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Renrum og tilknyttede kontrollerede områder – Del 15: Vurdering af udstyrs og materialers egnethed ved den kemiske luft- og overfladekoncentration

Cleanrooms and associated controlled environments –
Part 15: Assessment of suitability for use of equipment and
materials by airborne chemical concentration (ISO 14644-15:2017)

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EUROPÄISCHE NORM

December 2017

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English Version

Cleanrooms and associated controlled environments - Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration (ISO 14644-15:2017)

Salles propres et environnements maîtrisés
apparentés - Partie 15: Évaluation de l'aptitude
à l'emploi des équipements et des matériaux
par la détermination de la concentration
chimique aéroportée (ISO 14644-15:2017)

Reinräume und zugehörige Reinraumbereiche - Teil
15: Bewertung der Reinraumtauglichkeit von Geräten
und Materialien anhand der chemischen Luft- und
Oberflächenkonzentration (ISO 14644-15:2017)

This European Standard was approved by CEN on 27 October 2017.

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.

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Contents

Page

European foreword	3
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European foreword

This document ([EN ISO 14644-15:2017](#)) 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of an identical text or by endorsement, at the latest by June 2018 and conflicting national standards shall be withdrawn at the latest by June 2018.

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.

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Endorsement notice

The text of [ISO 14644-15:2017](#) has been approved by CEN as [EN ISO 14644-15:2017](#) without any modification.

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First edition
2017-10-20

Cleanrooms and associated controlled environments —

Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration

Salles propres et environnements maîtrisés apparentés —

*Partie : Évaluation de l'aptitude à l'emploi des équipements
et des matériaux par la détermination de la concentration
chimique aéroportée*



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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Symbols	4
5 Test setup	5
5.1 General.....	5
5.2 Closed design.....	5
5.3 Closed design special application.....	6
5.4 Open design.....	7
6 Representative mode	7
6.1 Equipment.....	7
6.2 Material.....	7
7 Visual inspection	8
7.1 General.....	8
7.2 Equipment.....	8
7.3 Material.....	8
8 Test description	9
9 Calculation of the measured concentrations	9
10 Calculation of specific emission rate	10
10.1 Calculation of specific emission rate — Closed design.....	10
10.2 Calculation of specific emission rate — Open design.....	11
11 Assessment	11
11.1 General.....	11
11.2 Required input data.....	12
11.3 Calculation to determine the effect on a cleanroom or controlled zone.....	12
11.4 Assessment of the suitability of material(s) or equipment for an existing cleanroom or controlled zone.....	13
12 Documentation	13
12.1 General.....	13
12.2 Common documentation requirements.....	13
12.3 Test documentation.....	14
12.4 Visual inspection.....	14
12.4.1 Equipment.....	14
12.4.2 Materials.....	14
Annex A (informative) Example calculation for suitability assessment of one equipment (existing installation)	15
Annex B (informative) Example calculation for suitability assessment of wall material (existing cleanroom/clean zone installation)	17
Annex C (informative) Suitability assessment of a combination of equipment and floor material in a cleanroom to be designed	19
Bibliography	21

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).

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

A list of all parts in the [ISO 14644](#) series can be found on the ISO website.

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Introduction

Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare).

This document addresses the cleanroom classification of air cleanliness by chemical concentration to the suitability of equipment for use in cleanrooms and associated controlled environments.

Examples and suitability assessments are given in [Annexes A, B](#) and [C](#).

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Cleanrooms and associated controlled environments — Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration

1 Scope

This document provides requirements and guidelines for assessing the chemical airborne cleanliness of equipment and materials which are foreseen to be used in cleanrooms and associated controlled environments which are linked to the ISO standard for cleanliness classes by chemical concentration (see [ISO 14644-8](#)).

The following are outside the scope of this document:

- health and safety requirements;
- compatibility with cleaning agents and techniques;
- cleanability;
- biocontamination;
- specific requirements of equipment and materials for processes and products;
- design details of equipment.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 14644-8:2013](#), *Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)*