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Cleanrooms and associated controlled environments —

Part 5: Operations

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation



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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Specification of requirements	3
Annex A (informative) Operational systems	7
Annex B (informative) Cleanroom clothing	13
Annex C (informative) Personnel	18
Annex D (informative) Stationary equipment	22
Annex E (informative) Materials and portable equipment	26
Annex F (informative) Cleanroom cleaning	33
Bibliography	43

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14644-5 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

- *Part 1: Classification of air cleanliness*
- *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*
- *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 airborne molecular contamination*

The following part is under preparation:

- *Part 6: Terms and definitions*

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Introduction

Industries and organizations of all kinds utilize cleanrooms. Operational procedures have a profound effect on the cleanliness levels achieved during the operation of the cleanroom and equipment. Consistent quality is cleanliness dependent. Operational cleanliness can only be attained and maintained through a deliberate programme established to specify, measure and enforce defined operational procedures. Regulatory agencies that have authority over processes and products produced in the cleanroom may require additional procedures and measures of cleanliness not covered in this general operating standard.

This part of ISO 14644 addresses normative and informative operational requirements related to:

- a) providing a system that defines policies and operational procedures;
- b) clothing used to isolate human-generated contamination from the cleanroom environment;
- c) training of personnel inside the cleanroom and monitoring their compliance to specified procedures and disciplines;
- d) transfer, installation and maintenance of stationary equipment (selection criteria is not discussed);
- e) selection and use of materials and portable equipment in the cleanroom;
- f) maintaining the cleanliness of the cleanroom through systematic cleaning and monitoring procedures.