INTERNATIONAL STANDARD

ISO 14644-2

Second edition
2015-12-15

Cleanrooms and associated controlled environments —

Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

Salles propres et environnements maîtrisés apparentés —

Partie 2: Surveillance du maintien des performances de la salle propre pour la propreté particulaire de l'air

This document is a preview generated by EVS

Reference number
ISO 14644-2:2015(E)

© ISO 2015

This document is a preview generated by EVS

COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

 © ISO 2015 – All rights reserved

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Creating, implementing and maintaining a monitoring plan **2**
4.1 Principle 2
4.2 Risk assessment 2
4.3 Monitoring plan 3
4.4 Calibration 3
4.5 Review and approval 4
4.6 Response to a deviation during monitoring 4
5 Periodic classification of air cleanliness by particle concentration **4**
Annex A (informative) **Matters to consider when developing a monitoring plan** **5**
Annex B (informative) **Considerations for setting alert and action levels** **9**
Bibliography **14**

This document is a preview generated by EVS

© ISO 2015 – 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 209, *Cleanrooms and associated controlled environments*.

This second edition cancels and replaces the first edition (ISO 14644-2:2000), which has been technically revised throughout.

ISO 14644 consists of the following parts, under the general title *Cleanrooms and associated controlled environments*:

— *Part 1: Classification of air cleanliness by particle concentration*

— *Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*

— *Part 3: Test methods*

— *Part 4: Design, construction and start-up*

— *Part 5: Operations*

— *Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

— *Part 8: Classification of air cleanliness by chemical concentration (ACC)*

— *Part 9: Classification of surface cleanliness by particle concentration*

— *Part 10: Classification of surface cleanliness by chemical concentration*

Attention is also drawn to ISO 14698, *Cleanrooms and associated controlled environments — Bio-contamination control*:

— *Part 1: General principles and methods*

— *Part 2: Evaluation and interpretation of bio-contamination data*

This document is a preview generated by EVS

 © ISO 2015 – All rights reserved

Introduction

This revision of ISO 14644-2 emphasizes the need to consider a monitoring strategy in addition to the initial or periodic execution of the classification of a cleanroom or clean zone in accordance with ISO 14644-1:2015, 5.1. The monitoring activity provides a continuing flow of data over time, thereby providing a more detailed view of the performance of the installation.

Potential benefits gained from monitoring are

— faster response to adverse events and conditions,

— ability to develop trends from data over time,

— integration of data from multiple instruments,

— enhanced knowledge of installation and process, which allows for more effective risk assessment, and

— improved control of operational costs and product losses.

ISO 14644-2 specifies the requirements of a monitoring plan, based on risk assessment of the intended use. The data obtained provide evidence of cleanroom or clean zone performance related to air cleanliness by particle concentration.

In some circumstances, relevant regulatory agencies may impose supplementary policies, requirements or restrictions. In such situations, appropriate adaptations of the monitoring procedures may be required. After a monitoring plan is initially established and implemented, it may be necessary to revise the plan when significant changes are made to the installation or process requirements. It is also prudent to conduct periodic reviews of a monitoring plan based on data obtained and experience in use.

This document is a preview generated by EVS

© ISO 2015 – All rights reserved

This document is a preview generated by EVS

Cleanrooms and associated controlled environments —

Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

This document is a preview generated by EVS

1 Scope

This part of ISO 14644 specifies minimum requirements for a monitoring plan for cleanroom or clean zone performance related to air cleanliness by particle concentration, based upon parameters that measure or affect airborne particle concentration.

This part of ISO 14644 does not address condition monitoring of aspects such as vibration or general maintenance of the engineering systems. It does not provide for monitoring of particle populations that are outside the specified lower threshold particle-size range, 0,1 µm to 5 µm. Concentrations of ultrafine particles (particles smaller than 0,1µm) will be addressed in a separate standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-1 and the following apply:

3.1
test
procedure undertaken in accordance with a defined method to determine the performance of an installation or an element thereof

3.2
monitoring
observations made by measurement in accordance with a defined method and plan to provide evidence of the performance of an installation

Note 1 to entry: Monitoring may be continuous, sequential or periodic; and if periodic, the frequency shall be specified.

Note 2 to entry: This information may be used to detect trends in operational state and to provide process support.

3.3
action level
level of a parameter set by the user which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

© ISO 2015 – All rights reserved