INTERNATIONAL STANDARD

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Cleanrooms and associated controlled environments — Biocontamination control —

Part 2: Evaluation and interpretation of biocontamination data

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

Partie 2: Évaluation et interprétation des données de biocontamination

Reference number
ISO 14698-2:2003(E)

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

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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 part of ISO 14698 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14698-2 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*

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Introduction

This part of ISO 14698 presents a framework for the evaluation of biocontamination data collected following the principles and methods given in ISO 14698-1. It may also be applied to biocontamination data collected by other systems.

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Cleanrooms and associated controlled environments — Biocontamination control —

Part 2: Evaluation and interpretation of biocontamination data

1 Scope

This part of ISO 14698 gives guidance on methods for the evaluation of microbiological data and the estimation of results obtained from sampling for viable particles in risk zones for biocontamination control. It should be used, where appropriate, in conjunction with ISO 14698-1.

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 14698-1:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

3 Terms and definitions

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

3.1
action level
microbiological level set by the user in the context of controlled environments, which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

3.2
alert level
microbiological level set by the user for controlled environments, giving early warning of a potential drift from normal conditions

NOTE When alert levels are exceeded, this should result in increased attention to the process.

3.3
audit trail
chain of related documents, or entries within records, that allows related information to be traced

3.4
biocontamination
contamination of materials, devices, individuals, surfaces, liquids, gases or air with viable particles

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