SWEDISH STANDARDS INSTITUTE

SVENSK STANDARD
SS-EN ISO 14698-2

Fastställd 2003-10-03
Utgåva 1

Renhetsteknik – Kontroll av mikrobiologiska föroreningar i renrum och tillhörande renhets-kontrollerade miljöer –
Del 2: Utvärdering och tolkning av data
(ISO 14698-2:2003)

Cleanrooms and associated controlled environments – Biocontamination control –
Part 2: Evaluation and interpretation of biocontamination data (ISO 14698-2:2003)

ICS 13.040.35
Språk: engelska
Publicerad: november 2003

Europastandarden EN ISO 14698-2:2003 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14698-2:2003.

The European Standard EN ISO 14698-2:2003 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14698-2:2003.

Dokumentet består av 16 sidor.

Upplysningar om **sakinnehållet** i standarden lämnas av SIS, Swedish Standards Institute, tel 08 - 555 520 00.

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E-post: sis.sales@sis.se. *Internet*: www.sis.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14698-2

September 2003

ICS 13.040.35

English version

Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data (ISO 14698-2:2003)

Salles propres et environnements maîtrisés apparentés - Maîtrise de la biocontamination - Partie 2: Evaluation et interprétation des données de biocontamination (ISO 14698-2:2003)

Reinräume und zugehörige Reinraumbereiche - Biokontaminationskontrolle - Teil 2: Auswertung und Interpretation von Biokontaminationsdaten (ISO 14698-2:2003)

This European Standard was approved by CEN on 10 July 2003.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 14698-2:2003 E

Foreword

This document (EN ISO 14698-2:2003) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2004, and conflicting national standards shall be withdrawn at the latest by March 2004.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

NOTE FROM CMC The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of ISO 14698-2:2003 has been approved by CEN as EN ISO 14698-2:2003 without any modifications.

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.

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

3.5
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]

3.6
data stratification
regrouping of data so that important trends and deviations can be more easily seen and understood

3.7
estimate
value of an estimator obtained as a result of an estimation

[ISO 3534-1:1993, 2.51] [2]

3.8
estimation
operation of assigning, from the observations in a sample, numerical values to the parameters of a distribution chosen as the statistical model for the population from which this sample is taken

[ISO 3534-1:1993, 2.49] [2]

3.9
estimator
statistic used to estimate a population parameter

[ISO 3534-1:1993, 2.50] [2]

3.10
hazard
biological, chemical or physical element or factor that adversely affects individuals, the environment, process or product

3.11
risk
combination of the probability of the occurrence of harm and the severity of that harm

[ISO/IEC Guide 51:1999, 3.2] [8]

3.12
risk zone
defined and delimited space where individuals, products or materials (or any combination of the above) are particularly vulnerable to biocontamination

3.13
target level
defined microbiological level set by the user, for its own purpose

3.14
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]

3.15
viable particle
particle that consists of, or supports, one or more live microorganisms

3.16
viable unit
VU
one or more viable particles that are enumerated as a single unit

NOTE When VU are enumerated as colonies on agar media, it is common usage to name them colony-forming units (CFU).

4 Evaluation and interpretation of biocontamination data

4.1 General

Information on the setting of action, alert and, where appropriate, target levels, the validation of counting methods and the collection of biocontamination data are discussed in ISO 14698-1. This part of ISO 14698 discusses the evaluation and interpretation of the data collected.

Management of microbiological results from risk zones should take the following factors into account:

— types of result to be collected;

— necessary information;

— methods to process the collected results (e.g. statistical procedures, correlation analysis, artificial intelligence, etc.);

— grouping of results to focus on important trends and deviations, i.e. data stratification;

— method by which the results will be expressed (e.g. qualitatively, quantitatively, graphically, numerically) and the units of measurement that will be used;

— robustness of, and potential problems posed by, the analytical methods;

— trend analysis;

— control charting;

— estimation, interpretation and reporting of results.

It is recommended that the evaluation of results be performed in two stages: during the initial monitoring (set-up procedure) phase and during the routine monitoring phase.

4.2 Estimation and evaluation of data from the initial monitoring phase (set-up procedure — see Figure 1)

4.2.1 Significance of biocontamination

To obtain reliable estimates of biocontamination gathered according to ISO 14698-1, it is necessary to consider the following variables:

— sampling-adequate number and homogeneity of the sample material and accuracy of dilution of the samples, if appropriate;

— composition of the viable particle spectrum involved; its variability with time and the effect of stress and injury on survival and recovery;

— results originating from different sampling sites in risk zones and other controlled environments;