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Cleanrooms and associated controlled environments —

Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

Salles propres et environnements maîtrisés apparentés —

Partie 7: Dispositifs séparatifs (postes à air propre, boîtes à gants, isolateurs et mini-environnements)

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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.

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 14644-7 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 4: Design, construction and start-up*

— *Part 5: Operations*

— *Part 6: Vocabulary*

— *Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

The following parts are under preparation:

— *Part 3: Test methods*

— *Part 8: Classification of airborne molecular contamination*

Introduction

In the spirit of the generic requirements of an International Standard, the term “separative devices” was developed by Technical Committee ISO/TC 209 to encompass the wide continuum of configurations from open unrestricted air overspill to wholly contained systems. Common terms-of-trade, such as clean air hoods, gloveboxes, isolators and mini-environments, have different meanings depending on the specific industry.

Difficulties experienced in the manufacture and handling of certain products or materials have driven the development of separative devices. These difficulties include product sensitivity to particles, chemicals, gases or microorganisms; operator sensitivity to the process materials or byproducts; and both product and operator sensitivity.

Separative devices provide assured protection in varying levels by utilising physical or dynamic barriers, or both, to create separation between operation and operator. Certain processes may require special atmospheres to prevent degradation or explosions. Some systems may be capable of providing 100 % recirculation of the contained atmosphere to allow inert gas operation or biodecontamination with reactive gases.

Usually people do not work directly inside the separative-device environment during production. These separative devices may be movable or fixed, and used for transport, transfer and process. The product or process, or both, are manipulated remotely with access devices either manually, with protection by barrier technology such as wall-integrated personal interface systems (e.g. gloves, gauntlets, half-suits), or mechanically with robotic handling systems.

Air cleanliness definitions and test methods covered in ISO 14644-1, 14644-2 and 14644-3 generally apply within separative devices. In applications with biological contamination requirements, ISO 14698-1 and 14698-2 will apply. However, some applications can have special requirements for monitoring because of extreme conditions that may be encountered. These unique conditions are covered in this part of ISO 14644.

Transfer devices to move material in and out of separative devices form an important portion of this part of ISO 14644. In addition, material can be moved from one fixed separative device to another in transport containers.

Design and construction of cleanrooms, including generic aspects of clean zones, are covered in ISO 14644-4. ISO 14644-4:2001, Figure A.4, illustrates aerodynamic measures or air overspill often used in industry-specific separative devices called clean air hoods and mini-environments. Mini-environments are often used in the electronics industry with transport containers, called boxes or pods, to provide very clean process conditions. The application of barrier technology used in industry-specific separative devices called isolators is shown in ISO 14644-4:2001, Figure A.5. Separative devices, often called gloveboxes, containment enclosures or isolators, are used in the medical products and nuclear industries to provide protection to the operator as well as the process. Isolators may be rigid- or soft-walled depending on the application. The Bibliography contains industry-specific references. However, from a unifying conceptual standpoint, a continuum of separation exists between the operation and the operator, ranging from totally open to totally enclosed systems depending on the application. Similarly, a continuum exists for containment.

The concept of separative devices is not limited to one specific industry, as many industries use these technologies for different requirements. In that light, this part of ISO 14644 provides a generic overview of the requirements involved.

Cleanrooms and associated controlled environments —

Part 7:
Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

1 Scope

This part of ISO 14644 specifies the minimum requirements for the design, construction, installation, test and approval of separative devices, in those respects where they differ from cleanrooms as described in ISO 14644-4 and 14644-5.

The application of this part of ISO 14644 takes into account the following limitations.

— User requirements are as agreed by customer and supplier.

— Application-specific requirements are not addressed.

— Specific processes to be accommodated in the separative-device installation are not specified.

— Fire, safety and other regulatory matters are not considered specifically; where appropriate, national and local regulations apply.

This part of ISO 14644 is not applicable to full-suits.

2 Normative references

The following referenced documents are indispensable for the application 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 10648-2:1994, *Containment enclosures — Part 2: Classification according to leak tightness and associated checking methods*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14644-2:2000, *Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

ISO 14644-3:—[1)], *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

1) To be published.

ISO 14698-1, *Cleanrooms and associated controlled environments — Part 1: Biocontamination control — General principles and methods*

ISO 14698-2, *Cleanrooms and associated controlled environments — Part 2: Biocontamination control — Evaluation and interpretation of biocontamination data*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-1, 14644-2, 14644-4 and the following apply.

3.1
access device
device for manipulation of processes, tools or products within the separative device

3.2
action level
level set by the user in the context of controlled environments, which, when exceeded, requires immediate intervention, including the investigation of cause, and corrective action

3.3
alert level
level set by the user in the context of controlled environments, giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention to the process

3.4
barrier
means employed to provide separation

3.5
breach velocity
velocity through an aperture sufficient to prevent movement of matter in the direction opposite to the flow

3.6
containment
state achieved by separative devices with high degree of separation between operator and operation

3.7
decontamination
reduction of unwanted matter to a defined level

3.8
gauntlet
one-piece glove covering the full arm-length

3.9
glove
⟨of separative devices⟩ component of an access device that maintains an effective barrier while enabling the hands of the operator to enter the enclosed volume of an separative device

3.10
glove port
attachment site for gloves, sleeves and gauntlets

3.11
glove sleeve system
multi-component access device that maintains an effective barrier while enabling replacement of the sleeve piece, connecting cuff piece and glove

3.12
half-suit
access device that maintains an effective barrier while enabling the head, trunk and arms of the operator to enter the working space of the separative device

3.13
hourly leak rate
R_h
ratio of the hourly leakage q of the containment enclosure under normal working conditions (pressure and temperature) to the volume V of the said containment enclosure

NOTE It is expressed in reciprocal hours (h^{-1}).

[ISO 10648-2:1994]

3.14
leak
⟨of separative devices⟩ defect revealed by testing under a pressure differential after corrections for atmospheric conditions

3.15
pressure integrity
capability to provide a quantifiable pressure leakage rate repeatable under test conditions

3.16
separation descriptor
$[A_a:B_b]$
numerical abbreviation summarizing the difference in cleanliness classification between two areas as ensured by a separative device under specified test conditions, where

A is the ISO class inside the device;

a is the particle size at which A is measured;

B is the ISO class outside the device;

b is the particle size at which B is measured

3.17
separative device
equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

NOTE Some industry-specific examples of separative devices are clean air hoods, containment enclosures, gloveboxes, isolators and mini-environments.

3.18
transfer device
mechanism to effect movement of material into or out of separative devices while minimizing ingress or egress of unwanted matter

4 Requirements

The following information shall be defined, agreed and documented between customer and supplier:

a) number, date of publication, and edition of this part of ISO 14644;

b) established role of other relevant parties to the project (e.g. consultants, designers, regulatory authorities, service organizations);

c) intended general purpose of equipment, planned operations and any constraint imposed by the operating requirements such as material compatibility, residues and effluents;

d) reliability and availability;

e) when appropriate, any applicable hazard analysis;

NOTE HACCP, HAZOP, FMEA, FTA methods or similar [23] have been found to be suitable;

f) required airborne particulate cleanliness class or demands for cleanliness in accordance with ISO 14644-1 and 14644-2. Where appropriate, airborne molecular contamination should be considered [18] [19];

g) specified operational states (e.g. as-built, at-rest, operational) (see ISO 14644-1) and recovery time (e.g. maintenance, cleaning, etc.);

h) where appropriate, a specified separation descriptor [25];

i) if devices depend on differential pressure, the differential pressure shall be continuously monitored and alarmed in some applications;

j) where appropriate, a specified hourly leak rate (for an example of methodology, see Annex E);

k) other operational parameters, including

1) test points,

2) alert and action levels to be measured to ensure compliance,

3) test methods;

l) contamination-control concept, including the establishment of installation, operation and performance criteria;

m) required methods of measurement, sample locations, control, monitoring and documentation;

n) mode of entry or exit of separative devices and related equipment, apparatus, supplies and personnel into the controlled environment required during

1) installation,

2) commissioning,

3) operation,

4) maintenance;

o) layout and configuration of the installation;

p) critical dimensions, mass and weight restrictions, including those related to available space;

q) process requirements that affect the installation;

r) process equipment list with utility requirements;

s) maintenance requirements of the installation;

t) responsibilities for the preparation, approval, execution, supervision, documentation, statement of criteria, basis of design, construction, testing, training, commissioning and qualification, including performance, witnessing, and reporting of tests;

u) identification and assessment of external environmental influences;

v) additional information required by the particular application and requirements in Clauses 5, 6, 7 and 8 of this part of ISO 14644;

w) compliance with local regulations.

5 Design and construction

5.1 Design shall include capability to support qualification and to comply with regulatory requirements.

5.2 Separative-device design shall provide the process, the operator or third party with protection against contamination appropriate to the operation being performed.

5.3 Consideration shall be given to separation means (see Annex A). The separation descriptor, where applicable, shall be taken into account.

The risk of concentrated leaks should be addressed.

5.4 Consideration shall be given to malfunction, procedures and ancillary systems involved with the separative-device application (see Annex B).

5.5 Consideration shall be given to access devices and transfer devices (see Annexes C and D).

5.6 Separative devices shall be ergonomically designed for easy access to all internal surfaces and work areas, and with respect to the process undertaken.

5.7 Access devices shall be of the minimum size and number consistent with operation, cleaning and maintenance. (See Clause 6.)

5.8 Consideration shall be given to differential operating pressure, including excursions.

5.9 Hourly leak rate, when applicable, shall be taken into account (see Annex A). The rigidity or flexibility of the separative device shall be taken into account if quantified leak rates are required.

5.10 External influences, such as air flow, vibration and pressure differences, shall be considered to avoid adverse effects on integrity and function.

5.11 Where appropriate, hazard analysis shall be performed [see 4 e)].

5.12 Provision for cleaning or decontamination, including possible disposal of the device or its components, shall form part of the design criteria.

5.13 Built-in test facilities and appropriate alarms shall be included.

5.14 Transfer device(s) shall be appropriate to process and routine operation.

5.15 Filtration shall be appropriate for application.

5.16 Volumetric flow rate shall be appropriate for application.

5.17 Exhaust effluents shall undergo treatment where appropriate.

5.18 Whenever possible, items requiring maintenance shall be external to the separative device.

5.19 Materials used in the construction of separative devices, including sealing materials, fans, ventilation systems, piping and associated fittings, shall be chemically and mechanically compatible with the intended processes, process materials, application and decontamination methods. Protection against corrosion and degradation during prolonged use shall be considered. Heat and fire resistant construction materials shall be considered when appropriate (see Annex B). Where appropriate, materials used shall be checked for thermal characteristics, sorption and out gassing properties. Materials selected for viewing panels shall be tested and proven to remain transparent and resistant to changes that would prevent clear visibility.

6 Access devices

6.1 Use

Access devices are used to manipulate processes, products or tools within the separative device. Manipulation is achieved by manual operation or robotic handling.

6.2 Manual operation

6.2.1 Devices for manual operation

Operator manual-manipulation devices consist of

a) gauntlets,

b) glove systems (e.g. sleeve, cuff-ring and glove),

c) half-suits and similar devices that allow extended reach,

d) remote manipulator.

Where full-suits are used, reference should be made to appropriate standards.

Where possible, consideration should be given to alternative manipulation devices that minimize the number of holes pierced through the structure of the separative device.

6.2.2 Gauntlets, glove systems, half-suits

6.2.2.1 When using gauntlets, glove systems and half-suits, these types of flexible-membrane access device systems shall be designed and constructed to allow for glove change without breaching the separative device (see Annex C). These systems are unlikely to maintain molecular containment, therefore alternative systems should be considered for applications requiring molecular containment.

6.2.2.2 Glove ports and glove cuff rings devices shall be designed for ease of change, integrity testing and security of operation.

6.2.2.3 The following selection criteria shall be considered in choosing gauntlet, glove sleeve and half-suit system materials that are vital in maintaining separation:

a) materials and tools to be handled within the separative device;

b) temperature limitations of the glove materials;

c) acceptable permeability;

d) chemical resistance or mechanical strength, or both;

e) sorption and desorption of chemicals;

f) known shelf and service lives of glove material;

g) differential pressures, including transient excursions (operating and abnormal pressures);

h) operations to be performed.

6.2.3 Remote manipulation

Remote-handling systems consist of mechanical or servo links between an operator's hands and arms to a mechanical manipulation system within separative devices designed for specific applications.

6.3 Robotic handling

Robotic handling consists of automated systems designed to manipulate materials in a separative device following a process sequence for specific applications.

7 Transfer devices

7.1 Use

Transfer devices shall not diminish the performance of separative devices. In specific applications, transfer devices become critical in maintaining integrity of the device or process. Some transfer devices are used as independent separative devices.

7.2 Selection

Selection of a transfer device shall be based on the level of separation required by the application. The hourly leak rate of the transfer device shall not be greater than the hourly leak rate of the separative device which the transfer device serves. Transfer devices shall minimize the transfer of unwanted matter. Outline diagrams and descriptions of possible types of transfer device are included in Annex D. These diagrams are only illustrative examples of possible configurations.

7.3 Fail-safe design

In the event of power failure, transfer devices that have electrical interlocking mechanisms shall prevent access via the transfer device.

8 Siting and installing

8.1 The cleanroom classification of the room housing the separative device depends on the application, the design, and the operational capability of the separative device. Reference should be made to ISO 14644-4.

8.2 The appropriateness of the following points shall be considered:

a) air classification of the room (ISO 14644-1);

b) operational ergonomics;

c) maintenance;

d) toxicity of materials;

e) all process hazards;

f) byproduct hazards;

g) potential cross-contamination;

h) disposal matters;

i) any mandatory regulatory requirements.

9 Testing and approval

9.1 General

9.1.1 Selection of test procedures depends upon location, design, configuration and application of the separative device.

9.1.2 If air supply and exhaust systems are an integral part of the separative device, these systems shall also be tested.

9.1.3 In some situations, the air cleanliness in the separative device is not measurable by ISO 14644-1. Therefore alternative test procedures are required.

EXAMPLE 1 Testing of molecular contamination [18] [19].

EXAMPLE 2 Testing by particle surface contamination [30].

9.1.4 Certain conditions or operational states (e.g. dusty materials, out-gassing materials, or both types of materials) may not permit particulate sampling during operations or would present a hazard. Alternative states (e.g. before and after operations, but still in the operational state) may need to be sampled to determine the possibility of intrinsic contamination.

9.1.5 In the case of small-volume separative devices, a risk exists that pressure integrity and particle/aero-biocontamination counts are affected by the sample airflow rate of the air sampling instrument, if the sample airflow rate of the instrument is similar to the airflow rate of the separative device.

9.1.6 Appropriate test parameters shall be agreed between customer and supplier.

9.1.7 Separative device and auxiliary equipment testing and approval shall generally be performed with reference to ISO 14644-1, 14644-2, 14644-3, and 14644-4. Guidance is given in the annexes in this part of ISO 14644.

9.2 Glove breach test

When appropriate, the airflow through one open glove port shall be measured by placing an anemometer at the centre of the glove port. The velocity shall be agreed between customer and supplier (guidance value: 0,5 m/s).

9.3 Operating differential pressure

9.3.1 The differential pressure shall be tested in the at-rest and operational states.

9.3.2 When devices depend on differential pressure, the differential pressure should be continuously monitored and alarmed.

9.4 Leak testing

9.4.1 When appropriate, a leak test shall be performed. Guidance is given in Annexes E and F.

NOTE Integrity testing on some separative devices that operate close to atmosphere pressure (less than 1 000 Pa) requires detailed procedures and sensitive test equipment to establish a quantifiable leak rate. The resulting leak determines acceptability for the intended application (see Annex A).

9.4.2 When appropriate, an induction leak test shall be performed. Guidance is given in Annex E.

NOTE Induction leaks can occur when the velocity across an orifice creates a pressure depression and induces a reverse flow through the orifice (Venturi effect). Devices that operate at low differential pressures may be compromised by induction leakage. Similarly, devices that utilise over pressure or flow to minimise or prevent the transfer of unwanted matter may be at risk from induction leakage when operating under transient volume changes such as glove entry or withdrawal.