected ISO classes .....	5
Figure F.1 Boundaries for pass or fail by the sequential sampling procedure .....	15
<b>Tables</b>	
Table 1 Selected airborne particulate cleanliness classes for cleanrooms and clean zones .....	3
Table C.1 Student's <i>t</i> distribution for the 95% upper confidence limit .....	9
Table F.1 Upper and lower limits for time at which <i>C</i> observed counts should arrive .....	16

© ISO 1999

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization  
Case Postale 56 • CH-1211 Genève 20 • Switzerland  
Internet iso@iso.ch

Printed in Switzerland

## 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 nongovernmental, 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.

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.

International Standard ISO 14644-1 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 testing and monitoring to prove continued compliance with ISO 14644-1*
- *Part 3: Metrology and test methods*
- *Part 4: Design, construction and start-up*
- *Part 5: Operations*
- *Part 6: Terms and definitions*
- *Part 7: Enhanced clean devices*

Users should note that the titles listed for parts 2 to 7 are working titles at the time of the release of part 1. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

Annexes B and C form an integral part of this part of ISO 14644. Annexes A, D, E, and F are for information only.

## Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate 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 healthcare.

This part of ISO 14644 assigns ISO classification levels to be used for the specification of air cleanliness in cleanrooms and associated controlled environments. It also prescribes the standard method of testing as well as the procedure for determining the concentration of airborne particles.

For classification purposes, this part of ISO 14644 is limited to a designated range of considered particle sizes for determination of particle concentration limits. This part of ISO 14644 also provides standard protocols for the determination and designation of cleanliness levels that are based on airborne concentrations of particles smaller or larger than the size range designated for classification.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides airborne particulate cleanliness must be considered in the design, specification, operation, and control of cleanrooms and other controlled environments. These are covered in some detail in other parts of the International Standards prepared by ISO/TC 209.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.