BS EN ISO 14644-8:2022

BSI Standards Publication

Cleanrooms and associated controlled environments

Part 8: Assessment of air cleanliness by chemical concentration (ACC)

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 14644-8:2022. It is identical to ISO 14644-8:2022. It supersedes BS EN ISO 14644-8:2013, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/30, Cleanroom technology.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 16125 0

ICS 13.040.35

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2022.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14644-8

July 2022

ICS 13.040.35

Supersedes EN ISO 14644-8:2013

English Version

Cleanrooms and associated controlled environments - Part 8: Assessment of air cleanliness by chemical concentration

Salles propres et environnements maîtrisés apparentés - Partie 8: Évaluation de la propreté chimique de l'air (ISO 14644-8:2022)

Reinräume und zugehörige Reinraumbereiche - Teil 8: Klassifizierung der Luftreinheit anhand der Chemikalienkonzentration (ACC) (ISO 14644-8:2022)

This European Standard was approved by CEN on 4 June 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 14644-8:2022 E

Contents

Page

European foreword **3**

European foreword

This document (EN ISO 14644-8:2022) 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 January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14644-8:2013.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14644-8:2022 has been approved by CEN as EN ISO 14644-8:2022 without any modification.

INTERNATIONAL STANDARD

ISO 14644-8

Third edition
2022-06

Cleanrooms and associated controlled environments —

Part 8: Assessment of air cleanliness by chemical concentration (ACC)

Salles propres et environnements maîtrisés apparentés —
Partie 8: Évaluation de la propreté chimique de l'air

Reference number
ISO 14644-8:2022(E)

© ISO 2022

COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**
3.1 General 1
3.2 Contaminant categories 2

4 Testing and monitoring using grading levels **3**
4.1 General 3
4.2 ISO-ACC descriptor format 3

5 Demonstration of compliance with an ISO-ACC level **5**
5.1 Principle 5
5.2 Testing 5
5.3 Test report 6

Annex A (informative) **Parameters for consideration** **7**

Annex B (informative) **Typical contaminants** **11**

Annex C (informative) **Typical methods of measurement** **15**

Annex D (informative) **Consideration of specific requirements for separative devices** **19**

Bibliography **21**

© ISO 2022 – 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 243, *Cleanroom technology*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 14644-8:2013), of which it constitutes a minor revision. The changes are as follows:

— the term class (classification, classified) changed to grade or assessment where appropriate;

— 3.1.2, definition revised;

— Bibliography updated;

— minor editorial changes.

A list of all parts in the ISO 14644 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2022 – All rights reserved

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels of cleanliness appropriate for accomplishing process activities sensitive to a range of contaminants. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food, healthcare, optics, instrumentation, vacuum technology, coatings, photovoltaics, displays, LEDs, coatings, automotive and surface analysis.

In some of these industries, the product or process can be sensitive to, or can be destroyed by, chemical contamination resulting from chemicals that are present due to external, process or other generated sources.

Within this document, the presence of chemicals is expressed as air chemical contamination. Chemical contamination is a three-step event. The first step is *generation* due to external sources such as process leakage, construction material, personnel or material outgassing. The second step is *transport* as airborne chemical contamination. The third step is *sorption* on the sensitive surface, which can be quantified as a surface chemical contamination.

The generating materials and the surfaces where sorption takes place will have a large influence on the steps of generation and sorption in addition to the actual air contamination. Thus, for these two steps, not only the contaminants but also the involved bulk and surfaces need to be defined. In order to make a standard generally applicable to any type of cleanroom or associated controlled environment, air chemical cleanliness (ACC) has been chosen for the level assessment.

This document assigns ISO grading levels to be used to specify the level of ACC within a cleanroom and associated controlled environment, where the product or process is deemed to be at risk from air chemical contamination.

For level assessment purposes, this document provides guidance for a range of ACC levels and provides standard protocols for specifying such levels with regard to chemical compounds, methods of test and analysis, and time weighted factors.

Annexes A to D contain the following information:

— parameters for consideration: Annex A;

— typical contaminating chemicals and substances: Annex B;

— typical methods of measurement and analysis: Annex C;

— considerations of specific requirements for separative devices: Annex D.

This document is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides ACC need to be considered in the design, specification, operation and control of cleanrooms and other controlled environments. These features are recognized in this document and covered in some detail in other parts of the International Standards prepared by ISO/TC 209, including the ISO 14698 series. In some circumstances, relevant regulatory agencies can impose supplementary policies or restrictions. In such situations, appropriate adaptations of this document can be required.

NOTE When assessment of ACC at critical control point(s) is used as an additional cleanliness attribute to classification of air cleanliness by airborne particle concentration in accordance with ISO 14644-1, then the space can be described as a *cleanroom* or *clean-zone*. If ACC is used alone, then the space must be described as a *controlled zone*.

© ISO 2022 – All rights reserved

Cleanrooms and associated controlled environments —

Part 8: Assessment of air cleanliness by chemical concentration (ACC)

1 Scope

This document establishes typical assessment processes to determine grading levels of air chemical cleanliness (ACC) in cleanrooms and associated controlled environments, in terms of airborne concentrations of specific chemical substances (individual, group or category), and provides a protocol to include test methods, analysis and time-weighted factors for their determination. This document currently considers only concentrations of air chemical contaminants between 10^0 g/m^3 and 10^{-12} g/m^3 under cleanroom operational conditions.

This document is not relevant for application in those industries, processes or productions where the presence of airborne chemical substances is not considered a risk to the product or process.

It is not the intention of this document to describe the nature of air chemical contaminants.

This document does not give a classification of surface chemical contamination.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
chemical contamination
non-particulate substances that can have a deleterious effect on the product, process or equipment

3.1.2
air cleanliness by chemical concentration
ACC
quantity of chemical detected in the air, expressed in terms of an ISO-ACC level N, which represents the maximum allowable concentration of a given chemical species or a group of chemical species, expressed in grams per cubic metre

Note 1 to entry: This definition does not include macromolecules of biological origin, which are judged to be particles.

© ISO 2022 – All rights reserved