BS EN ISO 14644-8:2022

BSI Standards Publication

Cleanrooms and associated controlled environments

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

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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 It supersedes BS EN ISO 14644-8:2013, which is withdrawn.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.

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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.

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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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.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.

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Endorsement notice

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

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INTERNATIONAL STANDARD

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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

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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.

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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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.

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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*.

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