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Cleanrooms and associated controlled environments

Part 4: Design, construction and start-up

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European foreword

This document (EN ISO 14644-4:2022) 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of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.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.

This document supersedes EN ISO 14644-4:2001.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 14644-4:2022 has been approved by CEN as EN ISO 14644-4:2022 without any modification.

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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 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 second edition cancels and replaces the first edition (ISO 14644-4:2001), which has been technically revised.

The main changes are as follows:

— normative content has been extended;

— the process of gathering and defining requirements has been added;

— the scope has been extended from classified cleanrooms to include additional cleanliness attributes;

— the entire text has been revised or clarified to aid its application.

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.

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination and, if relevant, other forms of contamination, to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food and research and development laboratories and some applications in healthcare.

Cleanrooms and associated controlled environments are classified for air cleanliness by particle concentration (ISO 14644-1). Cleanliness attributes relating to chemicals, nanoscale particles and viable particles (microorganisms), as well as cleanliness of surfaces, can also be considered.

This document is one of the series of International Standards concerned with cleanrooms and associated controlled environments prepared by ISO/TC 209.

This document provides guidance for the design, construction and start-up of cleanrooms, both new and those undergoing modification or refurbishment. In this edition, a more structured approach is provided with separate normative sections on requirements, design, construction and start-up, supported by four corresponding informative annexes.

For this edition, key recommendations and considerations include:

a) A structured approach with a logical sequential flow through the design, construction and start-up stages. There will normally be reviews and iterations of the requirements, contamination control concepts, layouts and other considerations. The final design should be reviewed against the requirements before construction commences and when construction is complete. The operation and performance are verified against the requirements during start-up.

b) Inclusion of other cleanliness attributes. The ISO 14644 series has parts that deal with other cleanliness attributes, namely chemicals, nanoscale particles, macro-particles and, in ISO 14698, viable particles (microorganisms), as well as cleanliness of surfaces. These other attributes should be considered if relevant, bearing in mind that the primary requirement for a cleanroom or clean zone is that it meets a classification by airborne particle concentration according to ISO 14644-1.

c) Importance of a contamination risk assessment. Assessments should be carried out to better understand the contamination risk and its impact on the process and product and to identify the critical control points (locations) in the cleanroom or clean zone.

d) A clear statement of requirements, namely everything needed for input into the design, including the purpose of the cleanroom and the acceptance criteria for performance parameters. This is critical and should be documented prior to the start of the design process.

e) Ventilation effectiveness. This revision focuses on the importance of ventilation effectiveness through control of air-flow patterns and clean-up recovery rates. Two measures are identified: air change effectiveness (ACE) and contaminant removal effectiveness (CRE).

f) Using air supply rate for calculations of contaminant dilution and removal. This will make it possible to achieve energy-efficient cleanrooms while achieving the required level of air cleanliness.

g) Energy efficiency and life cycle considerations. Energy efficiency in cleanrooms is very important and is covered by ISO 14644-16.

h) A clean build protocol. This is included to minimize contamination during construction of the cleanroom.

Information directly relevant to cleanrooms and associated controlled environments is included in the informative annexes. Supporting information is given in the Bibliography.

Cleanrooms and associated controlled environments —

Part 4: Design, construction and start-up

1 Scope

This document specifies the process for creating a cleanroom from requirements through to its design, construction and start-up. It applies to new, refurbished and modified cleanroom installations. It does not prescribe specific technological or contractual means of achieving these requirements. It is intended for use by users, specifiers, designers, purchasers, suppliers, builders and performance verifiers of cleanroom installations. The primary cleanliness consideration is airborne particle concentration. Detailed checklists are provided for the requirements, design, construction and start-up, which include important performance parameters to be considered. Energy management design approaches are identified to support an energy-efficient cleanroom design. Construction guidance is provided, including requirements for start-up and verification. A basic element of this document is consideration of aspects, including maintenance, that will help to ensure continued satisfactory operation for the entire life cycle of the cleanroom.

NOTE Further guidance is given in Annexes A to D. ISO 14644-1, ISO 14644-2, ISO 14644-8, ISO 14644-9, ISO 14644-10, ISO 14644-12 and ISO 14644-17 provide complementary information. ISO 14644-7 offers guidance on design, construction and requirements for separative devices (clean air hoods, glove boxes, isolators and mini-environments).

The following subjects are mentioned but not addressed in this document:

— specific operational activities, processes to be accommodated and process equipment in the cleanroom installation;

— fire and safety regulations;

— ongoing operation, cleaning and maintenance activities, which are covered by ISO 14644-5.

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 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 14644-16, *Cleanrooms and associated controlled environments — Part 16: Energy efficiency in cleanrooms and separative devices*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

3.1.1
air change effectiveness
ACE
ratio between the recovery rate at a location or locations in a *cleanroom* (3.1.4) and the overall recovery rate of the cleanroom after a contamination event

Note 1 to entry: The recovery rate is defined and measured in accordance with ISO 14644-3.

[SOURCE: ISO 14644-16:2019, 3.2.7]

3.1.2
classification
method of assessing level of cleanliness against a specification for a cleanroom or clean zone

Note 1 to entry: Levels should be expressed in terms of an ISO Class, which represents maximum allowable concentrations of particles in a unit volume of air.

[SOURCE: ISO 14644-1:2015, 3.1.4]

3.1.3
cleanliness
condition not exceeding a specified level of contamination

[SOURCE: ISO 14644-15:2017, 3.5]

3.1.4
cleanroom
room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes, such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations, might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

[SOURCE: ISO 14644-1:2015, 3.1.1]

3.1.5
clean zone
defined space within which the number concentration of airborne particles is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

Note 1 to entry: The class of airborne particle concentration is specified.

Note 2 to entry: Levels of other cleanliness attributes, such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations, might also be specified and controlled.

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

Note 4 to entry: A clean zone(s) can be a defined space within a cleanroom or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

[SOURCE: ISO 14644-1:2015, 3.1.2]

3.1.6
commissioning
planned and documented series of inspections, adjustments, measurements, tests and verifications carried out systematically to set the installation into correct technical operation as specified

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of testing other forms of determination, such as performing alternative calculations or reviewing documents

3.1.7
contaminant
particle, chemical or microorganism that adversely affects the product or process

3.1.8
contaminant removal effectiveness
CRE
ratio of particle concentration in the air leaving the cleanroom to the average of particle concentration in the working plane of the cleanroom, when particles entering from filtered supply air are ignored

Note 1 to entry: If the air leaves the cleanroom at more than one point then the weighted average of the particle concentrations based on the relative flowrates can be used.

Note 2 to entry: The number and positioning of the sampling locations for determining the average particle concentration in the working plane of the cleanroom can be based on the method given in 14644–1.

Note 3 to entry: The local particle concentration is dependent on the airflow pattern in the cleanroom and may vary significantly in the cleanroom. CRE in a sub-area of interest in the cleanroom may be calculated by selecting a single sampling location considered to be representative of the characteristics of the sub-area of interest.

Note 4 to entry: Particles may be replaced by another airborne contaminant.

[SOURCE: ISO 14644-16:2019, 3.2.5, modified — Definition revised and notes to entry added].

3.1.9
customer
person or organisation that could or does receive a product or a service that is intended for or required by this person or organisation

EXAMPLE Consumer, client, end-user, retailer, receiver of product or service from an internal process beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the organization.

[SOURCE: ISO 9000:2015, 3.2.4]

3.1.10
non-unidirectional airflow
non-UDAF
air distribution where the supply air entering the cleanroom or clean zone mixes with the internal air

[SOURCE: ISO 14644-1:2015, 3.2.8 modified — Definition revised.]

3.1.11
particle
minute piece of matter with defined physical boundaries

[SOURCE: ISO 14644-1:2015, 3.2.1]

3.1.12
setting to work
activities to bring a system from a static state into correct operation

3.1.13
source strength
number of airborne particles or other airborne contaminants considered emitted per time unit expressed as a rate

Note 1 to entry: A source can be a person, equipment or an object.

Note 2 to entry: Each rate should be indicated with a specific particle size. Particles are often emitted in multiple sizes and each size may have a different rate.

3.1.14
start-up
period following the construction of an installation when the systems and installation are brought into active service, including all commissioning activities, training and handover to the customer

3.1.15
supplier
organisation that provides a product or a service

EXAMPLE Producer, distributor, retailer or vendor of a product or service.

Note 1 to entry: A supplier can be internal or external to the organization.

Note 2 to entry: In a contractual situation, a supplier is sometimes called a "contractor".

[SOURCE: ISO 9000:2015, 3.2.5]

3.1.16
unidirectional airflow
UDAF
controlled airflow through the entire cross-section of a cleanroom or a clean zone with a steady velocity and airstreams that are considered to be parallel

Note 1 to entry: This type of airflow results in a directed transport of particles and other contaminants from the clean zone.

[SOURCE: ISO 14644-1:2015, 3.2.7, modified — Note 1 to entry added.]

3.1.17
ventilation effectiveness
dimensionless index that relates to both the dilution and removal of indoor airborne contaminants as it determines how effectively the filtered supply air is distributed to the critical areas in the occupied space and the contamination removed by the air leaving the room

Note 1 to entry: Ventilation effectiveness can be expressed in terms of air change effectiveness (ACE) or contaminant removal effectiveness (CRE). In cleanrooms, mostly ACE is used.

3.1.18
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection, testing or other forms of determination, such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

3.2 Installation

3.2.1
air-handling unit
AHU
unit or plant comprising fan, filtration, heating, cooling, humidification or dehumidification and mixing of fresh air and recirculated air, that provides conditioned air to a room or facility

3.2.2
air diffuser
device placed at the outlet of a room air supply terminal to improve distribution and mixing of supply air with room air

Note 1 to entry: A mesh grille or a perforated screen is not considered to be a diffuser.

3.2.3
installation
cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services and utilities

[SOURCE: ISO 14644-1:2015, 3.1.3]

3.2.4
filter system
assembly composed of filter, frame and other support mechanism or other housing

[SOURCE: ISO 14644-3:2019, 3.3.4]

3.2.5
final filter
last high-efficiency air filter in the system before the air enters the cleanroom or clean zone

Note 1 to entry: Terminal filter is a final filter located at the point where the air enters the cleanroom

[SOURCE: ISO 14644-3:2019, 3.3.5, modified — Definition revised and Note 1 to entry added.]

3.2.6
turn-down
controlled reduction of airflow velocity in unidirectional airflow cleanrooms and clean air devices or airflow rates in non-UDAF cleanrooms in order to save energy during periods when the cleanroom is not in operation

[SOURCE: ISO 14644-16:2019, 3.2.8]

4 Abbreviated terms

ACE	air change effectiveness
AHU	air-handling unit
CRE	contaminant removal effectiveness
ESD	electrostatic discharge
HEPA	high-efficiency particulate air (filter)
HVAC	heating, ventilation and air conditioning
MCP	microbe-carrying particle

non-UDAF	non-unidirectional airflow
UDAF	unidirectional airflow
ULPA	ultra-low penetration air (filter)
URS	user requirement specification

5 General

A cleanroom or clean zone can be used to protect products and processes that are sensitive to airborne particles and other types of contaminants. A cleanroom installation can be new or the expansion or modification of an existing installation.

The life cycle of the cleanroom shall be considered from the outset. This includes its design, construction, start-up, occupation, operation, renovation, expansion, repair and demolition and consequent recycling or disposal.

An analysis of the need for a cleanroom and its justification shall be performed. This analysis shall address, but is not limited to:

a) contamination risk to product, processes, people and environment (6.1);

b) statutory requirements;

c) relevant regulations;

d) business-related aspects (financial viability and resource capability);

e) future needs.

The flowchart in Figure 1 is intended to guide the user through this document with a logical sequence of the work. The annexes are aligned with the clauses in the main text (requirements, design, construction and start-up).

There shall be a review after each step based on the requirements and previous steps. In a small project these steps may be simplified.

This document can also be used for non-classified clean controlled environment and controlled zones.

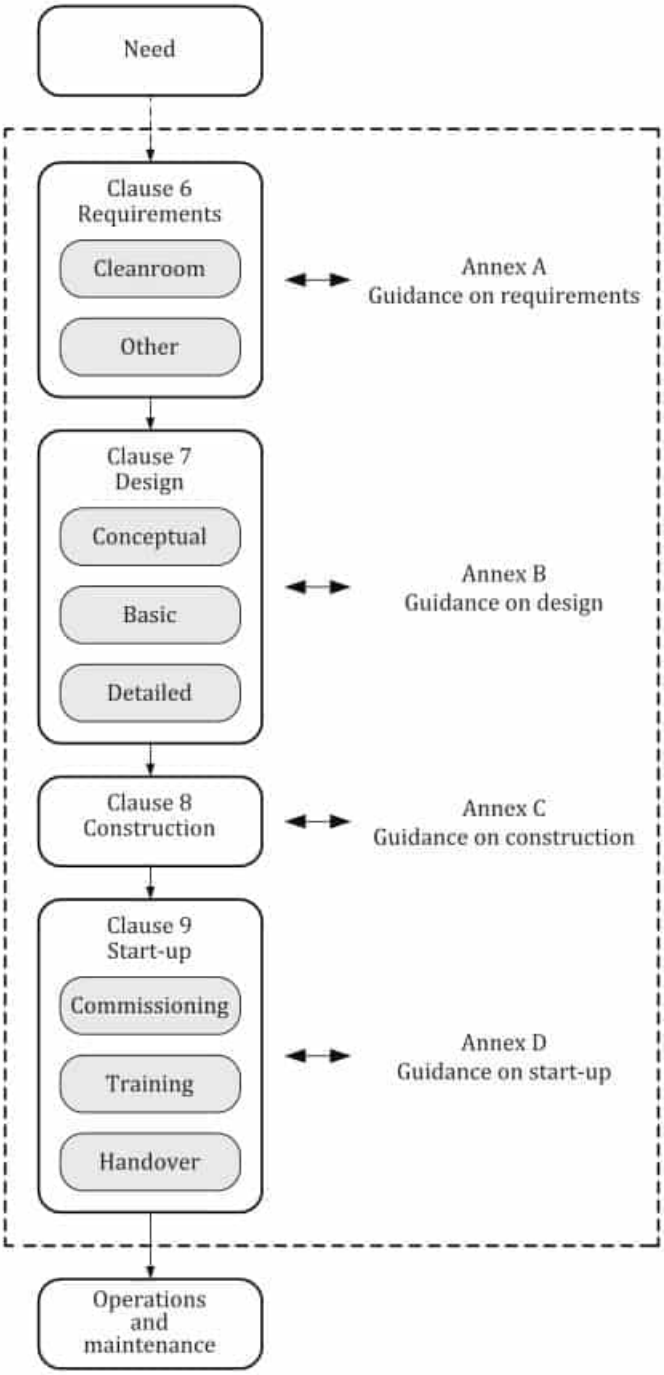


Figure 1 — Flowchart: from requirements to design, construction and start-up

6 Requirements

6.1 Cleanroom requirements

Cleanroom features and contamination control requirements are established as necessary to reliably and repeatably create environments of desired quality to protect patients, products, processes, personnel or the environment. An assessment can be carried out in order to identify potential risks of the facility to be designed.

The following items shall be considered and defined as appropriate by the customer and designer:

a) the intended use of the installation and the operations to be carried out therein;

b) regulatory requirements;

c) the relevant parts of ISO 14644 that will be used, including number, edition and year of publication;

d) the air cleanliness class at the designated particle size(s) and the defined occupancy states in accordance with ISO 14644-1;

e) any other requirements with respect to particles or other contaminants in air or on surfaces (e.g. particle number concentration and particle deposition rate) (see Clause A.4);

f) considerations of any other performance requirements such as ESD or vibration;

g) temperature, humidity, processes and operator comfort considerations;

h) performance parameters and their acceptance criteria, with any specific requirements for alert and action limits and their management;

i) entry and exit of personnel, equipment and materials, in terms of quantity, movement and controls applied, such as decontamination and gowning;

j) sources of contamination and their source strength data;

k) methods of testing, measurement and monitoring to meet the acceptance criteria;

l) cleanroom environmental control by stand-alone systems or integrated into building management system (BMS);

m) requirements for monitoring of environmental conditions and other parameters;

NOTE Guidance for monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration can be found in ISO 14644-2.

n) intended life cycle of the installation;

o) intended operational cycles and turn-down periods;

p) changes of the installation anticipated over time to be provided for in the design;

q) the intended location of the installation and any site constraints;

r) the identification of external environmental influences;

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

t) process and product requirements that affect the installation, including cleaning and disinfection;

u) the process equipment list with utility requirements;

v) the preferred contamination control concepts and overall strategy for contamination control;

w) environmental and energy efficiency targets;

x) process hazards;

y) internal cleanroom surface and finish requirements (including the need for smooth, impervious finishes which are cleanable and resistant to cleaning and decontamination agents and free of gaps or pathways to uncontrolled areas);

z) required availability in terms of acceptable downtime and back-up strategy in the event of failure;

aa) strategy of maintenance operations, space and time needed to maintain the installations during the process cycle;

ab) any other factors or constraints, not listed above, imposed by the operating requirements over the life cycle of the cleanroom;

ac) specific industry guidance.

Additional information on mechanisms of contamination and cleanliness attributes is given in Annex A, together with a comprehensive checklist regarding requirements.

6.2 Other requirements

The following items shall be considered and defined as appropriate:

a) roles and responsibilities of all involved parties during execution of the project;

b) project budget;

c) a time schedule, including milestones for provision of necessary information and documentation;

d) procedure for managing changes;

e) verifications to be carried out at each stage of the project and related documentation;

f) acceptance criteria for the various project stages, if applicable;

g) scope of documentation at designated project stages, its data format and approval procedures (see 9.5);

h) training for cleanroom personnel and technical staff who will manage, use, clean, test and maintain the installation;

i) any other approvals (e.g. management, financial, quality, process, regulatory, statutory);

j) competence and experience of designers, installers, constructors, commissioners and testers or verifiers, specifically in relation to cleanrooms and cleanroom technology;

k) required experience, roles and responsibilities for approvals.

6.3 Documentation

The requirements shall be agreed and documented to form a basis for subsequent anticipated design and allow changes to be managed in a traceable manner.

NOTE In some industries this is documented in a URS.

7 Design

7.1 General

The output of the requirements (Clause 6) is the input for the design. The design of the cleanroom shall take into account an effective contamination control strategy for all aspects of its construction, testing, operation, maintenance and life cycle. There are typically three stages in the overall design process: conceptual design, basic design and detailed design.

Depending on the nature and scale of the project, these stages can be executed in one or more steps with appropriate design iterations and reviews.

The design process shall progress in an agreed manner, shall take into account all the agreed requirements and shall be documented.

Consideration shall be given to energy efficiency (see ISO 14644-16) and use of separative devices (see ISO 14644-7).

Annex B gives additional information on contamination control concepts, calculation of air volume flow rates for non-UDAF cleanrooms, selection of materials and layout.

Occupational health and safety shall be considered throughout the design stage.

In each design phase, the cost estimate and time schedule shall be considered. For cleanrooms, the clean build stages and sequencing, construction method and verification shall also be considered.

7.2 Conceptual design

During the conceptual design, the contamination control concept(s) to be used shall be considered and determined. Guidance about contamination control concepts can be found in Clause B.2.

The following shall be considered as an output of the conceptual design:

a) design criteria, approach and potential solutions for architectural, structural, civil, mechanical, electrical, control and automation disciplines;

b) conceptual layouts of the installation, including locations and sizes of process equipment and materials;

c) material, product, personnel and waste flow diagrams overlaid on the concept layouts with brief descriptions;

d) specification of all environmental control requirements, including levels of air cleanliness, airflow control concepts, temperature, relative humidity and room-pressure differentials or zone segregation by airflow management;

e) preliminary calculations for performance parameters;

f) gowning specification to control source strength.

The conceptual design shall be reviewed by the customer and supplier to verify whether it meets the established requirements (concept design verification).

Consequent to this review it will possibly be necessary to update the requirements. This is subject to agreement.

At the completion of the conceptual design stage an agreed concept design document shall be produced.

7.3 Basic design

A basic design is developed based on the agreed concept design.

The following shall be considered for the basic design:

a) plan layout and section drawings, including locations and sizes of process equipment and materials;

b) room list with associated equipment identifying heat gain, potential for contamination and any other critical characteristics;

c) utility list;

d) schematics, such as airflow diagrams, room air balance and pressurization plan;

e) material, product, personnel and waste flow diagrams overlaid on the developed layouts;

f) supporting calculations to support the supply and extract air volume flow rates necessary to achieve required levels of air cleanliness, flow pressure cascade and recovery rate where required (see Annex B);

g) supporting calculations associated with controlling any other contaminant of interest (microorganisms, chemicals, nanoparticles or macroparticles in the air or on surfaces of interest);

h) associated design calculations for the HVAC environmental control system;

i) prefiltration and final air filtration and cleaning strategy for contaminants of interest, for environment and for personnel;

j) functional description to provide a description of the sequence of operations for critical performance parameters to aid controls system and software development;

k) any alternative designs considered, if applicable, and reasons for rejection;

l) energy-saving methods (as per ISO 14644-16);

m) automatic or manual system control to achieve the required airflow rate, airflow direction between rooms and pressure cascade;

n) material and component specifications;

o) finishes and construction joint details for the surfaces of the installation;

p) commissioning (setting to work and verification) approach (see 8.2);

q) reliability and redundancy strategy;

r) maintenance strategy;

s) building automation and control systems, sometimes known as building management systems (BMS).

The basic design shall be reviewed by customer and supplier to verify whether it meets the established requirements and concept design (basic design verification). It is important to include the practicality of both construction and maintenance in the review activity.

NOTE Consequent to review it will possibly be necessary to update the requirements. This is subject to agreement.

At the end of the basic design stage an agreed basic design document(s) shall be produced.

7.4 Detailed design

The detailed design develops the agreed basic design. Upon completion of the detailed design stage a detailed design document(s) shall be produced in sufficient depth to enable construction and verification to be carried out.

The detailed design shall be reviewed as part of design verification to ensure it conforms to the requirements in Clause 6 as implemented in the basic design. Any changes shall be approved by stakeholders and recorded as part of change control and management.

In addition, the output of the detailed design stage shall include the quality control requirements for the construction verification and commissioning, including the methods to be employed, the parties involved and any requirements for witnessing.

7.5 Change management

When changes are necessary, during design or construction, the requirements or other inputs from the prior design stages shall be referenced and may need to be refined or revised.

It is important that these changes and the implications of the changes are recorded, reviewed and agreed to by designated personnel. Responsibility for this coordination shall be defined.

The impact of changes on cost, project schedule and quality shall be considered and approved.

8 Construction

8.1 General

The installation shall be constructed in accordance with the agreed detailed design and specifications and the construction plan.

8.2 Construction plan

8.2.1 General

Roles, responsibilities and activities shall be described and assigned within the construction plan along with a schedule, a quality plan and a clean build protocol.

All contractors' and subcontractors' activities shall be coordinated for the duration of the entire project. Responsibility for this coordination shall be defined as a part of the construction plan.

8.2.2 Schedule

Construction activities shall be coordinated using a schedule that documents timing, sequence and key milestones for the project.

8.2.3 Quality plan

A quality plan shall be developed in consultation with the customer and other relevant parties and shall consider procedures for:

a) identifying changes that require an agreement;

b) identifying and documenting deviations;

c) assessing the impact of the consequences of these changes and deviations;

d) approval, by appropriate designated staff, of changes, deviations and corrective actions;

e) documenting the control of construction activities and information;

f) responsibility;

g) management of documentation.

NOTE Construction verifications can be part of the quality plan or exist as separate document(s), see 8.3.

8.2.4 Clean build protocol

A clean build protocol shall be considered for the construction project. Application across all construction- and assembly-related activities both on and off the construction site shall be considered. The protocol shall be relative to the classification of cleanroom being installed. For example, a stricter protocol can be applied to a cleanroom with a cleaner or more critical application.

Examples of requirements for a clean build protocol include the following:

— The construction site shall be protected from the external environment at the earliest practical opportunity.

— Areas shall be provided for the set-down of materials, including sufficient space for the inspection of incoming materials.

— Critical components, such as final filters, shall be protected from contamination and damage until fixed in their final position.

— Materials that are delivered to site in a clean condition, such as cleanroom panels and HVAC ducting, shall be kept clean.

— A cleaning programme for the installation as construction progresses shall be implemented.

— Demarcation of a clean boundary around cleanroom construction to prevent contamination from adjoining areas shall be established.

Considerations shall be given to include training and instruction for all personnel attending the construction site, including visitors. This shall outline safe working procedures and assist in ensuring good handiwork, correct conduct on site and adherence to any clean build protocol implemented on site.

Clause C.2 provides additional information on the clean build protocol.

8.3 Construction verification

A set of verifications shall be carried out throughout the construction to ensure that each part of the construction process and the final installation conforms with the approved design.

8.4 Documentation

At the conclusion of the construction process, a set of record drawings, operating instructions and construction verification results (see 8.3) shall be provided to the customer in a timely manner.

NOTE These drawings and operating instructions can be prepared and compiled progressively as work is completed.

In order to prepare for start-up, provision of the following information shall be considered:

a) checks and inspections to be completed prior to bringing the installation and systems into operation;

b) procedures to start, stop and restart the installation under normal and failure mode situations;

c) acceptable ranges of the performance parameters;

d) off-peak and turn-down procedure;

e) procedures to follow when alert or action limits are reached;

f) information on how to operate airlocks, pass-through hatches and other areas where special ventilation schemes are used;

g) information on calibration, operation and maintenance of the monitoring system;

h) procedure for verification and testing after maintenance activities.

9 Start-up

9.1 General

Upon completion of the construction of an installation, the period of start-up commences with commissioning to confirm that the installation is complete and functions and performs as specified. Annex D gives detailed guidance on start-up.

The handover of the installation to the customer concludes start-up.

9.2 Commissioning

9.2.1 General

The setting to work and verification activities shall be planned, scheduled, documented and approved prior to execution.

9.2.2 Setting to work

The installation will be set into operation. A series of measurements and adjustments are carried out until the performance parameters are achieved and the installation is operating in a stable condition as agreed.

9.2.3 Functional and performance verifications

A series of verifications shall be carried out to demonstrate that all the performance parameters are in accordance with the agreed specification and to determine that all parts of the installation operate together to achieve the designed conditions (further information is given in Annex D). For a cleanroom or clean zone this shall at least include a classification test in accordance with ISO 14644-1.

The verification tests shall be of sufficient duration to demonstrate consistent performance for the appropriate functional operating configurations and intended uses. Rationale shall be documented for the scope of verification.

9.3 Training

The customer shall ensure that the personnel operating and maintaining the installation are competent for their assigned duties and have received appropriate training for the specific installation in preparation for handover. Training shall include relevant practices for the installation's start-up, operation, energy management and maintenance. The responsibility for providing training shall be defined. Training shall be carried out as specified and documented.

9.4 Handover

The handover of an installation shall be defined and agreed on between the supplier and customer and documented.

9.5 Documentation

9.5.1 Commissioning documentation

In addition to the documentation provided during design and construction, the following information shall be provided to the customer during start-up and following commissioning:

a) data acquired during setting to work;

b) identification of setpoints and performance parameters determined during setting to work;

c) final and approved performance verification data, recording the values of conditions specified;

d) energy performance and turn-down data in accordance with ISO 14644-16.

9.5.2 Performance-monitoring instructions

Documentation shall include guidance and recommendations on:

a) performance parameters to be monitored;

b) cleanliness attributes to be monitored;

c) test and measurement frequency;

d) description of test and measurement methods;

NOTE Reference to standards and guidelines will possibly be sufficient.

e) real-time continuous performance monitoring and trend analysis, if appropriate;

f) action and alert limits, if appropriate.

9.5.3 Maintenance instructions

Maintenance activities and their frequency shall be defined and implemented. Impact on the installation and processes shall be considered when planning and executing all maintenance activities.

9.5.4 Maintenance record

A record of any maintenance carried out upon the installation during start-up shall be maintained.

9.5.5 Record of training

A record of all training given shall be maintained. Training content, identification of personnel providing and receiving the training and training date and duration shall form part of the record.

Annex A
(informative)

Guidance on requirements

A.1 General

When defining the cleanroom requirements, it is important to identify the cleanliness attributes and which mechanisms of contamination are relevant to the application.

A good understanding of the mechanisms of contamination (A.2) can help to identify the performance parameters that need to be controlled. Information on standards for different cleanliness attributes (A.3) can be applied to set cleanliness levels.

The requirements checklist (A.4) expands on 6.1 with further topics to consider.

A.2 Mechanisms of contamination

Cleanroom contamination can occur from a variety of sources and from several different mechanisms. Contamination can proliferate due to a range of environmental factors.

Contaminants can be in the solid, liquid or gaseous phase. Particles can be either inanimate, microorganisms or MCPs (viable or culturable).

Contamination can be generated within the cleanroom or brought into the cleanroom via equipment, tools, components, packaging, finished goods, consumables, personnel or the ventilation system. Contaminants can also migrate from adjacent spaces due to loss of room pressure differential when cleanroom doors are open or the HVAC system has failed. Surfaces can be both the source and the recipient of contamination. The total amount of contamination that is generated by machinery, equipment, tools, consumables or other sources of airborne contamination, per second, is known as source strength. Source strength is discussed in Annex B.

Contamination sources can introduce contaminants (e.g. particles, microorganisms, droplets and/or chemicals) into the air by impaction, friction, abrasion, vibrations, evaporation and reactions. Contaminants in the air can deposit onto surfaces. When there is airflow above a surface, a boundary layer influences the deposition from the air onto exposed surfaces and re-entry of contamination from the surface into the air. Deposition mechanisms are sedimentation, interception, diffusion and electrostatic attraction. Environmental factors that affect the deposition are airflow, temperature, humidity and other physical influences (e.g. vibrations, ESDs).

To achieve effective contamination control:

a) the amount of contamination brought into the cleanroom should be minimized;

b) the generation and transmission of contamination should also be minimized;

c) contamination that is generated should be quickly removed from the cleanroom or contained so as not to deposit and gather on surfaces;

d) the environmental conditions of the cleanroom should be controlled through an effective air-handling system and surface-cleaning programme.

A.3 Monitoring cleanliness attributes

The primary cleanliness attribute of a cleanroom or clean zone is airborne particle concentration. ISO 14644-1 specifies the classification of air cleanliness of the cleanroom or clean zone in terms of maximum permitted concentration of airborne particles for a range of particle size(s) in occupancy state(s) which must be defined. ISO 14644-2 specifies monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.

In addition to airborne particle cleanliness classified in accordance with ISO 14644-1, additional cleanliness attribute levels can be considered in the design of a cleanroom or clean zone. These other (monitoring) cleanliness attributes are listed in Table A.1 together with the relevant standard.

When defining the requirement, cleanliness attributes of interest should be specified and the maximum concentration (level) in air or on a surface at a critical location set according to the relevant standard.

Table A.1 — Monitoring cleanliness attributes

Contaminant	Air cleanliness	Surface cleanliness
Particles	ISO 14644-2 ISO 14644-17	ISO 14644-9
Chemicals	ISO 14644-8	ISO 14644-10
Nanoscale particles	ISO 14644-12	Not applicable
Viable particles (microorganisms)	EN 17141	

The requirement for a complementary cleanliness attribute will impact design, construction and start-up.

A.4 Checklist regarding requirements

The points listed in Table A.2 should be reviewed for their relevance to the project or process as an input for the design phase, as appropriate.

Table A.2 — Requirements checklist

No.	Item	Design input
1	Process information	
1.2	Intended use	— consideration of the process factors, personnel factors and environmental factors, requirements of authorities and regulatory bodies
1.1	Upstream, down-stream processes	— condition of product or starting material when delivered — description of subsequent process steps
2	Air cleanliness	
2.1	Particles	— class in accordance with ISO 14644-1: particle concentration, particle size(s) and occupancy state — recovery time, recovery rate or both in accordance with ISO 14644-3 — ventilation effectiveness
2.2	Chemicals	— excluded chemicals — concentration level in accordance with ISO 14644-8 — contaminant category as used in ISO 14644-8

Table A.2 *(continued)*

No.	Item	Design input
2.3	Microorganisms	— containment — sterility — fumigation — bioburden
2.4	Other adverse interfering factors	— vibrations (amplitude, frequency) — electromagnetic fields — electrostatic charges
3	Surface cleanliness	
3.1	Particles	— concentration levels and particle size ranges in accordance with ISO 14644-9 — cleaning in accordance with ISO 14644-13 — maximum particle deposition rate in accordance with ISO 14644-17
3.2	Chemicals	— concentration level in accordance with ISO 14644-10 — type of contamination, such as corroding surfaces — cleaning in accordance with ISO 14644-13
3.3	Microorganisms	control according to ISO 14698 — disinfection method — containment — sterility — bioburden
4	Process materials and utilities	
4.1	Solids	— list of solid substances for the equipment, to be used in the process — cleanliness or concentration — quantities
4.2	Liquids	— liquids to be used in the process, specified in terms of their influence on the product (for each item of equipment) — level of cleanliness (chemical, particulate) — quantities — pressure — temperature — flammability

Table A.2 *(continued)*

No.	Item	Design input
4.3	Gases	— all gases to be used in the process, specified in terms of their influence on the product (for each item of equipment) — level of cleanliness [chemicals, particles, viable particles (microorganisms)] — quantities — pressure — flammability — toxicity
4.4	Electricity	— electrical supply (for each item of equipment) — voltage or frequency — phase — load or power fluctuations and standby power supply (replacement for mains) — turn-down mode
4.5	Radiation	— ionising and non-ionising radiation
4.6	Hazards	— any hazard related to 4.1 to 4.5
5	Waste	
5.1	Solids	— list of solids to be disposed of from the process (for each item of equipment) — cleanliness or concentration — type, quantity — discharge method and location
5.2	Extract air	— list types of extract air from the process (for each item of equipment) — properties and chemical composition of extract air — types, quantities (volume flow) — pressure conditions — locations
5.3	Liquids	— list liquids to be disposed of from the process (for each item of equipment) — cleanliness or concentrations — type, quantity — properties e.g. temperature and acidity (pH) — discharge method and location
5.4	Hazards	— any hazard related to 5.1 to 5.3
6	Facility requirements to support the process, the equipment and the personnel	
6.1	Airflow type	— UDAF, non-UDAF or combined airflow
6.2	Direction of airflow	— direction of UDAF in the cleanroom, vertical or horizontal

Table A.2 *(continued)*

No.	Item	Design input
6.3	Temperature	— air temperature requirements in the cleanroom, including maximum, minimum and optimal values in terms of: — production processes — equipment and materials — thermal comfort (gowning) — maximum temperature variation in time and, if required, gradient per unit time — maximum local temperature variations, target values for temperatures
6.4	Humidity	— air humidity requirements in the cleanroom, including maximum, minimum and optimal values in terms of: — production processes — equipment and materials — thermal comfort (gowning) — target values for relative humidity — maximum humidity, with time considerations — maximum local humidity variations
6.5	Room pressure differential	the room's pressure differential value in respect to the surrounding reference pressure or to an adjacent area
6.6	Sound pressure level (noise)	— maximum permissible and optimal sound pressure levels from the cleanroom processes — personal comfort — health and safety — sound reflection — reverberation
6.7	Vibrations	maximum permissible and nominal vibration levels in the cleanroom processes
6.8	Lighting	indication of minimum and optimal required level of illuminance in the cleanroom and, if necessary, wavelength limitations — process requirements (task or local lighting) — personal comfort — glare — reflectance — uniformity — low energy measures — periods of use
6.9	Ceiling height	— required ceiling heights
6.10	Floor area	— required floor areas, i.e. lengths and widths

Table A.2 *(continued)*

No.	Item	Design input
6.11	Floor loadings	— maximum load to be carried — static load — maximum dynamic load
6.12	Surface finishes	— surface flatness, smoothness or roughness requirements — standards of handiwork (provide physical examples) — use of impervious materials — free of gaps and crevices and with appropriate sealing — cleanability — compatibility with cleaning and disinfection agents — use of different colour finishes to present a more aesthetically pleasant environment, avoid glare and provide area or zone demarcation
6.13	Ionization	— discharge time — offset voltage
6.14	Electrostatic discharge	— surface voltage level — resistivity of materials — electrostatic field
6.15	Site requirements	— earthquake zones — flood zones — outside contamination
6.16	Information technology	— IT infrastructure — public address devices — notification devices — alarm devices — cyber security
6.17	Electrostatic or magnetic fields	— continuous and transient radiated emission limit — spectrum for specific areas
7.	Safety aspects	
7.1	Separation of air circulation zones	— specific requirements concerning control and separation of individual areas (cross-contamination)
7.2	Storage and transport of hazardous materials	— provision of specific processes — total storage capacities of the cleanroom installation for hazardous goods (e.g. toxic, flammable)
7.3	Emergency egress	— maximum permissible distance to be covered when leaving the cleanroom installation (emergency exits)
7.4	Smoke control	— provision for smoke removal of sealed rooms — smoke and fire detectors
7.5	Fire protection	— sprinkler system — suppression system

Table A.2 *(continued)*

No.	Item	Design input
7.6	Process hazards	— toxic — flammable — explosive
8	Cleanroom use	
8.1	Availability	— availability of the installation (redundancy, uptime and time to repair) — availability of spare parts (quantity, type)
8.2	Movement of materials and personnel	— product and process flow requirements — personnel flow requirements — waste flow requirements — distances between individual processes — process separation requirements — personnel communication — airlocks and changing rooms
8.3	Utilization	— indication of operating mode of cleanroom, i.e. constant or intermittent — turn-down — tunability — adaptive control see ISO 14644-16
8.4	Cleaning and disinfection	— procedures — nature of chemicals used — potential for impact on process or surfaces — undesirable residue — emission — storage for devices and agents
9	Further requirements	
9.1	Energy saving	— set targets based on usage modes for optimized energy use
9.2	Legal requirements	— list of all legal provisions influencing the siting and the operation on site, including local development plans and regulations, local tax regulations and clearance requirements

Table A.2 *(continued)*

No.	Item	Design input
9.3	Utilities	— list utilities and external factors with quality, quantities and availability — water supply, list of properties — compressed air supply — electrical power supply V, Ph or Hz, stability — waste disposal arrangement — vibration conditions — influences from surrounding buildings (contaminations) — influences on surrounding buildings (e.g. process exhausts) — geotechnical conditions at the site — safety and access factors
9.4	Regulatory requirements	— licensing and inspections — regulations — standards — guidelines
9.5	Other	— ergonomics, aesthetic factors — future needs, flexibility — investment, consequential costs — cost of operation, energy consumption, cost of maintenance — dates (landmarks and milestones) — responsibilities for project tasks and milestones

Annex B
(informative)

Guidance on design

B.1 General

The output of the requirements in Clause 6 is the input for the design section. As with many of the requirements, the design is an integral part of an effective contamination control strategy that needs to address the operational context and life cycle of the cleanroom. There are three fundamental elements of an effective contamination control strategy:

a) engineering controls, i.e. the facility and environmental controls;

b) personnel and material controls, i.e. gowning and behaviour as part of procedures and a quality management system;

c) cleaning, including disinfection if required.

The cleanroom design in this document focuses primarily on the engineering controls that enable good operational practices to control contamination and meet the requirements in Clause 6.

ISO 14644-5 addresses the operational aspects of cleanrooms and associated controlled environments.

When designing a cleanroom, it is necessary to understand the contamination control concepts (B.2) in order to establish control and then demonstrate control on an ongoing basis.

An effective contamination control strategy requires:

— understanding of the activities and processes that are at risk of contamination and the type(s) of contamination);

— understanding of the sources of contamination, their likely concentrations, characteristics and impact;

— identifying the critical control points in the cleanroom environment where control is needed;

— establishing the accepted limits for each considered contaminant, type(s) and level(s) at each of these critical control points;

— considering engineering control measures of contamination risk elimination or mitigation, including isolation, segregation, separation and containment, e.g. creating a clean zone inside a less clean environment;

— limiting contamination sources inside a controlled environment (e.g. materials, equipment, people in cleanroom clothing);

— limiting introduction of contamination from outside into a clean or controlled zone [overpressure, entry procedure, transfer of goods (materials and equipment)];

— diluting or displacing and removing airborne contamination by supplying adequately filtered air, in order to achieve appropriate ISO cleanliness class;

— removing contamination by return and exhaust air and surface cleaning;

— environmental control system to maintain the cleanroom environment conditions within agreed parameters;

— environmental monitoring system or measures, including what parameters are required to be measured, the location, frequency and time of measurement along with how to evaluate and act on the data in terms of alert and action limits. This in order to demonstrate confidence that the cleanroom environment conditions are operating within agreed parameters.

The ventilation system or HVAC is a critical part of the engineering controls. Examples are given in References [16] and [20]. The required amount of supply air depends on the intended use of the cleanroom (B.3). The ventilation concept can be studied using computational fluid dynamics (B.4). In addition, the layout of the cleanrooms and the materials used in the construction of cleanrooms has to be considered (B.5 and B.6). These aspects of design are discussed in this annex. A checklist can be used to include all aspects (B.7).

B.2 Contamination control concepts

B.2.1 Zoning

For economic, technical and operational reasons, individual cleanrooms and clean zones are often enclosed or surrounded by further rooms or zones of lower cleanliness classification. This can allow a zone with the highest cleanliness demands, shown as that surrounding the process core in Figure B.1, to be reduced to the minimum size and be more effectively controlled.

Movement of material and personnel between adjacent clean zones increases the risk of contamination transfer, therefore special attention should be paid to the detailed layout and management of material and personnel flows.

Figure B.1 depicts an example of a contamination control principle called the box-in-box concept. In this configuration, the process core area would be regarded as the most stringently controlled portion of the cleanroom. Outgoing movements of personnel, finished product or waste can occur in several stages or a single stage, depending on the contamination transfer risks.

This is a two-dimensional diagram that should be interpreted in three dimensions to take into account contamination risks from all directions including from above and below the rooms and zones identified.

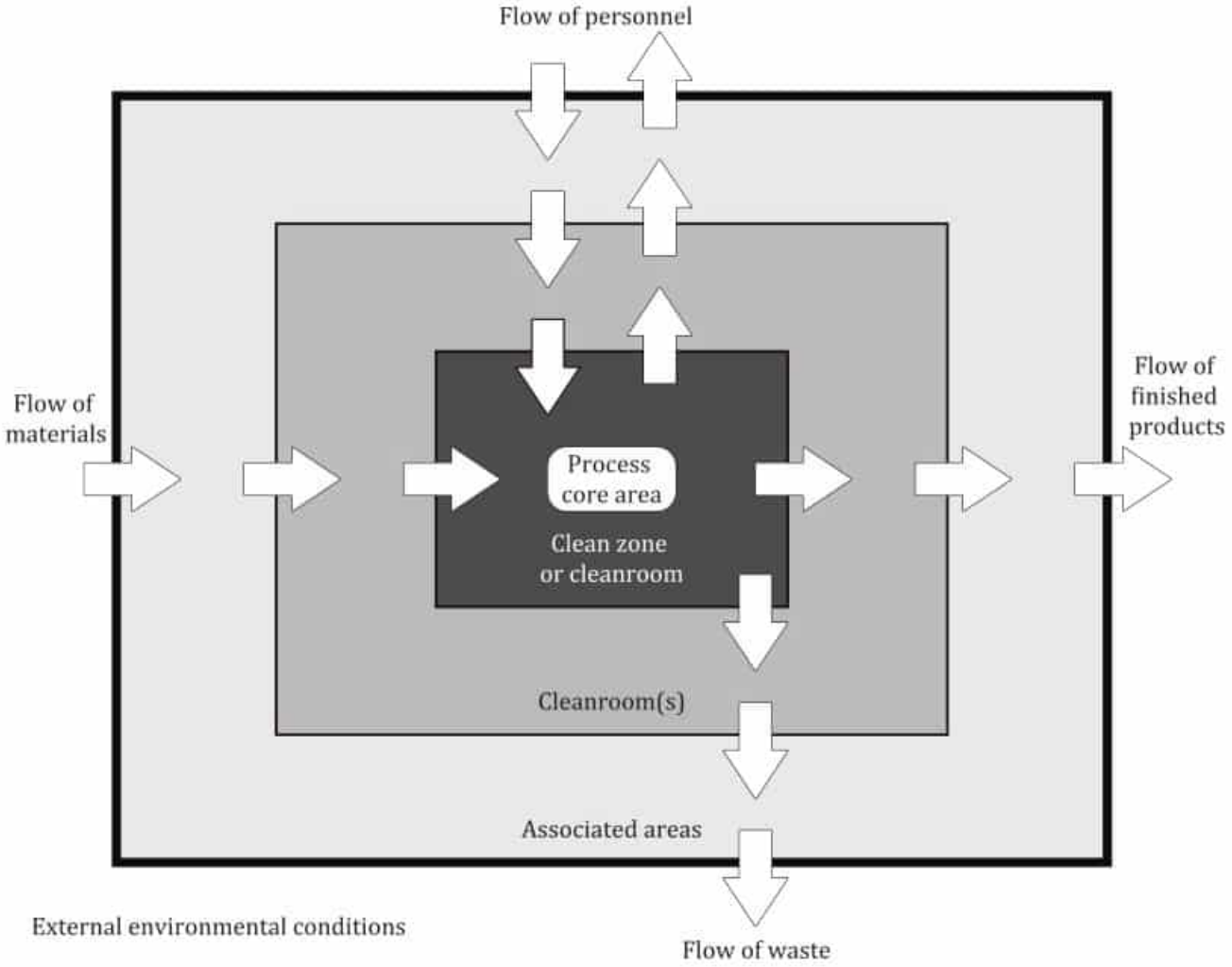


Figure B.1 — Example of a box-in-box contamination control concept

B.2.2 Segregation

B.2.2.1 General

Cleanroom installations can consist of multiple zones and/or rooms with different requirements for contamination control. The objective of the design should be to protect products or processes, or to contain them if hazardous. In some cases, a combination of protection and containment is required. Segregation can be achieved utilizing physical, aerodynamic or a combination of both means.

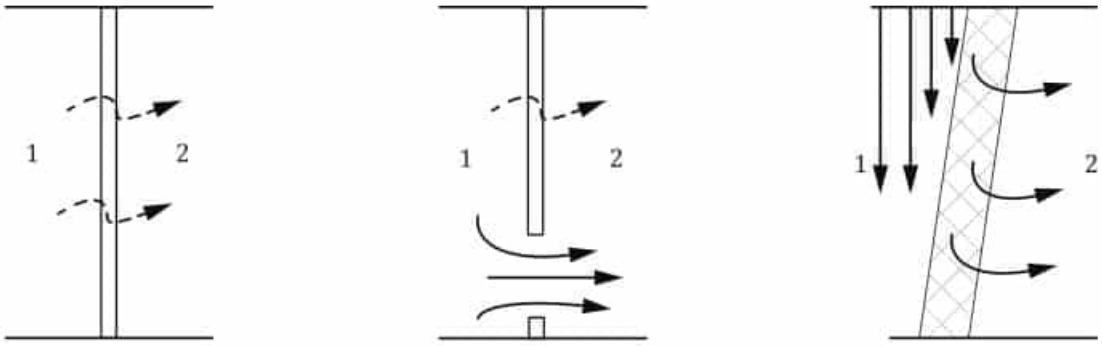
To protect cleanrooms from contamination from adjacent less clean spaces, the cleanroom should be maintained at an outward airflow in relation to those less clean spaces. To contain a hazardous process this airflow direction should be reversed. Some applications can require a combination of different airflow directions to both maintain cleanliness and contain hazards.

In the case of two zones separated by a physical barrier, an airflow should be established through the leakage paths connecting the spaces flowing from the cleaner to the less-clean space. Maintaining this airflow direction and pressure differential will require a suitable stable airflow volume rate difference (offset) between the mechanically ventilated supply and extract airflows and pressure to be maintained between the spaces to ensure that the airflow is always in the right direction. Where a series of spaces are separated by physical barriers, the pressure regime between spaces should be arranged to ensure the correct airflow direction at all interfaces between the spaces. This regime of increasing pressures for increasing cleanliness or decreasing pressures for containment is often referred to as a "pressure cascade(s)".

In the case of two zones separated without a physical barrier, a segregating airflow will only be effective where the flow path and the airflow velocity do not allow backflow or entrainment of contamination from the less-clean zone into the cleaner zone.

In cases where high levels of segregation are required, separative devices should be considered (ISO 14644-7).

Figure B.2 illustrates the basic concepts for cleanroom or clean zone segregation.



a) By physical barrier with leakage: static pressure $P_1 > P_2$

b) By physical barrier with leakage and overflow: static pressure $P_1 > P_2$

c) Aerodynamic: no practical difference between static pressure P_1 and P_2

Figure B.2 — Concepts of segregation

It is possible to combine aerodynamic segregation and a physical barrier in the case of larger distinct openings in a physical barrier (e.g. continuous product transfer).

NOTE 1 The effectiveness of the physical barrier concept can be demonstrated by undertaking a containment leak test as described in ISO 14644-3, as well as experimental airflow visualization.

NOTE 2 The effectiveness of the aerodynamic segregation concept can be demonstrated by undertaking a segregation test or airflow visualization as described in ISO 14644-3.

In cases where high levels of protection are required, separative devices should be considered (ISO 14644-7).

The quantity of make-up air should be sufficient for occupant ventilation purposes and to compensate for loss of air through leakage through the boundary of the cleanrooms or clean zones and exhaust air from other equipment, such as separative devices.

B.2.2.2 Physical barrier concept

In a physical barrier concept, two or more zones are separated by a solid structure into individual rooms or spaces. Physical barriers (e.g. walls, floors, ceilings, doors, screens) to form an enclosure can have various levels of integrity and can be equipped with local penetrations.

By designing the correct airflow, a correlated pressure differential range between adjacent cleanrooms or clean zones of different cleanliness level can be selected.

To prevent reversal of airflow direction between adjacent cleanrooms or clean zones of different cleanliness level from that intended, the design should balance the airflow in each of the segregated zones in a controlled manner in order to maintain the correct pressure differential.

A controlling airflow between zones can be established and maintained using various airflow regulating techniques. These include both active or automated and passive or manual systems that are configured to adjust the volume flow rates of supply and return or exhaust air.

Depending on the criticality of the segregation, pressure differentials between rooms should typically range from 7,5 Pa to 15 Pa. However, in multiple connected rooms with different cleanliness requirements, it might be necessary to design for smaller pressure steps (typically at least 5 Pa) to avoid excessive pressures in the highest-pressure room in the cascade. Higher-pressure differentials are sometimes required.

An increase in pressure differentials creates an increase in air velocity through any gaps. Pressure differentials in the range 7,5 Pa to 15 Pa results in velocity through gaps in the order of 3,5 m/s to 5,0 m/s.

Precautions should be taken to ensure accurate measurement of separating airflow or pressure and to investigate the stability of the installation through computer simulation or animation. Once the installation is operating, this can also be demonstrated by visualization (ISO 14644-3). Excessive pressure differences can be problematic because they can stress the structure of enclosures and make door opening difficult, for example.

In situations where the airflow volume through leakage paths is low due to high pressure integrity of the barrier (a more airtight enclosure), maintaining pressure stability can be more difficult, because in this instance small changes in the volume of supply and return or exhaust air can lead to large changes in the pressure differentials, unless there is precise control of airflow volumes. This phenomenon is often seen in bio-safety level 3 or level 4 laboratories.

B.2.2.3 Aerodynamic segregation concept

A segregating airflow can effectively separate clean and less-clean adjacent zones.

The necessary airflow pattern and velocity should be selected considering important conditions, such as thermal load between the zones, physical obstacles and the location and magnitude of heat sources, air exhausts and contamination sources. In order to create a defined particle concentration difference for an aerodynamic segregation, air velocity in the cleaner side should be higher than that in the less clean side, see Figure B.2 c). Applications of this type of segregation can be observed, for example, at a pharmaceutical filling station access door or a clean zone within an operating theatre.

B.2.3 Airflow concepts

B.2.3.1 Introduction

There are three types of airflow concepts used in cleanrooms and clean air devices for contamination control:

a) unidirectional airflow;

b) non-unidirectional airflow;

c) combined airflow.

Airflow patterns for cleanrooms of ISO class 5 and cleaner in operation are often unidirectional, while non-unidirectional is typical for cleanrooms of ISO class 6 or less clean in operation.

For all airflow concepts, it is preferable that contaminants be removed as close as possible to the source of contamination generation. Consideration should be given to avoiding or controlling airflow disturbance around equipment

Figure B.3 gives examples that illustrate the different airflow patterns in cleanrooms (thermal effects are not illustrated).

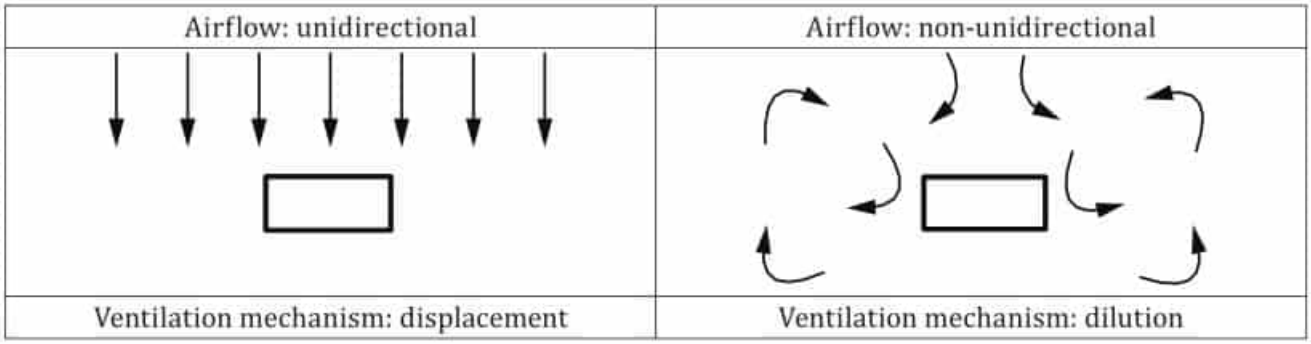


Figure B.3 — Examples of airflow concepts

B.2.3.2 Unidirectional airflow

Unidirectional airflow provides displacement of contaminated air by the supply of clean air. The airflow is most commonly either vertical (downwards) or horizontal but can be diagonal or upwards. UDAF relies upon a filtered supply of clean air delivered at the boundary face of the cleanroom or clean zone in such a way as to ensure a steady velocity and airstreams that are considered to be parallel. The important design feature is that the uniformity of airflow is maintained right to the process core. UDAF results in displacement and a directed transport of particles away from the process core.

All positions in a working plane at right angles to the clean airflow offer the same cleanliness level. Therefore, horizontally arranged processes require vertical UDAF and vertically arranged processes require horizontal UDAF. Working positions nearest to the clean air supply offer optimal contamination control conditions, because working positions downstream of these positions can be subject to particles generated or entrained upstream. Personnel placement should therefore be downstream of the protected processing at the process core.

For UDAF systems, the average air velocity is typically designed between 0,20 m/s to 0,60 m/s at a test distance (referenced in ISO 14644-3) of 150 mm to 300 mm from the supply air inlet face. The selected and agreed velocity can be influenced by other factors such as regulatory requirements, temperature, obstructions to airflow and the location of equipment within the airstream.

High velocities can create excessive turbulence and disruption to the air stream and low velocities can reduce the effectiveness of the displacement concept. Low velocities are also at the low end of the sensitivity of most velocity measurement instruments. However, lower velocities are preferred in order to save on energy consumption.

In UDAF cleanrooms, the design of physical obstacles such as the process equipment, as well as the operating procedures, personnel movements and product handling, should take into account basic aerodynamic requirements to prevent airflow disturbances in the vicinity of the contamination-sensitive activity in order to avoid cross-contamination. To ensure unidirectional flow to a critical location it can be necessary to have physical or aerodynamic barriers around the perimeter and arranged parallel to the air direction to maintain the required velocity and uniformity of airflow.

B.2.3.3 Non-unidirectional airflow

Non-unidirectional airflow provides control of the environment through dilution of any airborne contamination by the introduction of clean supply air into the cleanroom. The clean supply air mixes with contaminated room air and the mixed air is removed continuously. The clean air can be supplied at a specific temperature and humidity to control thermal environmental conditions and comfort of occupants also by mixing.

In practice, some management may be applied to the airflow in order to direct clean air towards critical areas where the suppression of contamination is paramount and then away into the exhausts. Likewise, exhaust points are often situated near to where contamination is generated, for example by equipment

or by personnel, so that this contamination is taken away as soon as it is generated. In changing rooms both effects can ensure airflow moves from the cleaner to the less clean areas.

The number, location and type of supply air diffuser and distribution are critical in achieving the required cleanroom performance. Similarly, the number and location of positions (return air or exhaust) where air exits the cleanroom is also an important design consideration. Supply air diffusers protect any terminally mounted filters from damage during general operations and cleaning.

NOTE Where there is a designed increase in cleanliness below the supply air inlet(s), it will be associated with a decrease in cleanliness in the rest of the cleanroom.

B.2.3.4 Combined airflow

Combined airflow cleanrooms are similar to non-unidirectional cleanrooms except that additional air cleanliness is provided for critical areas by means of a separative device, such as a UDAF ceiling or enclosure.

B.3 Calculation of air volume flow rate for non-UDAF cleanroom

B.3.1 General

This subclause relates to non-UDAF cleanrooms, where the air supply mixes with room air and dilutes the airborne contamination. The required air volume flow rate to maintain a specified particle concentration limit is determined by the rate of particles emitted in the cleanroom (source strength) and the ventilation effectiveness and is given by Formula (B.1). See Reference [21].

$$Q = \frac{S}{\varepsilon \cdot C} \tag{B.1}$$

where

Q is supply air volume flow rate to the cleanroom ($m^3 \cdot s^{-1}$);

S is rate of particle emission in cleanroom air (source strength) (number$\cdot s^{-1}$);

C is particle concentration limit in the cleanroom (number$\cdot m^{-3}$);

ε is ventilation effectiveness (dimensionless).

This formula assumes that the number of particles entering the cleanroom or clean zone from the supply air is negligible and can be left out of the formula. When using multi-staged filters with final HEPA or ULPA filters that have been tested for filter integrity, this is a reasonable assumption.

NOTE The airborne concentration in a non-UDAF cleanroom is determined by air volume flow rate and not the air change rate (air volume flow rate divided by room volume). The air change rate is not used in calculating the air supply as the air change rate depends on the volume of the cleanroom. The use of air change rate can lead to higher airborne concentrations than expected in small rooms. It can also lead to lower airborne concentrations than necessary in larger rooms, with associated high capital and energy costs. However, if required, the air change rate can be calculated after the air supply rate has been determined.

The source strength is the rate at which airborne particles are emitted in the cleanroom from people, machinery, equipment and other sources. The maximum source strength (of emitted particles) should be determined. In an operational cleanroom, these can have local variations and this should be taken into account when determining the total source strength of the cleanroom.

The effectiveness of the air system in removing airborne particles depends on the ventilation effectiveness. This is influenced by the type of airflow between the supply air terminals and exhausts, as well as disturbance of the airflow patterns by, for example, obstruction or thermal effects.

When evaluating the air volume flow rate, any specified recovery rate or recovery time that has been given in the requirements will have to be considered. This is discussed in B.3.5. If a higher supply air volume flow rate is required to satisfy these requirements then the higher value should be used.

During the air volume flow rate evaluation process, it is recommended that the safety margins are included to address uncertainties associated with source strength data, particle generation and distribution, and ventilation effectiveness. These safety margins should be clearly documented in the design and can then be revisited after the cleanroom becomes operational and the actual airborne concentration becomes known. ISO 14644-16 gives information on this topic in relation to energy saving.

B.3.2 Source strengths

In this subclause the source strength of particles is considered. For other contaminants, such as airborne chemicals and airborne microorganisms, a similar approach can be used.

The particle generation from sources of contamination is expressed as the number of particles dispersed per second. The cumulative number of particles larger or equal to a specific size between 0,1 µm and 5 µm and/or macroparticles larger than 5 µm is considered.

In a cleanroom, the contribution of all sources should be added to determine the source strength S, as shown in Formula (B.2):

$$S = \Sigma S_i \tag{B.2}$$

where S_i is the strength of each source (number·s^{-1}) at a specific particle size.

NOTE The source can be at one position (machinery) or can move around (people). In large cleanrooms where a source will not affect the complete cleanroom, the cleanroom can be divided into sections. The calculations would then be applied to each section. Sources do not emit particles at a constant rate, but the rate can vary in time depending on the operations in the cleanroom. When setting requirements, an allowance for excursions in excess of the assumed source strength can be considered.

In practice, the source strength can be difficult to determine if the cleanroom is a new design. In many applications, the contribution from machinery is small compared with that from people. Therefore, the maximum number of people to be found in a cleanroom and the garments they wear are important in determining the source strength. Examples of source strengths of people in cleanroom garments can be found in Reference [22]. The source strength of equipment should be provided by the supplier or can be determined by using measurement methods described in ISO 14644-14 and ISO 14644-15.

If the cleanroom and the application are similar to that of an existing installation, then a reasonable estimate of the total source strength in a cleanroom can be obtained if the airborne particle concentrations during operational conditions and the supply air volume flow rate are known. It can be calculated using Formula (B.3).

$$S = Q \cdot C \cdot \varepsilon \tag{B.3}$$

where

Q is supply air volume flow rate to the cleanroom (m^3·s^{-1});

S is rate of particle emission in cleanroom air (source strength) (number·s^{-1});

C is particle concentration limit in the cleanroom (number·m^{-3});

ε is ventilation effectiveness (dimensionless).

B.3.3 Ventilation effectiveness index

The ventilation effectiveness, ε, is used to include the correctional factors of the "actual mixing" condition and effectiveness of various airflow patterns. For an existing cleanroom, the ventilation effectiveness can be obtained in terms of ACE or CRE. The selection of the index depends on the application and the data that is available or can be acquired. See ISO 14644-16 and References [17], [18], [19] and [23].

Local particle concentrations can differ significantly from the concentration measured at the room air extract. Local particle control is dependent on local airflow patterns. ACE index depends on the location, and might be preferred to CRE, when particle concentration has to be controlled in critical locations. Depending on the choice made, cleanroom supply airflow rate should be calculated accordingly. For the calculation of the air supply rate where there are low level room extracts, ε can range from 0,5 to 0,8.

B.3.4 Further considerations for the calculation of air supply rate

Two corrections can be added to Formula (B.1) (see Reference [21]):

a) Larger particles, such as macroparticles and MCPs, can deposit by gravity onto cleanroom surfaces and reduce the airborne concentration in the cleanroom. When the cleanroom has a large floor surface area and low supply air volume flow rate, this effect should be considered.

b) The effect of the air supply from a separative device that returns filtered air to the cleanroom can have a dominant effect in small cleanrooms with large separative devices. This effect is also dependent on how efficiently the device air mixes with room air.

The additional effect of these variables can be calculated by Formula (B.4).

$$Q = \frac{S}{\varepsilon \cdot C} - \beta \cdot Q_D - V_D \cdot A \tag{B.4}$$

where

β is the ventilation efficiency coefficient of the device (dimensionless);

Q_D is the supply air volume flow rate of device ($m^3 \cdot s^{-1}$);

V_D is the particle deposition velocity ($m \cdot s^{-1}$), which can be 0,003 7 $m \cdot s^{-1}$ for particles ≥ 5 µm and 0,007 3 $m \cdot s^{-1}$ for MCPs;

A is the horizontal surface deposition area (normally the same as the floor) (m^2).

Formula (B.5) can also be used to obtain the local recovery rate at a critical location and by comparing it with the overall recovery rate of the cleanroom the ventilation effectiveness ACE index is obtained.

B.3.5 Particle removal rate

The ventilation performance of a cleanroom can be expressed by its ability to reduce the particle concentration when there is an increased particle concentration from a particle source for a short time. In addition, airlocks need to be designed to ensure that the airborne particles will be removed to an acceptable low concentration before the door is opened. It can also be necessary to determine the time required to wait for the normal supply air volume flow rate to a cleanroom to re-establish the correct operational conditions from a 'turn-down' condition. Finally, it might be necessary to obtain the ventilation effectiveness at a critical location by measuring the recovery rate at the critical location and then comparing it with the overall air change rate of the cleanroom so as to obtain the ACE index. All of these four requirements involve the application of the removal rate or recovery time methods suggested in ISO 14644-3.

The rate of removal of airborne particles introduced into a non-UDAF cleanroom is an exponential decay governed by Formula (B.5).

$$N = -2{,}3 \times \frac{1}{t} \log_{10}\left(\frac{C}{C_i}\right) \tag{B.5}$$

where

N is air change rate per hour, or removal rate per hour (h^{-1});

C_i is the initial airborne concentration of particles (number·m^{-3});

C is the concentration after a known time of particle removal (number·m^{-3});

t is the time elapsed between readings of particle concentration (h).

Formula (B.5) shows that the removal of particles is dependent on the air change rate, whereas the required airborne particle concentration during manufacturing is determined by supply air volume flow rate. The air change rate obtained by Formula (B.5) is the same as the recovery rate obtained by the method described by ISO 14644-3.

Formula (B.5) is used to calculate the air change rate required to give the required removal rate of the airborne concentration of particles in a non-UDAF cleanroom, such as required by ISO 14644-3 for measuring the recovery rate. If, for example, the airborne concentration of particles ≥ 0,5 µm in an operational ISO class 7 room was 352 000 per m^3, and a hundredfold reduction was required in 15 min to the 'at rest' condition of 352 0 per m^3, the required air change rate per hour can be calculated by Formula (B.5) and found to be 18,4 per hour. Formula (B.5) can also be used to obtain the local recovery rate at a critical location and by comparing it with the overall air change rate of the cleanroom the ventilation effectiveness ACE index is obtained.

Should information be required about a time required for (a) recovery time described in ISO 14644-3, (b) recovery time required for an airlock or (c) time delay after turn-down, Formula (B.6) from Reference [24] can be used:

$$t = \frac{1}{N} \ln \frac{C}{C_i} \tag{B.6}$$

where

N is air change rate per hour, or removal rate per hour (h^{-1});

C_i is the initial airborne concentration of particles (number·m^{-3});

C is the concentration after a known time of particle removal (number·m^{-3});

t is the time elapsed between readings of particle concentration (h).

It is assumed when using Formulae (B.5) and (B.6) in the various situations previously discussed that good air mixing is obtained and there is an even particle concentration across the cleanroom. If this is not the case, and the measuring location obtains less clean air than required, the air change rate will need to be increased. The ACE ventilation effectiveness index is used to modify the air change rate (see ISO 14644-16). To carry this out, the air change rate (N) in Formula (B.5) should be divided by the value of the ACE index. In Formula (B.6), the value of N should be multiplied by the value of the ACE index. In addition, if larger particles, including MCPs, are considered, the accuracy of the calculations can be increased if consideration is made of the reduction of the airborne concentration by deposition onto surfaces.

B.4 Application of CFD

Computational fluid dynamics (CFD) modelling (see Reference [25]) can be used in designing a cleanroom or clean air device by providing information on their likely airflow patterns and allowing the designer to optimize the design and achieve a more effective and efficient installation. By obtaining the likely airflow patterns at the pre-construction stage, unforeseen design errors, deficiencies and ineffectiveness can be minimized, and an optimized design approach can be documented for use in the construction.

Some important features of the CFD technique are as follows:

a) Effective CFD modelling requires the input of data that includes information on the geometry of the cleanroom or clean zone and its equipment; heat sources; air volume supply and extract flow rates; location of air inlets and exhausts and the aerodynamic performance of any selected air diffusers.

b) The technique allows visualization of airflow patterns and contaminant concentrations within a cleanroom or clean zone that enables the identification of areas that have poor cleanroom performance (e.g. unsuitable velocity, excessive eddy flows, high concentrations of particles, airflow from less-clean area to cleaner area, unsatisfactory contaminant removal).

c) The technique enables the modelling of contamination sources at 'worst case' point locations for use in assessing the impact of these sources on critical locations. The movement of particles is dependent on different factors (e.g. size, density) and, where necessary, the relevant particle distinctive features should be included in the CFD modelling. It may be useful to also study the deposition of airborne particles onto critical surfaces.

d) If required, most CFD software can track the emissions of a specified size of particle through a space. It may also be able to model movements of personnel, door operation and equipment, but this requires more programming effort and longer computation time.

e) The CFD technique allows the effectiveness of the ventilation and particle removal at critical locations to be obtained from the 'age of the air', and calculation of the ventilation effectiveness index; ACE or CRE. One of these indexes can be used as input to formulae that are used to calculate air volume supply rates (B.1 and B.3).

CFD analysis is a useful tool and is intended to predict approximate airflow patterns, velocities, temperature distribution and particle concentrations in a cleanroom based on a numerical simulation characterized by a set of assumptions and simplifications. CFD simulations can help, for example, in the selection of diffusers and their location through the knowledge gained from the resulting ventilation effectiveness index at a critical location.

CFD can be applicable to UDAFs as well as to non-UDAFs; however, the study of non-UDAFs is more challenging as extra care is needed to accurately represent different types of outlets which will often produce heterogeneous velocity and a degree of instability.

Transient rather than steady-state simulations can be needed to capture unsteady phenomena like movement.

Reports of the CFD modelling should document information for the traceability of data and conditions on which the analysis is based. Information required should include the software title and version, the chosen turbulence model and other relevant software settings, cell types and numbers used in the meshing of the model and adopted convergence criteria. Furthermore, sensitivity testing at different mesh sizes should be undertaken as part of the quality testing of the model.

Where possible, after the cleanroom has been installed and is functioning satisfactorily, a field verification should be performed to compare the output of the CFD simulation with the corresponding experimental data.

B.5 Selection of materials

B.5.1 General

The materials of construction installed should be selected and applied to meet the requirements of the installation. Consider the following:

a) the cleanliness class;

b) other cleanroom cleanliness attributes;

c) construction method;

d) the effects of abrasion and impact;

e) cleaning and decontamination methods and frequencies;

f) chemical or microbiological attack, leaching and corrosion;

g) electrostatic properties;

h) off-gassing material properties;

i) repair and maintenance;

j) end-of-life recycling.

All surfaces of the interior of the cleanroom or clean zone which come into contact with airflows can by their nature or condition influence the quality of the air supplied to the contamination-sensitive zones. For this reason, materials and finishes intended for the internal surfaces of the complete cleanroom environment and the associated air-handling system should be critically assessed and specifically approved for this purpose.

The selection of materials for the exposed surfaces of equipment and furnishings also requires a critical assessment and approval similar to that required for materials selected for cleanroom surfaces.

Consideration should be given to the chemical compatibility of all materials exposed, the cleaning and disinfection agents and process materials to be used within the cleanroom or clean zone. This can, for instance, influence the choice of fixings, adhesives and sealants for surface-finishing work (see ISO 14644-15).

Selection of materials should include consideration of the chemical, thermal and mechanical stresses during operation (production, setup, cleaning and decontamination as well as conductivity and outgassing characteristics). Additionally, flexibility, functionality, durability, aesthetics and maintainability should be considered by customer and supplier.

Many materials contain chemicals and volatile organic compounds (VOCs) that off-gas into the environment at room temperatures. Construction elements such as glues, adhesives, paints, rubbers, plastics and finishes (including vinyl surface finishes) can contain VOCs.

NOTE Known off-gassing factors from materials can impact the ventilation design in certain areas and also pre-start-up activities where initial off-gassing of materials will possibly need to be purged.

B.5.2 Control of electrostatic charging and discharge

Accumulation of electrostatic charge, and subsequent ESD, can present a risk of hazard such as explosion (in the presence of powders or gases), device damage (e.g. damage to electronic or optical components) or excessive attraction of particles to surfaces contributing to physical, chemical and microbiological contamination.

Where these risks cause concern, the selected materials of construction should neither generate nor retain a significant static charge. This significant value will be specific to each application and should be clearly specified in the requirements.

Relative humidity parameters should be specified considering ESD control. Other local ESD control mechanisms can be used, such as ionizing bars, dissipative flooring and earthing. It is important that the direction of the generated ions is well targeted towards the surfaces to be treated. See Reference [26].

B.5.3 Considerations for specific components

B.5.3.1 Basic requirements

Consider all relevant regulations concerning fire protection as well as sound, vibration and thermal insulation when selecting wall, ceiling, plenum, floor, door and glazing materials and their assembly. In order to avoid glare, consideration should be given to the interaction of surface colour and surface finish with the intended lighting conditions. In the case of equipment and material transfer airlocks, decontamination and cleaning procedures can impose special requirements for the selection of materials.

Construction details, including aspects such as window reveals, door frame or wall interfaces, surface-surface junctions, door furniture or light-fitting interfaces, should be specified carefully to avoid crevices, gaps and similar features that are difficult to decontaminate, clean or sanitise effectively. The use of coved or radiused junctions at wall-floor, wall-wall and wall-ceiling should be considered. Where deemed necessary, the detail should ensure a smooth continuous surface transition.

B.5.3.2 Walls, ceilings and associated systems

Materials and surface finishes should meet all general requirements for their application. Particular consideration should be given to impact and abrasion resistance, especially where surfaces of walls and doors are likely to be exposed to contact from frequent passage of trolleys, carts or personnel carrying material. Suitable rubbing strips or protective bars and panels can constitute satisfactory protection of otherwise vulnerable materials.

Walls and ceilings should be designed to prevent ingress of particles or other contaminants from adjacent spaces.

Where glazing is required in walls or doors, it should be of the non-opening type. Consideration should be given to the use of double glazing with airtight seal, which can enable flush mounting on both sides. Glazing frames should be smooth. Where flush fittings are not required, rounded edges or sloping surfaces should be considered for the frames.

Flush design details should be considered for door frames, electrical and data fittings and other service outlets and equipment such as control panels and display screens.

B.5.3.3 Floors

Floors or floor coverings should be non-porous, slip resistant, abrasion-resistant, conductive if necessary, resistant to the chemicals they will encounter in use (both cleaning and disinfection products and accidental spillage of process fluids) and easy to clean. The floor should support the specified static and dynamic loads with the required strength and durability. The floor composition should provide the appropriate electrostatic characteristics.

Consideration should be given to the impact that a non-slip or abrasive floor surface will have on cleaning operations and particulate generation.

Raised floors can be applied to create space for equipment utilities. Perforated raised floors can be used to create an air return duct.

B.5.3.4 Doors

Doors should present as few horizontal surfaces as possible, with particular attention being paid to the minimization of steps and ledges in the door surface. Thresholds should be avoided. Consideration should be given to the minimization of abrasion in the mechanical elements of the door (e.g. latches, locks and hinges) and also between the door and its frame and the floor. Door closers should be selected with minimal ledges and no uncleanable crevices or ledges. Door handles, where required, should be smooth, non-snagging and easy to clean. Consideration should be given to the use of D handles, push plates, automatic openings and appropriate door-swing direction where contamination transfer is a concern. Where possible, the use of latch and keep door furniture should be minimized to limit the introduction of crevices and ledges. When selecting doors and door seals, the designed leakage rate should be considered.

B.5.3.5 Air-handling systems

Attention should be paid to minimizing the contamination generated, retained and released by all components and surfaces exposed to the air throughout the air-handling system to prevent an excessive particulate load being placed on the air filtration system. Duct components should be specified for airtightness as appropriate, be cleaned and sealed after fabrication and delivered and stored onsite in that condition. It might be necessary to verify airtightness and cleanliness before setting to work.

Air-handling systems should include variable speed fan motors.

The final filter location should be terminal for cleanliness class ISO class 8 (operational) and cleaner. For defined and agreed technical reasons, the final filter location may be remote, but in such cases special precautions should be taken to avoid contamination ingress between these filters and the point where the air enters the cleanroom or clean zone (e.g. monitoring of the surface cleanliness and airtightness of ventilation ducts and supply air inlets to avoid induction of contamination as well as the deployment of cleaning and decontamination procedures). Remote final filters should only be used in lower class cleanrooms, due to the contamination risk and the difficulty of undertaking an effective in situ filter leak test.

Selecting the correct type of filter for all filtration stages is important to ensure an efficient and cost-effective solution (see References [17] and [18]). In determining final filter grades, consideration should also be given to how the filters will be in situ tested for leakage (see ISO 14644-3) and what those maximum designated leak limits will be.

The air-handling system should employ two or more stages of air filtration in sequence. Selecting the correct grade of air filtration at each stage is important to ensure the overall filtration is effective, energy efficient and sustainable. ISO 14644-3 provides specification for installed filter leak test methods and the design of HVAC system should consider the location for aerosol injection and upstream sampling of concentration.

Final filters should be HEPA filters for ISO cleanliness classes ISO class 8 (operational) and cleaner. ULPA filters may be selected where very low penetration levels are required. For example, ULPA filters should be considered when the filters are serving ISO class 4 or cleaner environments.

B.5.3.6 Fittings and furniture

Fittings and furniture should present as few horizontal surfaces as possible. Furniture should be kept to a minimum and the specification, including materials selected, should be the same as for the cleanroom.

B.5.3.7 Fixings, connections and sealings

Connections, such as walls to ceilings, walls to walls, walls to floors or components such as coving, door or window frames or penetrations require secure fixings and should be sealed. Fixings should be concealed and airtight. Sealants should be durable, flexible, easily applied and cured to provide a smooth, non-porous surface.

B.6 Layout

B.6.1 General

The volume of a cleanroom should be kept to the minimum practicable. If a large area cleanroom is required, consideration should be given to dividing it into several zones or rooms, with or without physical barriers, to assist the contamination control management. BIM (building information modelling) technology can be of great value in optimizing organization of space and integration of the various technologies required for the facility.

For cleanroom facilities that contain a hazardous process, a different design can be required to protect personnel, the product and the environment.

B.6.2 Airlocks

To minimize the transfer of contamination between rooms of different cleanliness classes during personnel and material transfer, a physical segregation by means of an airlock and/or pass-through box should be provided. The airlock and/or pass-through box should also maintain the pressure differential established between the rooms by ensuring the opposing doors are not opened simultaneously. For airlock types and selection see Reference [19].

Any airborne contamination released in the airlock and/or pass-through box should be contained and removed by a combination of interlocked doors and dilution by clean supply air for a defined flushing time. The effectiveness of air locks is dependent on the amount of air supplied and the time used to clear particle contamination. Information required to calculate these two variables is given in B.3.5. An airlock can have a higher air change rate than the cleanroom, to reduce recovery time and avoid contamination of the cleanroom upon entry.

Precautions should be taken to ensure that entry and exit doors associated with an airlock and/or pass-through box are not opened simultaneously. Clear windows can be provided at both points to allow a line-of-sight view. Consideration should be given to the use of electrical or mechanical interlock systems, including audio-visual indicators.

Stepover benches or other clear demarcation systems should be included within an airlock system for the passage of personnel.

Appropriate decontamination devices and procedures should be employed as necessary within a pass-through box for the transfer of materials.

The passage of material and personnel should be segregated.

B.6.3 Changing rooms

Changing rooms are specialized airlocks for the entry and exit of personnel to and from a cleanroom. They should include sufficient space for their function, and when required for the cleanroom class, space and provision for storing, donning and removing specialized cleanroom garments. They can also include washing, hand disinfection and specialized contamination control equipment and contamination control floor materials (adhesive or tacky mats) at the point(s) of entry and exit to the cleanroom.

Where storage of garments is required in airlocks or gowning rooms, consideration should be given to the use of hanging rails and perforated shelves rather than closed lockers.

Separation of the personnel entering from those leaving the cleanroom via the changing room should be ensured. This can be achieved by separation in time (temporal) or by providing physically separate entry and exit routes.

Where hazardous materials are processed, a separate changing and decontamination route should be considered.

Changing rooms should be provided with a level of contamination control and internal cleanliness control that ensures the integrity of the cleanroom is protected. Similarly, the methods and equipment for storage of garments and equipment for use in the cleanroom should be commensurate with the required cleanliness and contamination protection required by the contamination-sensitive operation. To provide the required protection, consideration should be given to three functional zones or regions of the changing room:

a) at the changing room entry: access from ancillary areas (either directly or via an airlock) configured for removal, storage, disposal and/or redonning of garments not permitted within the cleanroom;

b) the transition zone: area where garments or personal equipment dedicated to the cleanroom are stored, donned or removed, as appropriate;

c) the inspection or access zone: area where inspection of the completed gowning process is undertaken and which provides access to the cleanroom either directly or via an airlock.

The three functional zones can be separated (e.g. by a stepover bench or airflow) as appropriate to the operation and use of the changing room. The three zones should be established such that the zone closest to the cleanroom provides a high degree of assurance and that minimal adverse impact is caused by access or gowning procedures implemented in the adjacent zone.

The features that are required in the changing room will be specific to the cleanroom that the changing room serves. The following should be considered:

— the number of people passing through the gowning procedure, both in total and at any one time;

— the planned gowning time;

— the gowning procedure (i.e. what garments are to be taken off and put on, whether these are reusable or single-use, the required protocol to ensure garment cleanliness and the avoidance of cross-contamination);

— the frequency of garment replacement.

Consideration should be given to the following provisions in the changing room:

— storage and disposal of garments;

— storage before use, provision and disposal of consumable items and accessories (e.g. gloves, masks, protective glasses, overshoes);

— storage of personal items;

— hand-washing and drying or other typical decontamination or sanitisation processes;

— prominent display or posting of gowning sequence, with clear instructions;

— full-length mirrors to check effective donning of garments and protective equipment;

— ESD protection checkpoint when required.

B.6.4 Workstation arrangement

Consideration should be given to the following provisions regarding workstation placements within the cleanroom:

a) entry and exit points;

b) major traffic pathways;

c) features which can cause disruption of the airflow pattern;

d) ancillary equipment;

e) contamination sources;

f) thermal effects;

g) airflow directions;

h) waste discharge points;

i) access to services;

j) access for maintenance;

k) storage and movement of parts, tools and finished goods.

B.6.5 Ancillary support areas and adjacent cleanrooms

Consideration should be given to the location and integration of ancillary support areas such as cleaning, preparation, toilet and refreshment facilities, in order to avoid compromise of the critical conditions maintained within the cleanrooms. Effective training and management of personnel behaviour should be implemented to minimize disturbance and cross-contamination due to movement between ancillary areas and cleanrooms.

B.6.6 Utility services and ancillary equipment

Utility services provided for the cleanroom should be designed, located and installed such that the cleanroom is not compromised by contamination from such services.

In general, exposed piping, tubing and cable runs within the cleanroom should be minimized, as these can present problems for adequate cleaning and cause damage by contact with, for example, cleanroom garments or wipes. This should be balanced against the potential for contamination within, for example, protective housings or covers, which can also hinder cleaning, disinfection or fumigation. Where possible, consideration should be given to the routing of such services in external service areas or closed sealed ducts.

Power take-off points, data access point, taps and connections should be designed and installed to facilitate regular cleaning, and to avoid the build-up of contamination in or behind blanking covers. Wherever possible, the design should ensure that maintenance activities can be performed outside the cleanroom. Where that is not possible the design should encompass suitable access to maintainable items.

B.7 Checklist regarding design

The points listed in Table B.1 should be considered and checked for their relevance in the design phase.

Table B.1 — Design checklist

No.	Item	Description specified
1	Information on process equipment	
1.1	Technical features	— dimensions and weight of each part of the equipment — space required around the equipment for operational access and maintenance — the space and additional equipment required for loading and unloading processing materials — access requirements for installing the equipment in the cleanroom — heat gain from equipment — utilities required — air exhaust requirements, if applicable — contamination source strength — installation of siphons equipped with anti-return valves (accessible for maintenance) on floor drains
1.2	Assembly, operation, maintenance	— operation and maintenance instructions — storage and handling of change parts
1.3	Throughput	— quantity or number of items produced per unit time — the space and additional equipment required for loading and unloading processing materials
2	Cleanroom design considerations	
2.1	System(s) design	— system reserve capacity — redundancy and standby provision — overdimensioning of the system (design coverage) — alternative sources of power or primary utilities for switch-over
2.2	Prerequisites	The following documentation should be available: — technical specification, including, if necessary, safety and environment handbook — listing or schedule of regulations, standards and guidelines to be taken into account and identification of approvals required — list of process equipment (see 1.1) — approval or clearance for planning

Table B.1 *(continued)*

No.	Item	Description specified
2.3	Construction plan	The construction plan should have the following components: — planning documentation, including calculations — scheduled dates (milestones) — list of major risks — planning options, including an assessment of their advantages and disadvantages — overview of maintenance requirements — overview of degree of flexibility — listing of redundant capacities — quality plan
3	Cleanroom	The planning of the cleanroom should take into consideration the following items: — cleanroom concept — requirements regarding product quality — capital investment and cost of operation (consequential, lifetime costs) — energy consumption, energy-saving measures — safety — health and well-being of the personnel — requirements and limitations set by equipment or procedures — reliability, ease of operation and maintenance — environmental issues (such as waste management and packaging) — requirements imposed by authorities
4	Layout of a clean-room installation	When planning the layout, the following items should be taken into consideration: — size — siting of workplace and organization — associated areas and adjacent cleanrooms — media supply and preparation and, if required, disposal — vacuum cleaning system — sprinkler systems — communication systems — glazing — access for personnel and materials (airlocks, if required) — changing rooms (changing procedures, equipment) — technical areas and accessibility for maintenance — emergency exits

Table B.1 *(continued)*

No.	Item	Description specified
5	Selection of materials for interior construction and equipment	Materials should be selected to match the requirements of the project. In particular, the following items should be taken into consideration: — cleanliness class — effects of abrasion and shocks — cleaning and disinfection techniques and frequency — chemical or microbiological influences and corrosion — mechanical or physical strength — reduction of electrostatic charging and discharging — interior furnishing, durability and maintainability — smooth, impervious and crevice-free
6	Ensuring air supply cleanliness	Air filter systems should be selected in accordance with the required cleanliness class. Filter standards that apply as appropriate are EN 1822-1 and ISO 29463-1. Three basic stages of particulate air filtration are recommended: — outdoor-air pre-filters, ensuring sufficient quality of supply air to the air-conditioning system — secondary filters in the air-conditioning system for protecting final filters and chemical absorption filter requirements — final filters: HEPA or ULPA filter requirements
7	Interfaces to process planning	The interfaces to other parties involved in planning the overall project should be defined by appropriate means. These may be: — component data sheets — room data sheets — unit specifications — detail drawings
8	Ventilation system design	Design of the ventilation system in the cleanroom: — system layout and process and instrumentation diagram (P&ID) — room and system ventilation list (outdoor air, supply air, exhaust air, extract air, leakage air, overflow air) — climate and flow pressure cascade controls — functional design specification
9	Design parameters	
9.1	Air supply	— air volume flow rate, airflow velocity and uniformity of airflow velocity (in case of UDAF)
9.2	Air distribution system design	— design of the air distribution system in the cleanroom — number and location of air inlets — type of air diffusers — position of air exhausts and returns — temperature difference between incoming and room air

Table B.1 *(continued)*

No.	Item	Description specified
9.3	Flow or pressure cascade	— permitted directional flow — clean areas (outward flow with respect to adjacent less-clean areas) — containment (inward flow with respect to adjacent less-hazardous areas) — pressure differential, including tolerance with respect to adjacent rooms and ambient — instrumentation — alarms
9.4	Monitoring and controls	— real-time online monitoring of conditions in critical zones — automatic controls of room environmental conditions — building management system (BMS)
10	Performance parameters	— airflow rates — outside and/or make-up air proportions — flow or pressure cascade — filter ratings or grades — AHU system pressures — classification — other cleanliness attributes — recovery rate or recovery time — temperature and humidity — noise — lighting — power consumption (operational and turn-down modes)
11	Design verification	Verification should be made to ensure that design and planning fulfils the requirements and includes as a minimum: — cleanroom concept — description of the installation — design drawing of the units — plans, layout, drawing, P&I (process and instrumentation) diagrams — integration of all other agreed systems and functionality

Annex C
(informative)

Guidance on construction

C.1 Construction and assembly of an installation

C.1.1 General

Construction and assembly of an installation should conform with the information and details included in the specifications, drawings and the agreed construction plan. Any changes required during the construction phase should be managed by a documented change control procedure that includes assessment of technical, cost and schedule implications. Changes should be reviewed and approved prior to implementation.

Construction and assembly activities should follow a documented and agreed sequence and schedule.

Procedures to control the entry of unauthorised personnel and a pest control programme may be necessary in the construction area.

The quality of the completed cleanroom, including all exposed surface finishes, should be approved. Consideration should be given to preparing or referencing samples of all critical finishing details to act as a benchmark for inspection and approval of completed works, since these will have a significant impact on the ability of the installation to achieve the required performance throughout the life of the installation.

NOTE Annex C only considers cleanroom contamination-control-related aspects of construction and installation assembly. Other matters concerning health and safety, fire precautions, personnel welfare and hygiene, planning and building controls and other regulatory approvals can also be addressed.

C.1.2 Material management during construction

All components and materials used in the construction and subsequent maintenance of the installation should be appropriately manufactured, packed, transported, stored, protected and inspected before use to ensure their suitability.

The following points should also be considered:

— approved materials should be clearly labelled and be segregated from unapproved materials;

— areas for storage of acceptable and unacceptable or non-conforming materials should be clearly identified to avoid mix-ups;

— rejected, damaged or incorrect materials should be removed as soon as possible.

This guidance can also be applied to locations where materials are manufactured, prepared and stored off-site.

For further information see C.2.

C.1.3 Construction of ceilings, walls and floors

C.1.3.1 Basic requirements

The selection of construction technique, choice of materials and effectiveness of the design details are all intended to ensure finishes are fit for purpose by being smooth, crevice-, crack- and cavity-free, laid

on even surfaces and flush with minimal steps and ledges that can create areas for contamination to collect in.

During construction and assembly special attention should be given to the interfaces between cleanroom surfaces and features, such as door and window frames, light fittings, electrical accessories and ventilation system terminals. Where coving is applied to internal corners (floor-to-wall; wall-to-wall; wall-to-ceiling) the finished surface should be fully supported, smooth, impervious and crevice-free.

Walls, floors and ceilings in cleanrooms and in clean zones should be constructed in such a way that the surfaces are accessible for cleaning. This generally includes the walls, floor, ceilings, windows and doors, the cleanroom side of air diffusers and floor drains.

C.1.3.2 Ceilings

Ceilings should be sealed to prevent ingress of particles or other contaminants from the ceiling void. Filters, filter frames, filter housings and diffusers mounted in the ceiling should be sealed. Penetration points (e.g. for utility services, sprinklers and lighting) should be flush where possible and sealed.

C.1.3.3 Walls and wall systems

Cover strips or seals between panels should be smooth and flush to facilitate efficient cleaning and limit retention of contaminants. Particular attention should be paid to smoothness and effective sealing of penetrations for utility services and any other penetrations.

C.1.3.4 Floors

Construction and expansion joints in the floor structure should be stable and sealed prior to application of the final floor finish.

The constructed flooring complex should ensure the integrity of any intended electrostatic dissipative characteristics.

During the application of final floor finishes, personnel access should be carefully controlled and post installation, prior to handover, the flooring should be protected.

C.2 Clean build protocol

C.2.1 Cleanliness and cleaning during construction

Many tasks involved in the construction and assembly of an installation can generate and allow ingress of contamination. A clean build protocol should be considered during the design phases of the project and be developed and implemented on the construction site. This will assist with achieving the specified contamination control objectives and provide an easier transition from construction and assembly of an installation.

There are three main sources of contamination during construction:

— construction-related activities;

— material that enters from the outside environment;

— material that accumulates due to inadequate cleaning practices and waste removal.

In addition, materials will require protection from damage as they are installed and, as such, the frequency and type of cleaning will change.

The clean build protocol should be appropriate to the final classification of the completed installation and method of construction and assembly. Cleanrooms that are designed to contain aseptic processing operations can require special procedures.

Additional requirements can also be required if the construction occurs in close proximity to operational facilities. See ISO 14644-5.

NOTE For some construction methods, such as masonry with an applied high-performance finish, clean practices cannot be employed until surfaces are sealed.

The following should be common to all protocols:

— The movement of materials onto and off the construction site should be planned and documented during the design phase.

— All waste should be removed from the construction area in a controlled manner as soon as practicable.

— Critical surfaces, such as the interior of ductwork and air-handling systems, equipment and fixture surfaces, should be kept clean and dry, and appropriately protected by wrapping and sealing before installation and connection.

— Subcontractor amenities should be in a designated area. They should be kept clean and orderly at all times.

The arrangement and maintenance of the material set-down area should be documented. At specific stages during the construction or installation process procedures will need to evolve and change as the building site transitions from an open to an enclosed, controlled space. Each new stage generally concludes with the completion of a construction or commissioning element. These stages can include the following:

— external building envelope;

— cleanroom shell, finishes and penetrations;

— building services and ventilation or HVAC;

— final ventilation or pressurization, filters installed, finishing complete;

— commissioning.

At each of these stages, specific procedures will be required for the following:

— Dress disciplines: ranging from industrial work safety wear through to full coveralls and overshoes. Setting apart of contaminated garments and garment disposal. Dress requirements for specific construction zones should be dedicated to that zone and should not be worn outside the protected zones.

— Cleaning methods: these vary depending on the stage and type of construction and the category and quantity of contamination to be removed. For example, the transition from sweeping to vacuum, mopping or wiping should occur when the sweeping action generates as much contamination as is being removed.

— Cleaning frequency: these will increase in scope and intensity as the construction progresses.

For some installations, specific requirements can also include the following:

— Ventilation and pressurization of the construction space: this may be with a temporary portable system or by the use of sacrificial air filters within the installation's HVAC system.

— Temporary screens or walls: to contain the construction site, providing protection for the construction area and separation from any adjacent operations.

— Separation and containment of hazardous activities such as grinding, welding and drilling.

— Airlocks: these are useful as transition zones for critical construction areas where specified dress disciplines are required from the earliest stages and equipment, both temporary and for the intended process, needs to be decontaminated before entry.

— Decontamination zones: a demarcated zone on the edge of the construction zone. It can be a threshold where construction personnel will change footwear or don overboots, or an area where equipment is cleaned before entry into the critical zone.

— Monitoring: if work is being performed on a live site, particle monitoring may be required on the live side of the manufacturing or construction site interfaces. Microbial monitoring may also be required.

C.2.2 Clean build protocol implementation

The clean build protocol should be overseen by an experienced individual. All trades that will be affected by the requirements should be made aware of the protocol and agree to its contents.

The protocol requirements should comprise part of the contractor induction programme. Specific requirements of the protocol, such as cleaning practices, may require input from previous similar experience and additional training.

C.3 Construction personnel

Site inductions (training and instruction) should be given to all relevant personnel with the focus on site safety, cleanroom site behaviour and quality of handiwork.

Due to the criticality of cleanroom performance, a high level of handiwork is required. All works should be supervised by appropriately qualified personnel.

If special gowning is required during cleanroom construction, personnel should be instructed on the correct gowning procedure and those garments should not be worn outside the construction zone.

C.4 Construction verification

Construction verification should be carried out to ensure that the construction and assembly of the installation, its components and execution, including details, conform with the design. This verification will generally be performed at the construction site; however, for pre-assembled components, it may be carried out at the supplier's premises.

The scope of verification should include at least the following items:

a) inspection and testing for the completeness and construction quality of the installation according to the approved design documents;

b) confirmation of surface finishes quality and cleanliness;

c) receipt and approval of materials and test certificates;

d) inspection of all building services, including HVAC, control and monitoring systems;

e) calibration and functional testing of control, monitoring, alert and alarm systems;

f) testing of the cleanroom shell or envelope for pressure integrity and leakage as specified;

g) testing of the duct work for pressure integrity and leakage as specified;

h) receipt of spare parts list;

i) receipt and review of operation and maintenance instructions.

C.5 Checklists regarding construction

The points listed in Table C.1 should be checked for their relevance to the project or process in the construction phase.

Table C.1 — Construction checklist

No.	Item	Confirm that the following have been addressed or provided
1	Before construction	
1.1	Construction plan	— schedule — quality plan — clean build protocol — health and safety plan — access and security
1.2	Schedule	— clean build stages and sequencing — hazardous construction activities — activities with high dirt or waste generation and dispersal — commissioning sequence — testing and inspection phasing — hand-over logistics and mechanisms
1.3	Quality plan	— design revision management — change control management — deviation management (snagging)
1.4	Documentation	— specifications — drawings — approvals — construction site layout and logistics — change control records
1.5	Clean build protocol	— clear management responsibility — materials management – receipts, storage and use — stages of the construction and assembly and associated controls — cleaning — cleanroom-compatible vacuum cleaner — waste removal
1.6	Site preparation	— staff amenities — set-down area — access — waste storage and disposal

Table C.1 *(continued)*

No.	Item	Confirm that the following have been addressed or provided
2	During construction	
2.1	Training and instruction	Consider: — basic cleanroom behaviour education — clean-build-related toolbox meetings — instruction on the identified clean build stages — signposting of applicable stages, clean work permits and gowning instructions
2.2	Access	The location has the following locations with paved access connections: — labour lockers, canteen and restrooms — set-down site for material storage — offloading site of construction materials and equipment — personnel access control — pathways for large equipment installation
2.3	Temporary protection	Coverings for: — finished architectural surfaces (e.g. walls, floors, ceilings, doors, windows) — openings — unfinished mechanical and electrical services (e.g. ducting, pipework, inlets and outlets) — equipment
2.4	Prototype	Creation of a sample reference room to provide a quality benchmark of the materials, construction quality and execution of details.
2.5	Temporary segregation	The short-term provision of: — temporary walls — temporary ventilation systems, including air filtration if necessary
2.6	Temporary functionality	— sacrificial construction phase air filters in ventilation systems
2.7	Building services	— scope and sequence of connection to utilities and testing — scope and sequence of start-up and testing HVAC
2.8	Energy management	— minimize construction activities that consume excessive energy
3	Completion of construction	
3.1	Final clean stage	— access and dress discipline requirements — multi-stage cleaning instructions — responsibilities — assessment of stage cleanliness criteria and procedure
3.2	Documentation	— operation and maintenance manuals — change control documentation — as-built drawings — verifications — approvals

Annex D
(informative)

Guidance on start-up

D.1 General

Start-up comprises a series of activities planned, organized and executed in a logical order to take the installation from the fully built and constructed or assembled state into operation. The activities should include documented inspections, tests and measurements to provide evidence that verifies satisfactory functional operation and finally verifies that the performance satisfies all the user requirements originally defined.

The activities described in this annex are pre-commissioning and commissioning culminating in operational verification and finally performance verification. Alternative strategies can be used to achieve the same objectives. The scope and scale of start-up activity should be commensurate with the size, complexity and novelty of the installation.

This annex specifically considers the engineering systems that directly affect control of cleanliness (cleanroom fabric and air-handling systems). It should be recognized that start-up practices, including engineering commissioning, equally apply to all the mechanical and electrical systems that support and enable the installation to operate. These are out of the scope of this document.

D.2 Pre-commissioning

The construction and assembly of the installation activities should be completed and all the necessary construction verification tasks executed and approved prior to starting commissioning.

Prior to the fitting of final and/or terminal filters all ducts, walls, ceilings, floors and installed fittings should be clean.

Controls, monitoring and automation systems should be functionally checked and tested (e.g. calibration of instruments, confirm correct function of control loops and actuators).

Mechanical systems should be functionally checked and tested (e.g. drive belt tension, motor rotation).

Visual inspections of the area should be undertaken to ensure potential leakage paths are sealed.

D.3 Commissioning

D.3.1 General

The commissioning activities apply to all mechanical and electrical services, equipment and systems required to support the operation of the cleanroom installation.

D.3.2 Setting to work

The systems and equipment required to support the installation are systematically started and their operational performance parameters established by undertaking a series of measurements and adjustments carried out until the installation is operating in a stable condition and in accordance with its agreed specification.

Upon completion of the setting to work phase, a documented set of test result data and associated test report should be issued as evidence that specified performance parameters have been achieved. Tests should be of sufficient duration to demonstrate consistent performance.

It is expected that a final set of measured values are recorded and documented. These final values may be used as part of the functional verification.

D.3.3 Verification

D.3.3.1 General

In order to demonstrate that an installation has been completed, is properly constructed and assembled and performs to meet all contamination control requirements, a specific range of inspections and tests should be carried out on the installation at key stages. These are functional verifications upon the completion of the setting to work phase and performance verification as a final step.

D.3.3.2 Functional verification

Upon completion of the setting to work phase a set of functional tests should be executed to confirm satisfactory technical function of the installation. ISO 14644-3 provides guidance on sequencing and testing as well as reference test methods and test instrument specifications. The following tests are typically carried out as part of functional verification:

a) door interlock function and timing;

b) supply air volume flow rate in non-UDAF systems;

c) air velocity in UDAF systems;

d) air-handling systems pressure drops;

e) room pressure differentials;

f) in situ HEPA filter leak test;

g) containment leak test;

h) electrostatic ion generator test;

i) temperature and humidity test;

j) noise and light levels;

k) failure modes tests (fan interlocks, stand-by systems);

l) energy consumption and efficiency evaluation – operational and turn-down (see ISO 14644-16).

D.3.3.3 Performance verification

Upon completion of setting to work and functional verification phases, a set of performance tests should be executed to confirm satisfactory performance of the installation in maintaining required cleanliness classes and levels. ISO 14644-1, ISO 14644-3, ISO 14644-8, ISO 14644-9, ISO 14644-10 and ISO 14644-17 provide guidance on the testing as well as reference test methods and test instrument specifications. The following tests are typically carried out as part of performance verification:

a) air cleanliness classification by particle concentration (see ISO 14644-1);

b) surface cleanliness level at critical control points by particle concentration (see ISO 14644-9);

c) air cleanliness level at critical control points by chemical concentration (see ISO 14644-8);

d) surface cleanliness level at critical control points by chemical concentration (see ISO 14644-10);

e) particle deposition rate (see ISO 14644-17);

f) airborne particle recovery time in non-UDAF systems (see ISO 14644-3);

g) airflow visualization (see ISO 14644-3).

NOTE Air and surface microbial cleanliness can also be assessed, if a required cleanliness attribute of the installation. EN 17141 provides guidance on bio-contamination control.

D.4 Start-up documentation

The reports of the start-up, including pre-commissioning, commissioning and verifications, should be documented and approved. The documentation should include:

a) supplier's commissioning and test documentation;

b) calibration certificates of instrumentation used;

c) relevant as-installed drawings and details;

d) all commissioning and verification results;

e) witnessed verification of conformity with design specification;

f) test report information as specified in ISO 14644-1, ISO 14644-3, ISO 14644-8, ISO 14644-9, ISO 14644-10 and ISO 14644-17.

D.5 Checklists regarding start-up

The points listed in Table D.1 should be reviewed for their relevance to the project or process in the start-up phase.

Table D.1 — Start-up checklist

No.	Item	Description specified
1	Preparing for commissioning	
1.1	Documentation	The following supporting documentation should be available: — drawings — schematics — agreed commissioning format or reporting template — clean build protocol (at the appropriate stage) — approved completed construction verification — system start-up, shutdown and turn-down procedures
1.2	Construction completeness	The following should be confirmed as completed: — construction integrity — ductwork pressure testing — supporting utilities connected — ductwork cleaning — cleanroom cleaned

Table D.1 *(continued)*

No.	Item	Description specified
1.3	Design parameters	Required performance parameters to be checked at start-up: — airflow rates — outside and/or make-up air proportions — flow or pressure cascade — filter ratings or grades — AHU system pressures — classification — recovery rate — other cleanliness attributes — temperature and humidity — noise — lighting
1.4	Access and resources	The following should be confirmed as in place: — safe access to areas, plant and equipment — necessary permits — relevant system isolations — sufficient resources of competent personnel — appropriate material and equipment — calibrated measuring instruments — warning signage — access restrictions
1.5	Planning	The following should be identified or obtained: — list of commissioning activities — logical sequence of tasks or programme — responsibilities — supporting operating manuals — witnessing arrangements — timing of cleaning activities — preliminary maintenance programme

Table D.1 *(continued)*

No.	Item	Description specified
2	Commissioning	
2.1	Execution of commissioning	The following should be available during and after commissioning: — agreed stages of sign off — collated commissioning documentation for AHU, HVAC, utilities, control system, associated integrated equipment — filter manufacturer test certificates — start-up and shutdown procedures — control system set points and actual operating performance (comparison) including turn-down — actual system spare capacity — calibration of critical instrumentation — commissioning approval
2.2	Execution of verification	See D.3.2
3	Handover	Considerations for handover: — commissioning records (completed and approved setting to work and performance verification) — operating and maintenance manuals — critical spare parts list — instrument list and calibration schedule — maintenance programme — training programme and records — competency of trainers — detailed planned preventative maintenance procedures and programme

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