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Cleanrooms and associated controlled environments —

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

Salles propres et environnements maîtrisés apparentés —

Partie 7: Enceintes séparatives (postes à air propre, boîtes à gants, isolateurs, mini-environnements)

ICS 13.040.30

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with subclause 5.1 of the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

Contents

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 3.

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 fo the elements of this part of ISO 14644 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard 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 3: Metrology and test methods*
- *Part 4: Design, construction and start up*
- *Part 5: Operations*
- *Part 6: Terms and definitions*
- *Part 7: Separative enclosures (clean air hoods, glove boxes, isolators and minienvironments)*

Users should note that the titles listed for parts 3 to 6 are working titles at the time of the release of part 7. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

Annexes A to G of this part of ISO 14644 are for information only.

Introduction

In the spirit of the generic requirements of an ISO standard, the term “separative enclosures” was developed by Technical Committee ISO/TC 209 to encompass the wide continuum of configurations from open unrestricted air over spill to wholly contained systems. Common terms-of-trade such as minienvironments and isolators have different meanings depending on the specific industry.

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

Separative enclosures provide assured protection in varying levels by utilizing 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 of these systems may be capable of providing 100 % air or gas recirculation to allow inert gas operation or bio-decontamination with reactive gases.

Usually people do not work directly inside the separative enclosure environment during production. These separative enclosures 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 metrology covered in ISO 14644-1, 14644-2 and 14644-3 generally apply within separative enclosures. In applications with biological contamination requirements, ISO 14698-1 and 14698-2 will apply. However, some applications may have special requirements for monitoring because of extreme conditions which may be encountered. These unique conditions are covered in this standard.

Transfer devices to move material in and out of separative enclosures form an important portion of this part of ISO 14644. In addition, material may be moved from one fixed separative enclosure 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, figure A.4, illustrates aerodynamic measures or air over spill often used in industry-specific separative enclosures called clean air hoods and minienvironments. Minienvironments are often used in the electronics industry with transport containers called pods to provide very clean process conditions. The application of barrier technology used in industry-specific separative enclosures called isolators is shown in ISO 14644-4, figure A.5. Isolators, often called glove boxes or containment enclosures, 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. Therefore, minienvironments are not always isolators. However, from an 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.

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

Cleanrooms and associated controlled environments —

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

1 Scope

This part of ISO 14644 specifies the minimum requirements for the design, construction, installation, testing and approval of separative enclosures in those respects where they differ from cleanrooms as described in ISO 14644-4 and 14644-5. Separative enclosures range from open to closed systems (see annex A).

Limitations:

— Application-specific requirements are not addressed.

— User requirements are as agreed by customer and supplier.

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

— Fire, safety and other regulatory matters are not considered specifically; the appropriate national and local requirements shall be respected.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14644. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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: Metrology and test methods*

ISO 14644-4:—[1)], *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

[1)] To be published.

ISO 14644-5:—[1)], *Cleanrooms and associated controlled environments — Part 5: Operations*

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

ISO 14698-2: —[1)], *Cleanrooms and associated controlled environments — Part 2: Biocontamination control, Evaluation and interpretation of biocontamination data.*

3 Terms and definitions

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

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

3.2
action level
established levels set by the user in the context of controlled environments

NOTE When action levels are exceeded, immediate follow-up is required, as well as investigation with subsequent corrective action.

3.3
alert level
established levels set by the user for controlled environments, giving early warning of a potential drift from normal conditions

NOTE When alert levels are exceeded, this should result in an investigation to ensure that the process and environment is under control.

3.4
barrier
means employed to provide separation

3.5
barrier techniques
means employed to provide an element of separation

3.6
breach velocity
air flow rate through an aperture sufficient to prevent movement of airborne particles in the opposite direction to the flow

3.7
clean air hood
an industry-specific separative enclosure

3.8
containment
state achieved by separative enclosures with high degree of separation between operator and operation

3.9
decontamination
reduction of unwanted matter to a defined degree

3.10
gauntlet
one piece, full arm-length glove

3.11
glove
component of an access device that maintains an effective barrier while enabling the hands of an operator to enter the enclosed volume of an separative enclosure

3.12
glove box
an industry-specific separative enclosure

3.13
glove port
attachment site for gloves, sleeves and gauntlets

3.14
glove sleeve system
multi-component access device that maintains an effective barrier while enabling the replacement of sleeve piece, connecting cuff piece and the glove

3.15
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 enclosure

3.16
hourly leak rate, T_f
ratio expressed in reciprocal hours between the hourly leakage F of the separative enclosure under normal working conditions (pressure and temperature) and the volume V of the said separative enclosure

3.17
isolator
an industry-specific separative enclosure

3.18
leak (of separative enclosures)
defect revealed by pressure change after corrections for atmospheric conditions

3.19
minevironment
an industry-specific separative enclosure

3.20
pressure integrity
capability to provide a quantifiable pressure leakage rate under repeatable test conditions

3.21
separation descriptor, [A_a : B_b]
numerical abbreviation summarizing the difference in cleanliness classification between two areas as ensured by an separative enclosure under defined test conditions, where:

A = ISO class inside;

a = particle size at which A is measured;

B = ISO class outside;

b = particle size at which B is measured

3.22
separative enclosure
equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

3.23
transfer device
mechanism to effect movement of material into or out of separative enclosures while minimizing ingress or egress of unwanted matter

4 Specification of requirements

The information listed in 4.1 to 4.21 shall be defined, agreed and documented between customer and supplier:

4.1 Number, revision, and date of this part of ISO 14644.

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

4.3 Intended general purpose of equipment, planned operations and any constraint imposed by the operating requirements such as material compatibility, residues and effluents.

4.4 When appropriate, any applicable hazard analysis.

NOTE Recommended methods are HACCP, HAZOP, FMEA, FTA or similar [4].

4.5 Required airborne particulate cleanliness class or demands for cleanliness in accordance with ISO 14644-1 and 14644-2.

4.6 Specified operational states (e.g. as-built, at-rest, operational) (ISO 14644-1).

4.7 Where appropriate, a specified separation descriptor (see annex F).

4.8 Where appropriate, a specified hourly leak rate (for an example methodology, see annex G).

4.9 Other operational parameters, including:

a) test points;

b) alert and action levels to be measured to ensure compliance;

c) test methods.

4.10 Contamination control concept, including the establishment of installation, operation and performance criteria.

4.11 Required methods of measurement, control, monitoring, and documentation.

4.12 Mode of entry or exit of separative enclosures and related equipment, apparatus, supplies, and personnel into the controlled environment required during:

a) installing;

b) commissioning;

c) operating;

d) maintaining.

4.13 Layout and configuration of the installation.

4.14 Critical dimensions and weight restrictions, including those related to available space.

4.15 Process requirements that affect the installation.

4.16 Process equipment list with utility requirements.

4.17 Maintenance requirements of the installation.

4.18 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.

4.19 Identification and assessment of external environmental influences.

4.20 Additional information required by the particular application and requirements in clauses 5, 6, 7 and 8 of this part of ISO 14644.

4.21 Compliance with local regulations.

5 Design and construction

5.1 Design should include qualification and regulatory requirements.

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

5.3 Consideration should be given to separation means (see annex A).

5.4 Consideration should be given to malfunction, procedures and ancillary systems involved with the separative enclosure application (see annex B).

5.5 Consideration should be given to access devices and transfer devices (see annexes C and D).

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

5.7 Access devices should be of the minimum size and number consistent with operation, cleaning and maintenance.

NOTE Refer to clause 6.

5.8 Hourly leak rate when applicable shall be specified (see ISO 10648-2). The rigidity or flexibility of the separative enclosure should be taken into account if quantified leak rates are required.

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

5.10 Where appropriate, hazard analysis should be performed (see 4.4).

5.11 Provision for cleaning or decontamination including possible disposal of the device or its components should form part of the design criteria.

5.12 Built-in test facilities and appropriate alarms should be included.

5.13 Transfer device(s) should be appropriate to process and routine operation.

5.14 Air filtration should be appropriate for application.

5.15 Air volumetric flow and exchange rate should be appropriate for application.

5.16 Exhaust effluents should undergo treatment where appropriate.

5.17 Whenever possible, items requiring maintenance should be designed and constructed external to the separative enclosure to allow safe change handling processes.

5.18 Materials used in the construction of separative enclosures, including sealing materials, fans, ventilation systems, piping and associated fittings, should be chemically and mechanically compatible with the intended processes, process materials, application and decontamination methods. Protection against corrosion and degradation during prolonged use should be considered. Heat and fire resistant construction materials should be considered when appropriate (see annex B). Where appropriate, materials used should be checked for sorption and out gassing properties.

5.19 Materials chosen for viewing panels should be capable of withstanding expected cleaning, pressures and temperatures, and exhibit chemical compatibility with the application and process. Materials selected for this purpose should 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 for manipulation of processes, products or tools within the separative enclosure. Access interface may be achieved by hand operation or robotic handling.

6.2 Hand operation

Operator hand manipulation devices may 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.

NOTES

1 Full-suits may be considered separative enclosures in their own right.

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

6.2.1 Gauntlets, glove systems, half-suits

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

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

6.2.1.3 The following selection criteria should be considered in choosing gauntlet, glove sleeve and half-suit system materials which are vital in maintaining separation:

a) materials and tools to be handled in the separative enclosure;

b) temperature limitations of the glove materials;

c) acceptable permeability;

d) chemical or mechanical strain, or both;

e) sorption and desorption of chemicals;

f) known shelf and service life of glove material;

g) separative enclosure pressures (operating and excursion pressures);

h) operations to be performed.

6.2.2 Remote manipulation

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

6.3 Robotic handling

Robotic handling may consist of automated systems designed to manipulate materials in separative enclosure following a process sequence for specific applications.

7 Transfer Devices

7.1 Use

Transfer devices enhance the performance of separative enclosures. In specific applications, transfer devices become critical in maintaining integrity of the device or process. Transfer devices may be used as separative enclosures.

7.2 Selection

Selection of a transfer device should be based on the level of separation required by the application. The percentage leak rate of the transfer device should not be greater than the hourly leak rate of the separative enclosure the transfer device serves while minimizing the transfer of unwanted matter. Outline diagrams and descriptions of possible types of transfer devices are included in annex D. These diagrams are only intended to be 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 Installating

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

8.2 The appropriateness of the following points should be considered:

a) air classification of the room;

b) operational ergonomics;

c) maintenance;

d) toxicity of products;

e) all process hazards;

f) by-product hazards;

g) cross contamination;

h) disposal matters;

i) any mandatory regulatory requirements.

NOTE For biocontamination risks, ISO 14698 and its parts should also be taken into consideration.

9 Testing and Approval

9.1 General

9.1.1 Test procedure selection

9.1.1.1 Selection of test procedures depends upon location, design, configuration and application of the separative enclosure.

9.1.1.2 Where air supply and exhaust systems are an integral part of the separative enclosure, these systems should also be tested.

9.1.1.3 In some situations, the air cleanliness in the separative enclosure may not be measurable by ISO 14644-1. Therefore alternative test procedures may be required.

EXAMPLE Testing of molecular contamination [22].

9.1.1.4 In some cases, product properties (e.g. dusty materials, out-gassing materials, or both types of materials) may interfere with testing or present a hazard during testing under certain operational states. However, it is important to sample the air in a manner to the extent possible to characterize the true extrinsic particulate contamination to which the product is exposed.

9.1.1.5 In the case of small volume separative enclosures there may be a risk that pressure integrity and particle/aero-biocontamination counts are affected by the airflow rate of the air sampling instrument when the instrument airflow rate is similar to the airflow rate of the separative enclosure.

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

9.1.2 Separative enclosure and auxiliary equipment testing and approval should generally be performed with reference to ISO 14644-1, 14644-2, 14644-3, and 14644-4 and annexes contained in this document.

9.2 Glove breach test

The airflow through an open glove port should be measured by placing an anemometer at the center of the glove port. The velocity should be agreed between customer and supplier (guidance value: not less than 0,7 m/s).

9.3 Operating differential pressure

9.3.1 The static differential pressure under operating conditions between the separative enclosure and background environment should be determined according to the specific application as agreed between customer and supplier.

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

9.4 Leak testing

Depending on the operating conditions agreed between customer and supplier, a leak test may be performed following the recommendations in annex E.

NOTES

1 Integrity testing on separative enclosures that operate close to atmosphere pressure require detailed procedures and sensitive test equipment to establish a quantifiable leak rate. The resulting leak will determine acceptability for the intended application (see annex A).

2 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 utilize over pressure or mass flow to minimize 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 exiting.

9.5 Routine testing

9.5.1 The following covers routine testing for separative enclosures not covered in other parts of ISO 14644 or in ISO 14698.

9.5.2 The routine test and check will be a function of the application and instrumentation/detection systems. Routine tests should be established and recorded for comparison preventative maintenance requirements.

9.5.3 The following are recommendations for testing frequency.

a) Half suit/glove testing:

   1) on commissioning;

   2) prior to and after completion of work;

   3) after glove/glove sleeve changes;

b) Pressure testing:

   1) on commissioning;

   2) after any airflow or filter pressure parameters changes;

   3) after maintenance affecting the separative enclosure envelope or pressure adjustment devices;

c) Induction testing:

   1) on commissioning;

d) Instrumentation and alarm system testing:

   1) on commissioning;

   2) after maintenance affecting the control system;

   3) the peridoicity dictated by the instrumentation manufacturer;

   4) at predetermined periods consistant with use and operational requirements.

Annex A
(informative)

Separation continuum concept

A.1 Separation continuum

A.1.1 A separative enclosure utilizes physical means, aerodynamic means, or both, to create improved levels of separation between the inside and outside of a defined volume. Physical separation means include both rigid and flexible barriers. Aerodynamic means include air/gas flow with or without filtration. Generally, the assurance of maintaining separation increases with the degree of rigidity of the physical separation as shown schematically in figure A.1. Examples of common types of separative enclosures for a variety of applications are given in table A.1. However, it must be emphasized that there is not a direct relationship between airborne particulate cleanliness class, as defined in ISO 14644-1, and the position of an separative enclosure in the separation continuum. Two measures of this separation are the separation descriptor and hourly leak rates (integrity). This is a convenient measure when hourly leak rate is not an appropriate measure. A four-level classification system of hourly leak rate (T_l) is given in ISO 10648-2. This is generally applied to devices with rigid physical barriers.

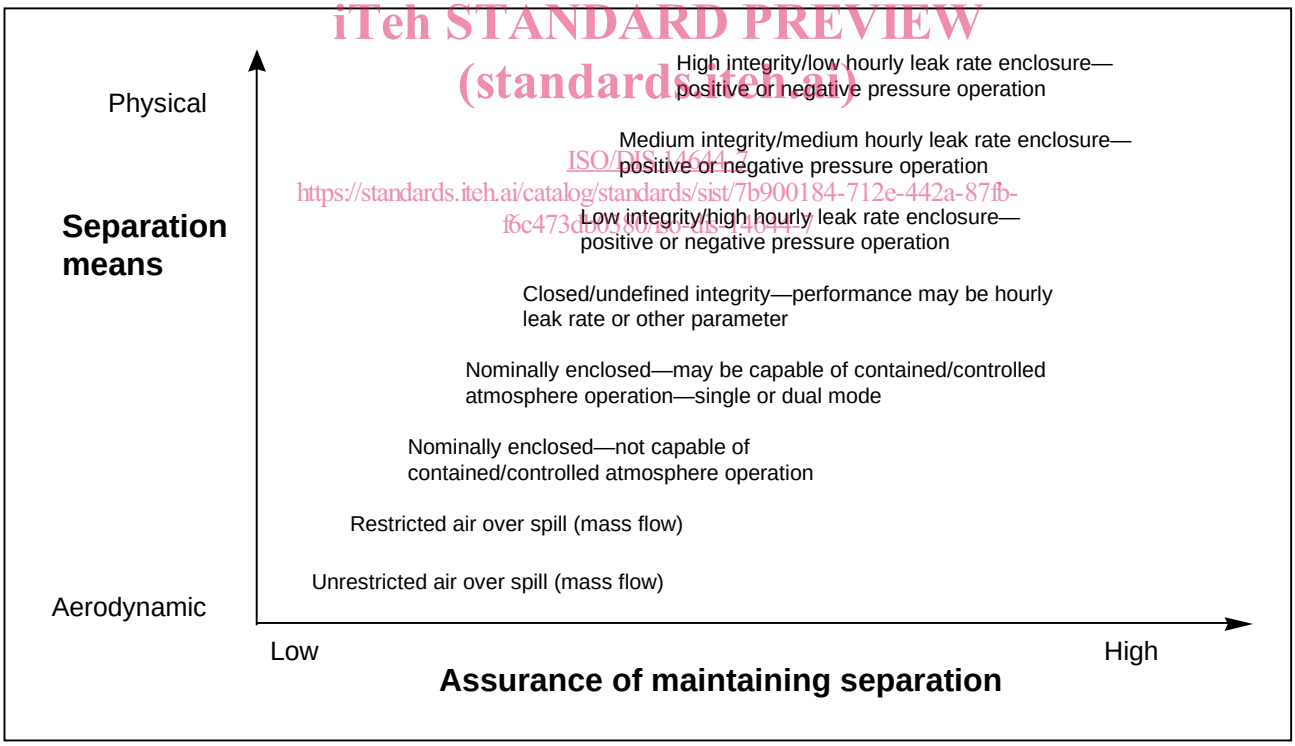

Figure A.1 — Schematic of the separation continuum illustrating increasing assurance of maintaining separation as the separation ranges from aerodynamic to physical means with overlapping separation approaches as a parameter.

Table A.1 — Separation continuum

Separation approaches	Means	Device descriptor	Examples: Terms in common usage and synonyms
Unrestricted air over spill (Mass flow)	Aerodynamic measures and filtration	Open—no curtains or screens. Operator equipped with normal cleanroom garments and gloves may reach into device for access and transfer. Clean zone is at positive pressure.	Clean air device, laminar flow hood, clean air hood
Restricted air over spill (Mass flow)	Aerodynamic and physical	Access severely restricted by curtains or fixed screens.	Laminar flow hood, clean air hood, directed air hood, clean work station;
Nominally enclosed—not capable of contained/ controlled atmosphere operation	Aerodynamic and physical	Nominally enclosed; May incorporate access devices and transfer devices.	Point of fill device, filling tunnel
Nominally enclosed—may be capable of contained/controlled atmosphere operation—single or dual mode	Aerodynamic and physical	Large degree of physical separation in design. May be capable of controlled/contained atmosphere operation.	Filling tunnel, point-of-fill device, laminar flow tunnel, clean tunnel, sterilizing oven, minienvironments for electronics
Closed/undefined integrity—performance may be hourly leak rate or other parameter	Physical	Closed devices with undefined integrity. May have flexible film walls.	Isolators, glove bags, powder transfer control or hopper, flexible film/half-suit isolator, minienvironments for electronics
Low integrity/high hourly leak rate enclosure—positive or negative pressure operation	Physical	Rigid construction allows pressure integrity test of leak rate. May be operated under negative pressure.	Isolators, glove boxes, powder transfer control or hopper, animal test house isolator, university biochemical instructional isolators; containment enclosures
Medium integrity/medium hourly leak rate enclosure—positive or negative pressure operation	Physical	Medium pressure integrity.	Isolators, glove boxes, containment enclosures
High integrity/low hourly leak rate enclosure—positive or negative pressure operation	Physical	High pressure integrity, vacuum and inert gas operation, containment at molecular level	Isolators, glove boxes, nuclear glove box, low molecular containment enclosures

NOTES

1 Examples are not design specifications or recommendations.

2 Device boundaries may overlap.