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

Reference number
ISO 14698-1:2003(E)

© ISO 2003

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2003

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 either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

 © ISO 2003 — All rights reserved

Contents

Page

Foreword ... iv
Introduction ... v
1 Scope ... 1
2 Normative references ... 1
3 Terms and definitions ... 1
4 Principles of biocontamination control ... 4
5 Establishing the Formal System ... 5
6 Expression, interpretation and reporting of results ... 10
7 Verification of the Formal System ... 11
8 Training ... 11
9 Documentation ... 11
Annex A (informative) **Guidance on determining airborne biocontamination** ... 12
Annex B (informative) **Guidance on validating air samplers** ... 15
Annex C (informative) **Guidance on determining biocontamination of surfaces** ... 18
Annex D (informative) **Guidance on determining biocontamination of textiles** ... 20
Annex E (informative) **Guidance on validating laundering processes** ... 22
Annex F (informative) **Guidance on determining biocontamination of liquids** ... 26
Annex G (informative) **Guidance on training** ... 28
Bibliography ... 31

© ISO 2003 — All rights reserved

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 14698-1 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

ISO 14698 consists of the following parts, under the general title *Cleanrooms and associated controlled environments — Biocontamination control*:

— *Part 1: General principles and methods*

— *Part 2: Evaluation and interpretation of biocontamination data*

© ISO 2003 — All rights reserved

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.

© ISO 2003 — All rights reserved

Cleanrooms and associated controlled environments — Biocontamination control —

Part 1: General principles and methods

1 Scope

This part of ISO 14698 establishes the principles and basic methodology of a formal system of biocontamination control (Formal System) for assessing and controlling biocontamination when cleanroom technology is applied for that purpose. This part of ISO 14698 specifies the methods required for monitoring risk zones in a consistent way and for applying control measures appropriate to the degree of risk involved. In zones where risk is low, it can be used as a source of information.

Application-specific requirements are not given. Neither are fire and safety issues addressed; for these, see regulatory requirements and other national or local documentation.

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 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

ISO 14698-2:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 General

3.1.1
action level
level set by the user in the context of controlled environments, which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

3.1.2
alert level
level set by the user in the context of controlled environments, giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention to the process

© ISO 2003 — All rights reserved

3.1.3
bioaerosol
dispersed biological agents in a gaseous environment

3.1.4
biocontamination
contamination of materials, devices, individuals, surfaces, liquids, gases or air with viable particles

3.1.5
cleanroom
room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters e.g. temperature, humidity, and pressure, are controlled as necessary

[ISO 14644-1:1999, 2.1.1][1]

3.1.6
contact device
specially designed appliance holding an appropriate, sterile, culture medium with an accessible surface used for surface sampling

3.1.7
contact plate
contact device where the container is a rigid dish

3.1.8
control point
point in a controlled environment at which control is applied and a hazard can be prevented, eliminated or reduced to acceptable levels

3.1.9
controlled environment
defined zone in which sources of contamination are controlled by specified means

3.1.10
corrective action
action to be taken when the results of monitoring indicate that alert or action levels are exceeded

3.1.11
Formal System
system of biocontamination control with established and documented procedures

3.1.12
hazard
potential source of harm

[ISO/IEC Guide 51:1999, 3.5][2]

3.1.13
impact sampler
device designed to sample particles in the air, or other gas, through a collision with a solid surface

3.1.14
impingement sampler
device designed to sample particles in the air, or other gas, through a collision with a liquid surface and the subsequent entering into the liquid

© ISO 2003 — All rights reserved

3.1.15
qualification
process of demonstrating whether an entity — activity or process, product, organization, or any combination thereof — is capable of fulfilling specified requirements

3.1.16
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51:1999, 3.2][2]

3.1.17
risk zone
defined and delimited space where individuals, products or materials (or any combination of these) are particularly vulnerable to contamination

3.1.18
settle plate
suitable container (e.g. a Petri dish) of appropriate size, containing an appropriate, sterile, culture medium, which is left open for a defined period to collect viable particles depositing from the air

3.1.19
swab
sterile collection device, non-toxic and non-inhibitory to the growth of the microorganisms being sampled, consisting of a specific matrix of suitable size, mounted on an applicator

3.1.20
target level
defined level set by the user as a goal for routine operations, for the user's own purpose

3.1.21
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[ISO 9000:2000, 3.8.5][3]

3.1.22
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[ISO 9000:2000, 3.8.4][3]

NOTE Monitoring and auditing methods, procedures and tests, including random sampling and analysis, can be used in the verification of the Formal System.

3.1.23
viable particle
particle that consists of, or supports, one or more live microorganisms

3.1.24
viable unit
VU
one or more viable particles which are enumerated as a single unit

NOTE When viable units are enumerated as colonies on agar media, it is common usage to name them colony forming units (CFU). One CFU might consist of one or more VU.

© ISO 2003 — All rights reserved