INTERNATIONAL STANDARD

ISO 14644-9

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



Con	tent	S	Page
Forev	word		iv
Intro	ductio	n	v
1	Scop	e	1
2	Norn	Normative references	
3	Terms and definitions		1
4	Abbr	eviated terms	2
5	The : 5.1 5.2 5.3	ISO-SCP grading level format	3 6
6	Dem 6.1 6.2 6.3	onstration of conformity Principle Testing Test report	6
Anne	x A (in	formative) Surface characteristics	9
Anne	x B (in	formative) Descriptor for specific particle size ranges	12
Anne	x C (in	formative) Parameters influencing the SCP grading level assessments	15
Anne		nformative) Measurement methods for determining surface cleanliness by icle concentration	17
Bibli	Bibliography		

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.