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

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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).

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 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.

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)*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

air chemical contamination

any non-particulate chemical specie(s) in the air that can, by its chemical nature, adversely affect the product, process or equipment

[SOURCE: ISO 14644-8:2013, 3.1.3, modified — “substance” has been replaced by “non-particulate chemical specie(s)”.]