## INTERNATIONAL STANDARD

ISO 14698-1

> First edition 2003-09-01

# Cleanrooms and associated controlled environments — Biocontamination control —

### Part 1: General principles and methods

Salles propres et environnements maîtrisés apparentés — Maîtrise de la biocontamination —

Partie 1: Principes généraux et méthodes



#### Contents Page Foreword ......iv Introduction ......v Scope.......1 1 2 Normative references ....... 1 3 Terms and definitions.......1 Principles of biocontamination control ...... 4 5 Establishing the Formal System ......5 Expression, interpretation and reporting of results......10 6 7 Verification of the Formal System......11 8 Training ...... 11 Documentation ...... 11 Annex A (informative) Guidance on determining airborne biocontamination ....... 12 Annex B (informative) Guidance on validating air samplers ....... 15 Bibliography ...... 31

### Introduction

The principles described here are intended to promote appropriate hygienic practices. This part of ISO 14698 is one of a number of standards considering factors important for the creation of clean, controlled environments.

Hygiene has become increasingly important in many areas of modern society. In such areas, hygiene or biocontamination control methods are, or will be, used to create safe and stable products. International trade in hygiene-sensitive products has greatly increased. At the same time, the use of antimicrobial agents has been reduced or forbidden, creating a need for increased biocontamination control.

This part of ISO 14698 is the first general International Standard for biocontamination control. However, many factors besides cleanliness must be considered in the design, specification, operation and control of cleanrooms and associated controlled environments.

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