
Cleanrooms and associated controlled environments —

**Part 4:
Design, construction and start-up**

Salles propres et environnements maîtrisés apparentés —

Partie 4: Conception, construction et mise en fonctionnement



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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

Attention is drawn to the possibility that some of the elements of this part of ISO 14644 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14644-4 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

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

- *Part 1: Classification of air cleanliness*
- *Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*
- *Part 3: Metrology and test methods*
- *Part 4: Design, construction and start-up*
- *Part 5: Operations*
- *Part 6: Vocabulary*
- *Part 7: Separative enclosures (clean air hoods, glove boxes, isolators, mini-environments)*

Users should note that the titles listed for parts 3 and 5 to 7 are working titles at the time of the release of part 4. In the event that one or more of these parts are deleted from the work programme, the remaining parts may be renumbered.

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

Introduction

Cleanrooms and associated controlled environments provide for the control of airborne particulate 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 and healthcare.

This part of ISO 14644 specifies the requirements for the design and construction of cleanroom facilities. It is intended for use by purchasers, suppliers and designers of cleanroom installations and provides a check list of important parameters of performance. Construction guidance is provided, including requirements for start-up and qualification. Basic elements of design and construction needed to ensure continued satisfactory operation are identified through the consideration of relevant aspects of operation and maintenance.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and associated subjects. Many factors besides design, construction and start-up should be considered in the operation and control of cleanrooms and other controlled environments. These are covered in some detail in other International Standards prepared by ISO/TC 209.

Cleanrooms and associated controlled environments

Part 4: Design, construction and start-up

1 Scope

This part of ISO 14644 specifies requirements for the design and construction of cleanroom installations but does not prescribe specific technological or contractual means to meet these requirements. It is intended for use by purchasers, suppliers and designers of cleanroom installations and provides a checklist of important parameters of performance. Construction guidance is provided, including requirements for start-up and qualification. Basic elements of design and construction needed to ensure continued satisfactory operation are identified through the consideration of relevant aspects of operation and maintenance.

NOTE Further guidance in respect of the above requirements is given in annexes A to H. Other parts of ISO 14644 may provide complementary information.

Application of this part of ISO 14644 is restricted in the following:

- user requirements are represented by purchaser or specifier;
- specific processes to be accommodated in the cleanroom installation are not specified;
- fire and safety regulations are not considered specifically; the appropriate national and local requirements should be respected;
- process media and utility services are only considered with respect to their routing between and in the different zones of cleanliness;
- regarding initial operation and maintenance, only cleanroom construction-specific requirements are considered.

2 Normative references

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

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

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

ISO 14644-3:— ¹⁾, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods.*

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

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

ISO 14698-3:— ¹⁾, *Cleanrooms and associated controlled environments — Biocontamination control — Part 3: Measurement of the efficiency of processes of cleaning and/or disinfection of inert surfaces bearing biocontaminated wet soiling or biofilms.*

3 Terms and definitions

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

3.1

changing room

room where people using a cleanroom may change into, or out of, cleanroom apparel

3.2

clean air device

stand-alone equipment for treating and distributing clean air to achieve defined environmental conditions

3.3

cleanliness

condition of a product, surface, device, gas, fluid, etc. with a defined level of contamination

NOTE Contamination can be particulate, non-particulate, biological, molecular or of other consistency.

3.4

commissioning

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

3.5

contaminant

any particulate, molecular, non-particulate and biological entity that can adversely affect the product or process

3.6

non-unidirectional airflow

air distribution where the supply air entering the clean zone mixes with the internal air by means of induction

3.7

particle

minute piece of matter with defined physical boundaries

NOTE For classification purposes refer to ISO 14644-1.

3.8

pre-filter

air filter fitted upstream of another filter to reduce the challenge on that filter

¹⁾ To be published.

3.9

process core

location at which the process and the interaction between the environment and the process occurs

3.10

start-up

act of preparing and bringing an installation into active service, including all systems

EXAMPLE Systems may include procedures, training requirements, infrastructure, support services, statutory undertakings requirements.

3.11

unidirectional airflow

controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel streamlines

NOTE This type of airflow results in a directed transport of particles from the clean zone.

4 Requirements

4.1 The parameters listed in 4.2 to 4.18 shall be defined and agreed between purchaser and supplier:

NOTE In the requirements stated below, references are made to annexes A to H which are for information only.

4.2 The number, edition and date of publication of this part of ISO 14644 shall be given.

4.3 The role of other relevant parties to the project (e.g. consultants, designers, regulatory authorities, service organizations) shall be established (see examples in annex C).

4.4 The general purpose for which the cleanroom is to be used, the operations to be carried out therein and any constraint imposed by the operating requirements (see examples in annexes A, B and D).

4.5 The required airborne particulate cleanliness class or demands for cleanliness in accordance with the relevant International Standard (ISO 14644-1, ISO 14698-1, ISO 14698-2 and ISO 14698-3) (see examples in annex B).

4.6 The critical environmental parameters, including their specified set points, alert and action levels to be measured to ensure compliance, together with the measurement methods to be used, including calibration (ISO 14644-2 and ISO 14644-3) (see examples in annex F).

4.7 The contamination control concept, including installation, operating and performance criteria, to be used to achieve the required cleanliness level (see examples in annex A).

4.8 The methods of measurement, control, monitoring and documentation required to meet the parameters agreed (see examples in annexes C and F).

4.9 The entry or exit of equipment, apparatus, supplies and personnel required to support the installation (see examples in annex D).

4.10 The specified occupancy states selected from "as-built", "at-rest" and "operational" under which the required parameters shall be achieved and maintained including variations with time, and the methods of control (see examples in annex C).

4.11 The layout and configuration of the installation (see examples in annex D).

4.12 Critical dimensions and mass restrictions, including those related to available space (see examples in annex D).

- 4.13** The process and product requirements that affect the installation (see examples in annexes B and G).
- 4.14** The process equipment list with utility requirements (see examples in annexes D, E and H).
- 4.15** The maintenance requirements of the installation (see examples in annexes D and E).
- 4.16** The assignment of tasks for the preparation, approval, execution, supervision, documentation, statement of criteria, basis of design, detailed design, construction, testing, commissioning and qualification (including the performance and witnessing) of tests (see examples in annexes E and G).
- 4.17** The identification and evaluation of external environmental influences (see examples in annex H).
- 4.18** Additional information required by the particular application (see examples in annex H).

5 Planning and design

5.1 Planning procedure

5.1.1 A project plan shall be developed, in consultation with the user and all other involved parties, to define the requirements of the products, the processes and the scope of the installation.

5.1.2 In order to determine the needs of an installation, a process equipment list shall be compiled, and shall include the critical requirements for each piece of process equipment.

5.1.3 Diversity factors shall be defined, considering peak and average demand for each utility and environmental control system.

NOTE A system may include multiple subsystems which require individual diversity-factor determination.

5.1.4 A contamination control concept shall be developed for each zone of an installation (see examples in annex A).

5.1.5 The specifications as defined in clause 4 shall be reviewed and refined based on financial and timescale requirements.

5.1.6 The project plan shall include the following elements:

- a) design documentation with support calculations;
- b) cost evaluation;
- c) timescale evaluation;
- d) an outline of anticipated project complications;
- e) design options with records of advantages and disadvantages and any recommendations;
- f) a review of maintenance requirements of the installation;
- g) a review of the degree of flexibility to be included in the installation;
- h) a review of the stand-by capacities to be included in the installation;
- i) a review of the constructability of the design of the installation;
- j) a quality plan.

The use of a quality system, such as the ISO 9000 family of international standards (e.g. ISO 9000 and ISO 9001), should be considered, in conjunction with industry-specific quality assurance strategies.

5.1.7 The completed project plan shall be reviewed and agreed upon between purchaser and supplier.

5.2 Design

5.2.1 The design shall accommodate all of the relevant product and process requirements in conjunction with the selected contamination control concept (see examples in annex A).

5.2.2 The purchaser and supplier shall formally accept the design in accordance with predetermined acceptance criteria.

5.2.3 The design shall conform to an agreed list of requirements, such as building, environmental and safety regulations, good manufacturing practice guidelines (e.g. ISO 14001 and ISO 14004).

The design should be reviewed at periodic stages of development, including final completion, to ensure compliance with the specifications and the acceptance criteria.

6 Construction and start-up

6.1 Construction of an installation shall comply with the drawings and specifications.

6.2 Any changes required during the course of construction shall be checked for acceptance, approved and documented prior to implementation of the change in accordance with a change control procedure.

6.3 Construction work, whether performed at a manufacturing location or *in situ*, shall observe the specific contamination control requirements of the quality plan.

6.4 A clean construction protocol and cleaning procedures shall be developed as part of the quality plan and enforced to achieve the specified contamination control requirements. Security and access control is essential to maintain the clean construction protocol.

6.5 The cleaning methods and methods to determine and approve the achieved cleanliness shall be defined and documented in the quality plan.

6.6 The cleaning of the air systems shall be specified and shall be carried out at assembly, before initial operation and whenever rebuilding work, repair work and maintenance work are performed.

6.7 In the case of start-up of new installations or re-starting existing installations after repair or modification, final cleaning of the cleanroom is necessary and provisions shall be made for the removal of adherent, imported or released contamination.

6.8 Before commencing any operational activities, the complete and satisfactory function of the installation shall be determined by tests carried out in accordance with clause 7.

NOTE In the case of packaged units, such as clean air devices, a manufacturer's certificate of compliance with the requirements of this part of ISO 14644 may be sufficient, provided that the supplier is qualified (i.e. knowledgeable of or competent in cleanroom requirements) and the risk of damage during transport, storage and installation can be controlled adequately.

6.9 During acceptance testing, commissioning and initial operation, the personnel in charge of the installation shall be trained. Testing, approval of the installation and training shall include all relevant practices for proper cleanroom operation, maintenance and in-process control. The responsibility for providing training shall be defined.

When training is carried out, all relevant persons such as operators, maintenance and service personnel should be included.

7 Testing and approval

7.1 General

During and upon completion of the construction of an installation, an agreed series of documented tests shall be specified and undertaken prior to operational use of the installation. Annex C gives examples of the design, testing and approval processes.

7.2 Construction approval

A systematic range of inspections, adjustments, measurements and tests shall be carried out to ensure that each part of the installation complies with the design requirements.

7.3 Functional approval

A series of tests and measurements shall be carried out to determine that all parts of the installation operate together to achieve the required conditions in the "as-built" or "at-rest" states.

7.4 Operational approval

A series of tests and measurements shall be carried out to determine that the complete installation achieves the required "operational" performance with the specified process or activity functioning, and with the specified number of personnel present working in the agreed manner.

8 Documentation

8.1 General

Details of a completed installation (including instrumentation calibration) and all operation and maintenance procedures shall be documented. Documents shall be made readily available to all personnel responsible for start-up, operation and maintenance of the installation.

Such personnel should fully understand the documentation.

8.2 Record of an installation

Details of the completed installation shall be provided and shall contain:

- a) a description of the installation and its function;
- b) a set of final and approved performance test data, derived from the tests carried out in accordance with clause 7 of this part of ISO 14644, recording the values of all conditions defined in the specification for the installation and achieved during the commissioning, testing and start-up procedures;
- c) a set of drawings, diagrams (e.g. layout of wiring, piping and instrumentation) and specifications describing the completed and approved "as-built" installation and its components;
- d) a list of parts and equipment and any recommendation for stocking spare parts.

8.3 Operational instructions

Each installation or system shall be provided with a clear set of operating instructions. Such operating instructions shall contain:

- a) schedules of checks and inspections to be completed prior to the start-up of an installation;

- b) schedules of the acceptance range of the critical performance parameters specified;
- c) procedures to start and stop the installation under normal and failure mode situations;
- d) procedures to be adopted in the event of alert or action levels being reached.

8.4 Instructions for performance monitoring

Performance-monitoring of an installation is essential to demonstrate satisfactory operation. Documentation shall include:

- a) test and measurement frequency;
- b) description of test and measurement methods, (or reference to standards and guidelines);
- c) action plan in the event of non-compliance;
- d) frequency required for assembly, analysis and retention of performance data to enable trends to be analysed.

8.5 Maintenance instructions

Maintenance shall be implemented in accordance with a specified method and programme.

Maintenance and repairs shall be carried out during the construction, commissioning, testing, start-up and normal operation of an installation. The following items shall be considered:

- a) definition of safety procedures prior to carrying out maintenance or repairs;
- b) specification of maintenance actions to be taken when the acceptance range of any critical performance parameter is exceeded;
- c) agreed definition of permitted adjustments;
- d) methods of making permitted adjustments;
- e) methods of checking and calibrating control, safety and monitoring devices;
- f) requirements for checking and replacing all wearing parts (e.g. driving belts, bearings, filters);
- g) specification for cleaning of the installation or components prior to, during and after maintenance work;
- h) definition of actions, procedures and tests required after maintenance is completed;
- i) inclusion of any user-specific or relevant regulatory authority requirements.

8.6 Maintenance record

A documented record of any maintenance carried out upon the installation during construction, commissioning and start-up shall be maintained. The following items shall form part of the record:

- a) definition of the maintenance tasks;
- b) identification and approval of personnel undertaking the maintenance;
- c) date of carrying out the maintenance;
- d) a condition report prior to undertaking the maintenance;

- e) a list of spare parts used;
- f) a report upon completion of the maintenance.

8.7 Record of operation and maintenance training

A documented record of training shall be maintained. The following items shall form part of the record:

- a) definition of the training content;
- b) identification of personnel providing and receiving the training;
- c) training date and duration;
- d) a report upon each period of training as it is completed.

Annex A (informative)

Control and segregation concepts

A.1 Contamination control zones

For economic, technical and operational reasons, clean zones are often enclosed or surrounded by further zones of lower cleanliness classification. This can allow the zones with the highest cleanliness demands to be reduced to the minimum size. Movement of material and personnel between adjacent clean zones gives rise to the risk of contamination transfer, therefore special attention should be paid to the detailed layout and management of material and personnel flow.

Figure A.1 illustrates an example of a contamination control concept. In this configuration, the clean zone would be regarded as a more stringently controlled portion of the cleanroom.

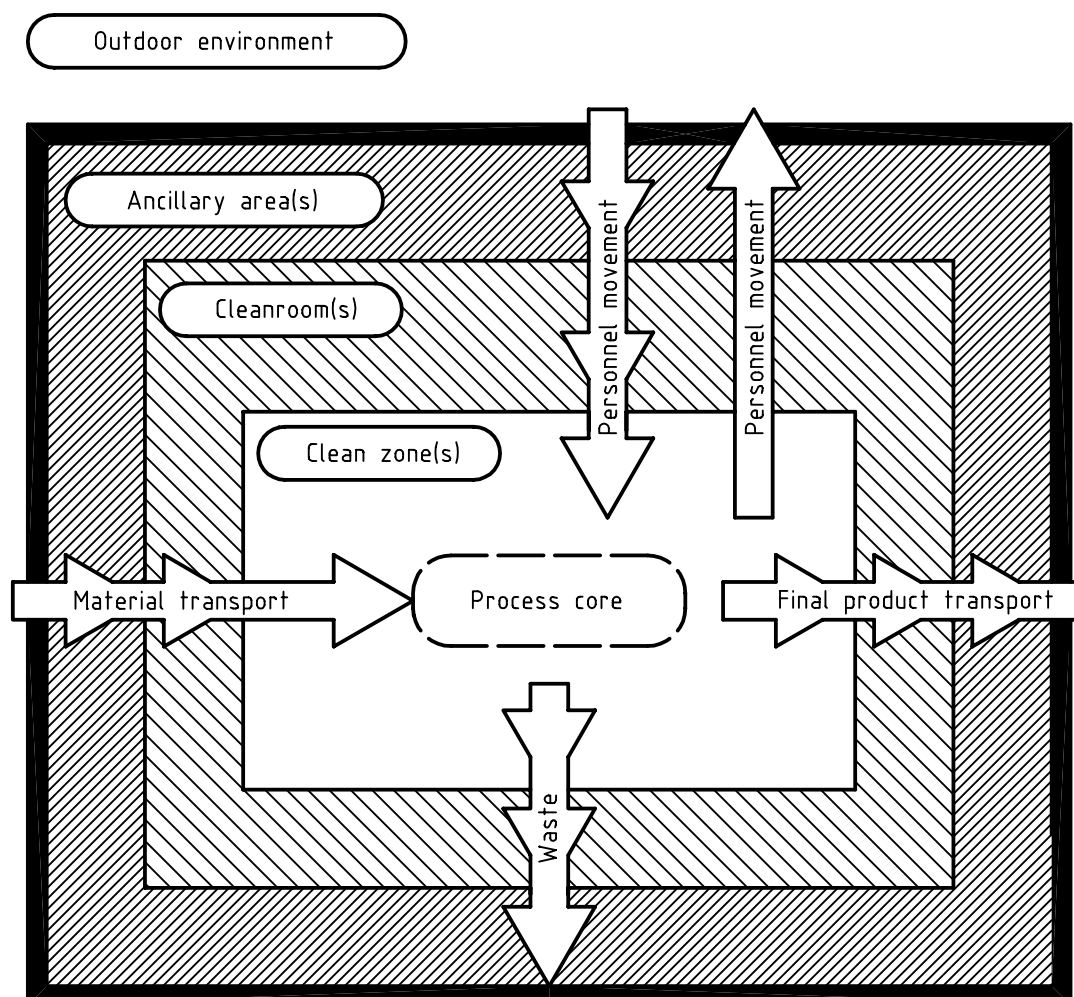


Figure A.1 — Shell-like contamination control concept

A.2 Airflow patterns

A.2.1 Cleanroom airflow patterns can be categorized as either unidirectional or non-unidirectional. When a combination of the two is used it is frequently called mixed airflow. Airflow patterns for cleanrooms of ISO Class 5 and cleaner in operation are often unidirectional, while non-unidirectional and mixed flow is typical for cleanrooms of ISO Class 6 and less clean in operation.

A.2.2 Unidirectional airflow may be either vertical or horizontal (see Figure A.2). Both types of unidirectional airflow rely upon a final filtered air supply and air return inlets which are nearly opposite one another in order to maintain the airstream in as straight a flow pattern as possible. In both designs, the important design feature is the ability to ensure that the airflow pattern is disrupted as little as possible at the process core.

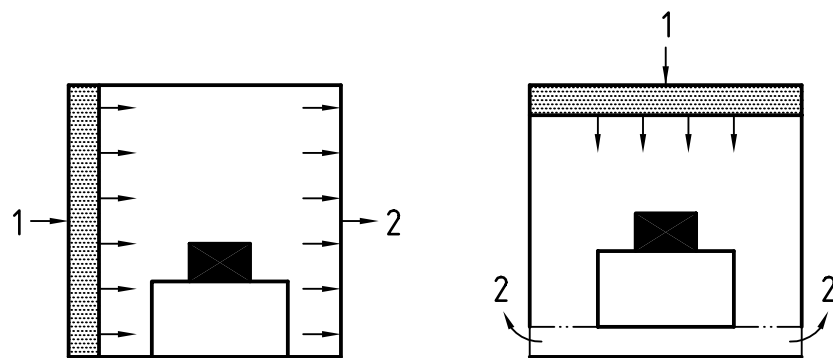
In a working plane perpendicular to the clean airflow, all positions offer the same cleanliness level. Hence, horizontally integrated or distributed processes require vertical airflow and vertically integrated processes require horizontal airflow. Working positions immediately adjacent to the clean air supply offer optimal contamination control conditions, because working positions downstream of these positions may be subject to particles generated upstream. Personnel placement should be therefore downstream of clean processing.

A.2.3 In non-unidirectional airflow cleanrooms, air flows from filter outlets located in multiple positions distributed across the inlet plane and is returned through remote locations. Filter outlets may be distributed at equal intervals throughout the cleanroom or clean zone or grouped over the process cores. The location of filter outlets is important for the cleanroom performance. The final filter location may be remote, but special precautions should be taken to avoid contamination ingress between these filters and the cleanroom (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 decontamination procedures). While return air locations in non-unidirectional airflow systems are not as critical as those in unidirectional applications, care should be taken to distribute the returns, as is done with the supplies, to minimize dead zones within the cleanroom.

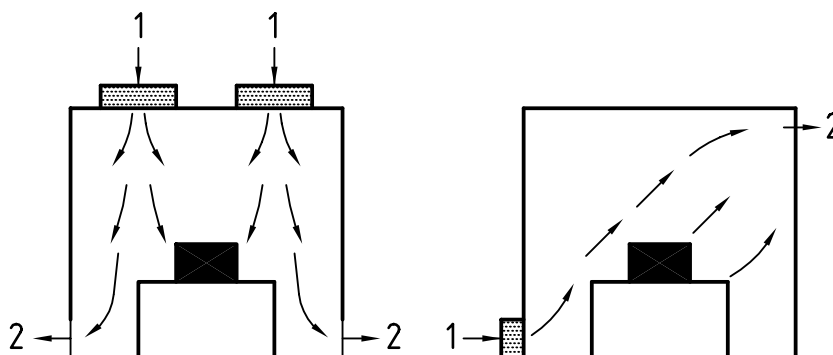
A.2.4 Mixed-airflow cleanrooms combine both unidirectional and non-unidirectional airflow in the same room.

NOTE Some special designs are available that provide protection to specific working zones by other managed airflow techniques.

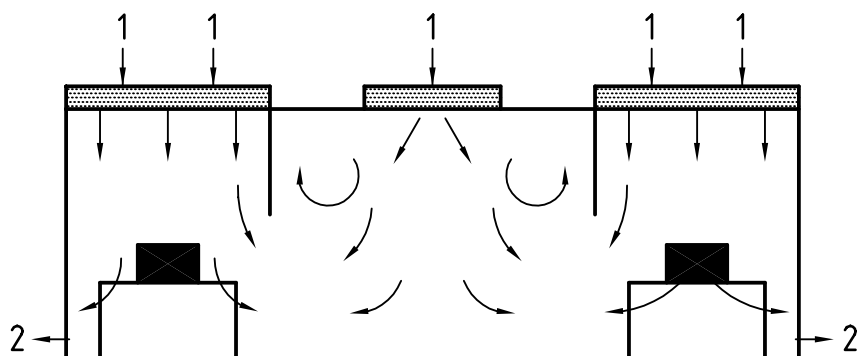
Figure A.2 gives examples that illustrate the different airflow patterns in cleanrooms. (Thermal effects are not considered.)



a) Unidirectional airflow



b) Non-unidirectional airflow



c) Mixed airflow

Key

- 1 Supply air
- 2 Return air

Figure A.2 — Airflow patterns in cleanrooms

A.3 Disturbance of unidirectional airflow

In unidirectional airflow cleanrooms, the design of physical obstacles such as the process equipment, and the operating procedures, personnel movements and product handling, should consider basic aerodynamic requirements to prevent serious turbulence in the vicinity of the contamination-sensitive activity. Appropriate measures should be taken to avoid flow disturbances and cross-contamination between different work stations.

Figure A.3 shows the influence of physical obstacles (on the left) and appropriate measures for minimizing the impact of these (on the right).

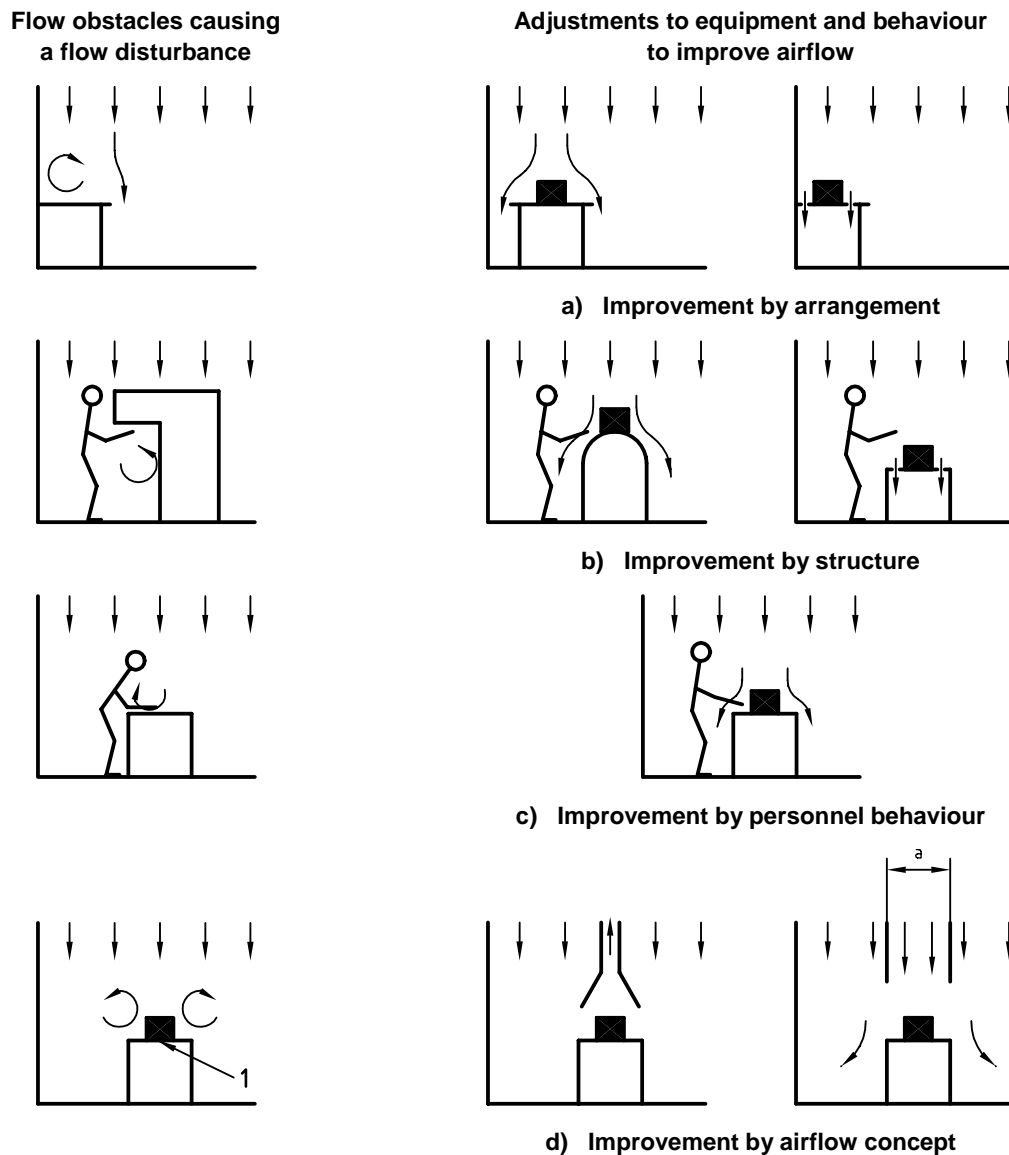


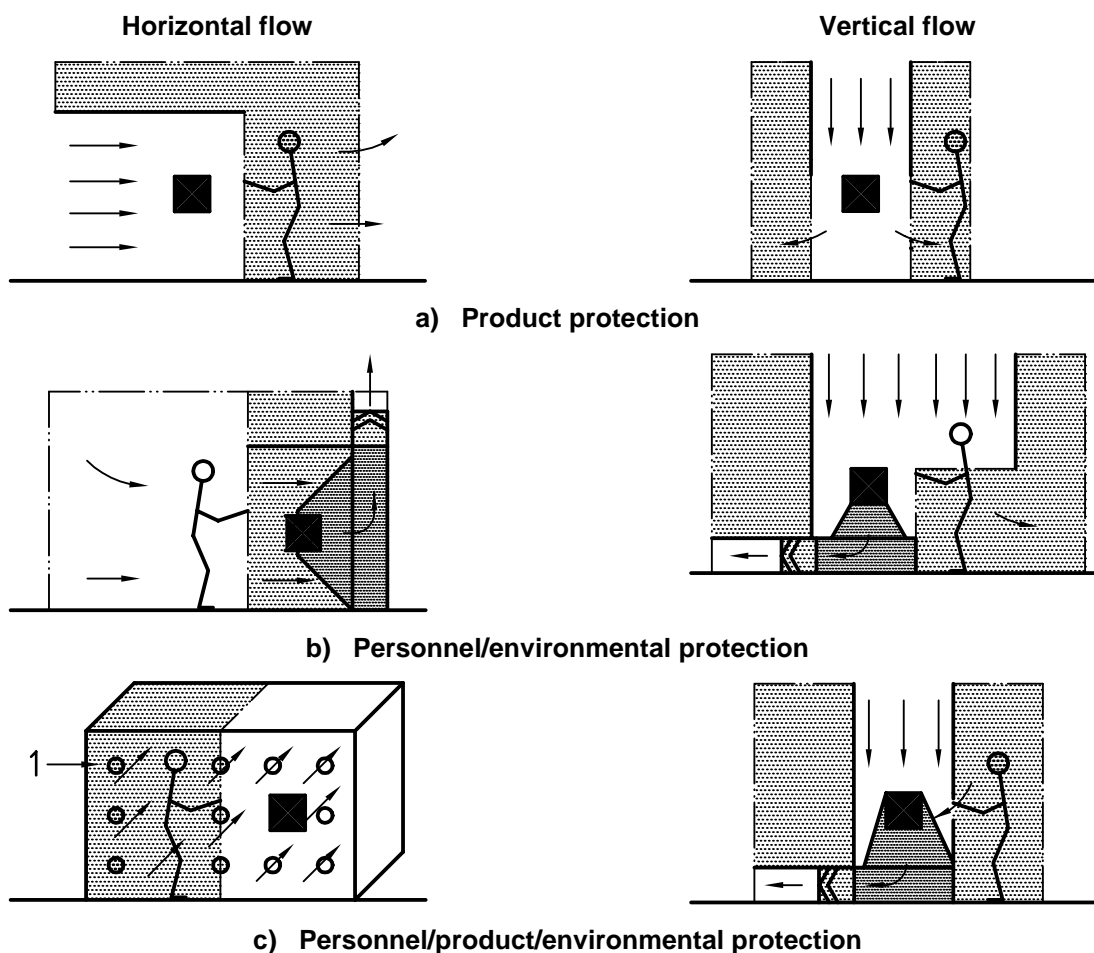
Figure A.3 — Influence of personnel and objects on unidirectional airflow

A.4 Contamination control concepts

To select the proper technique for a given contamination control problem, Figures A.4 and A.5 show some different contamination control concepts that may be considered.

The transfer of contaminants into a zone protecting a process and/or personnel can be prevented by using aerodynamic measures, i.e. by arrangement and flow direction (Figure A.4), or by physical barriers, i.e. by both active and passive isolation (Figure A.5), if any contact between product and operator/environment is to be prevented.

If necessary, process exhaust should be treated to prevent contamination of outdoor environment.



NOTE In particular cases (e.g. dry atmosphere, shielding and protecting gas or extreme temperatures), the gas flow routing chosen should be adapted to the process.

Figure A.4 — Contamination control concepts using aerodynamic measures

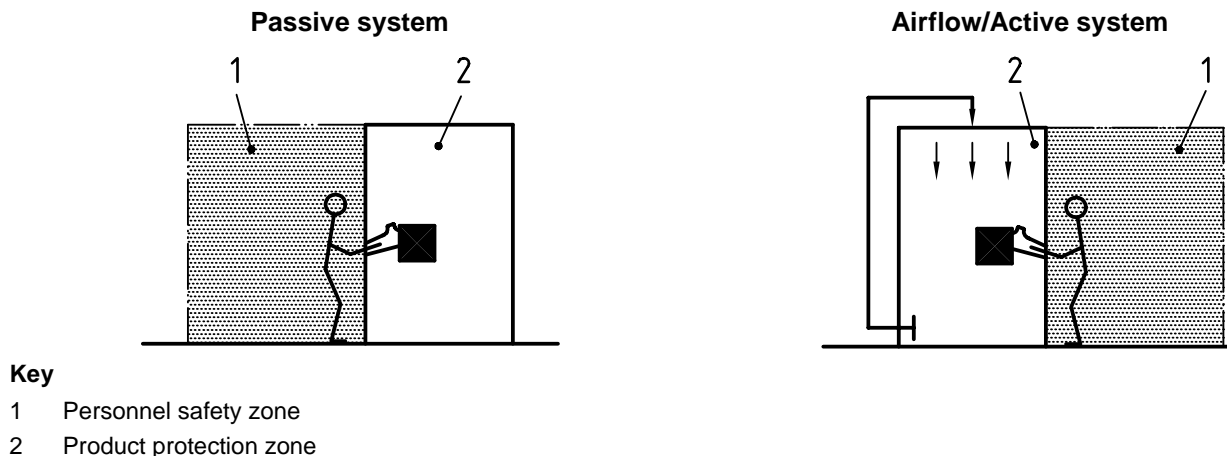


Figure A.5 — Contamination control concepts using physical segregation for product and personnel protection

A.5 Concepts to achieve segregation of cleanrooms and clean zones

A.5.1 General

A suite of cleanrooms can consist of multiple rooms with different requirements for contamination control. The objective of the design can be to protect the product or process, or to contain the product, and in some cases a combination of these requirements. In order to protect cleanrooms from contamination from adjacent less clean spaces, the cleanroom should be maintained at a higher static pressure than the adjacent spaces, or alternatively a controlling air velocity should be established across the leakage paths between the spaces flowing from the cleaner to the less clean space. The converse can be applied to contain a hazard. In both cases, an impervious physical barrier can be used as an alternative.

The quantity of make-up air should be sufficient for ventilation purposes and to compensate for the leakage of air from the boundary of the cleanrooms or clean zones and any exhaust air for other purposes.

The following comparison of three basic concepts has been prepared to facilitate the selection of a suitable cleanroom or clean zone segregation concept.

A.5.2 Displacement concept (low pressure differential, high airflow)

A low pressure differential can effectively separate clean and less clean adjacent zones, i.e. by means of a low turbulent "displacement" airflow, e.g. larger than 0,2 m/s (see Figure A.6).

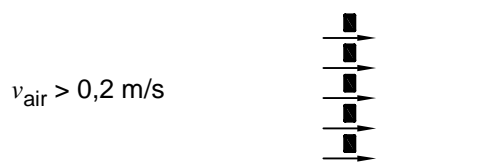


Figure A.6 — Displacement concept

Displacement airflow velocity should be typically above 0,2 m/s, from the cleaner zones towards the less clean zones. The necessary airflow velocity should be selected considering important conditions such as physical obstacles, heat sources, exhausts and contamination sources.

A.5.3 Pressure differential concept (high pressure differential, low airflow)

A pressure differential exists across the barrier between the cleaner zone towards the less clean zone. A high pressure differential between adjacent zones can be easily controlled but care is recommended to avoid unacceptable turbulence (see Figure A.7).

The pressure differential should be of sufficient magnitude and stable to prevent reversal of airflow direction from that intended. The pressure differential concept should be carefully considered, whether used alone or in combination with other contamination control techniques and concepts.

The pressure differential between adjacent cleanrooms or clean zones of different cleanliness level should lie typically in the range of 5 Pa to 20 Pa, to allow doors to be opened and to avoid unintended cross-flows due to turbulence.

The static pressure between cleanrooms of different class, and cleanrooms and unclassified areas can be established and maintained using various airflow balancing techniques. These include both active/automated and passive/manual systems that are configured to adjust the relative quantities of air that are delivered and removed from each space by the ducted air system, air transfer system and losses.

In situations when pressure differentials at the lower end of this range are accepted, special precautions should be taken to ensure accurate measurement of separating flow or pressure and to prove the stability of the installation.

NOTE Flow visualization, either experimentally or by computation, can be used to demonstrate both the effectiveness of the displacement flow concept and the pressure differential concept.

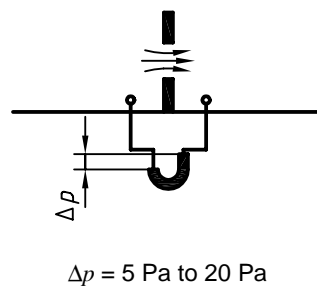


Figure A.7 — High pressure differential concept

A.5.4 Physical barrier concept

This concept involves the use of an impervious barrier to prevent contamination transfer to a clean zone from a less clean zone.

NOTE All three concepts can be applied in the healthcare products, semiconductor, food and other industries.

Annex B (informative)

Classification examples

B.1 Healthcare products

For the manufacture of healthcare products, a frequently used correlation of typical manufacturing applications and cleanroom classification levels is given (see Table B.1). At the process core, the sterile product is filled through an aseptic assembly of components in a clean zone, controlled for particulate and microbiological contamination.

To access the process core, both the personnel and the process materials traverse several shells of increasing cleanliness (decreasing particulate concentrations). Personnel moving between various zones of different levels of cleanliness may change garments between zones, in accordance with the requirements of the zone that they are entering. Materials that enter each zone should be treated in a method appropriate to the level to be entered to remove particulate and/or microbiological contamination.

Table B.1 — Cleanroom examples for aseptic processing of healthcare products

Air cleanliness class (ISO Class) in operation ^a	Airflow type ^b	Average, airflow velocity ^c m/s	Examples of applications
5 (at $\geq 0,5 \mu\text{m}$)	U	> 0,2	Aseptic processing ^d
7 (at $\geq 0,5 \mu\text{m}$)	N or M	na	Other processing zones directly supporting aseptic processing
8 (at $\geq 0,5 \mu\text{m}$)	N or M	na	Support zones of aseptic processing, including controlled preparation zones

NOTE 1 Application-specific classification requirements should take into account other relevant regulations.

NOTE 2 na = not applicable

^a Occupancy states associated with the ISO Class should be defined and agreed in advance of establishing optimum design conditions.

^b When airflow type is listed, it represents the airflow characteristics for cleanrooms of that class: U = unidirectional; N = non-unidirectional; M = mixed (combination of U and N).

^c Average airflow velocity is the way that unidirectional airflow in cleanrooms is usually specified. The requirement on unidirectional airflow velocity will depend on specific application factors such as temperature, and configuration of the controlled space and the items to be protected. Displacement airflow velocity should be typically above 0,2 m/s.

^d Where operator protection is required to ensure safe handling of hazardous materials, the use of segregation concepts (see examples in annex A) or appropriate safety cabinets and devices should be considered.

B.2 Microelectronics

In the microelectronics industry, the minimum device feature size or film thickness dictates the target level of contamination control and the corresponding cleanliness class.

The cleanliness class with the lowest particle concentration is often selected with reference to the critical particle size. The critical particle size (often assumed to be 1/10th of the minimum feature size) is used to help select the required cleanliness classification for the cleanroom.

Determination of cleanroom or clean zone cleanliness for different process cores is based upon the probability of contamination and the potential for device failure.

For example, **photolithography** is a process which involves exposure of wafers to the environment with a high probability of contamination and also a very high potential for device failure when contamination occurs. Accordingly, protection in microelectronics for this type of risk often involves the use of physical barriers which protect process cores in order to lower particle concentrations or alter other process parameters (e.g. temperature, humidity, pressure).

Work zones are zones where wafers or die are handled by people and/or automated handling equipment, and the potential for contamination is high if the product is directly exposed to the environment. The most common responses for the protection of the product within work zones involve unidirectional flow, minimizing occupancy and production load per cubic meter of cleanroom, segregating personnel from exposed product(s) increasingly including barrier techniques. Work zones are most commonly separated from adjacent, less critical zones, by physical barriers and airflow.

Utility zones are zones where the non-operator interface portions of the wafer processing equipment are typically located. In the utility zones it is typical that work in progress is not exposed to the environment. The utility zone of a process core is usually adjacent to its corresponding work zone.

Service zones are zones where neither product nor process equipment are located, but service zones are sited next to work or utility zones to help separate the cleaner zones from the less clean zone (see Table B.2).

B.3 Influence of cleanroom clothing

The number of personnel and the type of cleanroom clothing may require specific consideration with respect to particle emission (see relevant parts of this International Standard, e.g. ISO 14644-5).

Table B.2 — Examples for microelectronic cleanrooms

Air cleanliness class ^a (ISO Class) in operation	Airflow type ^b	Average, airflow velocity ^c m/s	Air changes per hour ^d m ³ /m ² · h	Examples of applications
2	U	0,3 to 0,5	na	Photolithography, semiconductor processing zone ^e
3	U	0,3 to 0,5	na	Work zones, semiconductor processing zone
4	U	0,3 to 0,5	na	Work zones, multilayer masks processing, fabrication of compact discs, semiconductor service zone, utility zones
5	U	0,2 to 0,5	na	Work zones, multilayer masks processing, fabrication of compact discs, semiconductor service zone, utility zones
6	N or M ^f	na	70 to 160	Utility zones, multilayer processing, semiconductor service zones
7	N or M	na	30 to 70	Service zones, surface treatment
8	N or M	na	10 to 20	Service zones

NOTE na = not applicable

^a Occupancy states associated with the ISO Class should be defined and agreed in advance of establishing optimum design conditions.

^b When airflow type is listed, it represents the airflow characteristics for cleanrooms of that class: U = unidirectional; N = non-unidirectional; M = mixed (combination of U and N).

^c Average airflow velocity is the way that unidirectional airflow in cleanrooms usually is specified. The requirement on unidirectional airflow velocity will depend on local parameters such as geometry and thermals. It is not necessarily the filter face velocity.

^d Air changes per hour is the way that non-unidirectional and mixed airflow is specified. The suggested air changes are related to a room height of 3,0 meter.

^e Impervious barrier techniques should be considered.

^f With effective separation between contamination source and zones to be protected. Could be a physical or airflow barrier.

Annex C (informative)

Approval of an installation

C.1 Test preparation and final cleaning

Prior to carrying out any inspection, test or measurement procedure, running systems should be allowed time to reach stability; this period of time should be agreed upon in advance. Tests should be of sufficient duration to demonstrate consistent performance (see clause 4, and examples in annex H).

Prior to the fitting of filters and after cleaning as described in E.1.2/E.3.3 in annex E has been completed, all ducts, walls, ceilings, floors and installed fittings should be cleaned to remove contamination which could prejudice the classification of the cleanroom.

Following cleaning, the final filters should be fitted and the commissioning tests conducted to demonstrate compliance.

C.2 Inspection, tests and approvals

C.2.1 General

In order to demonstrate that an installation is complete in every respect and performs to meet all contamination control requirements included in clause 4, a specific range of inspections and tests should be carried out upon the installation in question. Typical activities are identified in C.2.2 to C.2.5 and Figure C.1 for graphic representation.

C.2.2 Concept and design approval

A check should be carried out to ensure that the concept, design, and developed details satisfy the agreements between the purchaser and supplier. Review should include at least:

- a) contamination control concept;
- b) layout of equipment;
- c) description of the installation;
- d) schemes and drawings;
- e) incorporation of all other agreed requirements.

C.2.3 Construction and installation approval

C.2.3.1 Construction approval (at supplier's site)

A check should be carried out to ensure that the components and assemblies comply with the design. The check should include at least the following items:

- a) inspection and testing for completeness and quality according to specification;

- b) approval for compliance with safety regulations, ergonomic requirements, relevant guidelines and normative regulations;
- c) approval of certificates.

C.2.3.2 Installation approval (at the site of the installation)

A check should be carried out to ensure that the construction of the installation complies with the design. The check should include in addition to C.2.3.1 at least the following items:

- a) completeness of the installation;
- b) interfaces with other suppliers;
- c) correct function of utilities and auxiliary equipment;
- d) calibration of all control, monitoring, warning and alarm systems;
- e) fitting and in-situ testing of final filters;
- f) proving the reserve capacity of the air treatment system;
- g) testing enclosure for leakage;
- h) confirming that the proportion of recirculation to make-up air complies with the design specification;
- i) surface cleanliness and suitability of the installation (see examples in annex E);
- j) spare parts package.

C.2.4 Functional approval

After having completed the checks and approvals according to C.2.3.2, at least the following functional tests should be performed:

- a) determine clean zone segregation;
- b) measure and record contamination control recovery time;
- c) determine ability to maintain temperature and relative humidity requirements;
- d) determine airborne particulate cleanliness class;
- e) where appropriate, determine particulate surface cleanliness and microbiological contamination levels;
- f) determine light and noise levels;
- g) demonstrate and record airflow patterns and air change rate if necessary.

C.2.5 Operational approval (equipment installed in a manner agreed in advance)

Certain of the previous tests may be repeated to determine compliance with the operational conditions, namely:

- a) confirm clean zone segregation regime;
- b) determine ability to maintain temperature and relative humidity;
- c) determine airborne particulate cleanliness class;

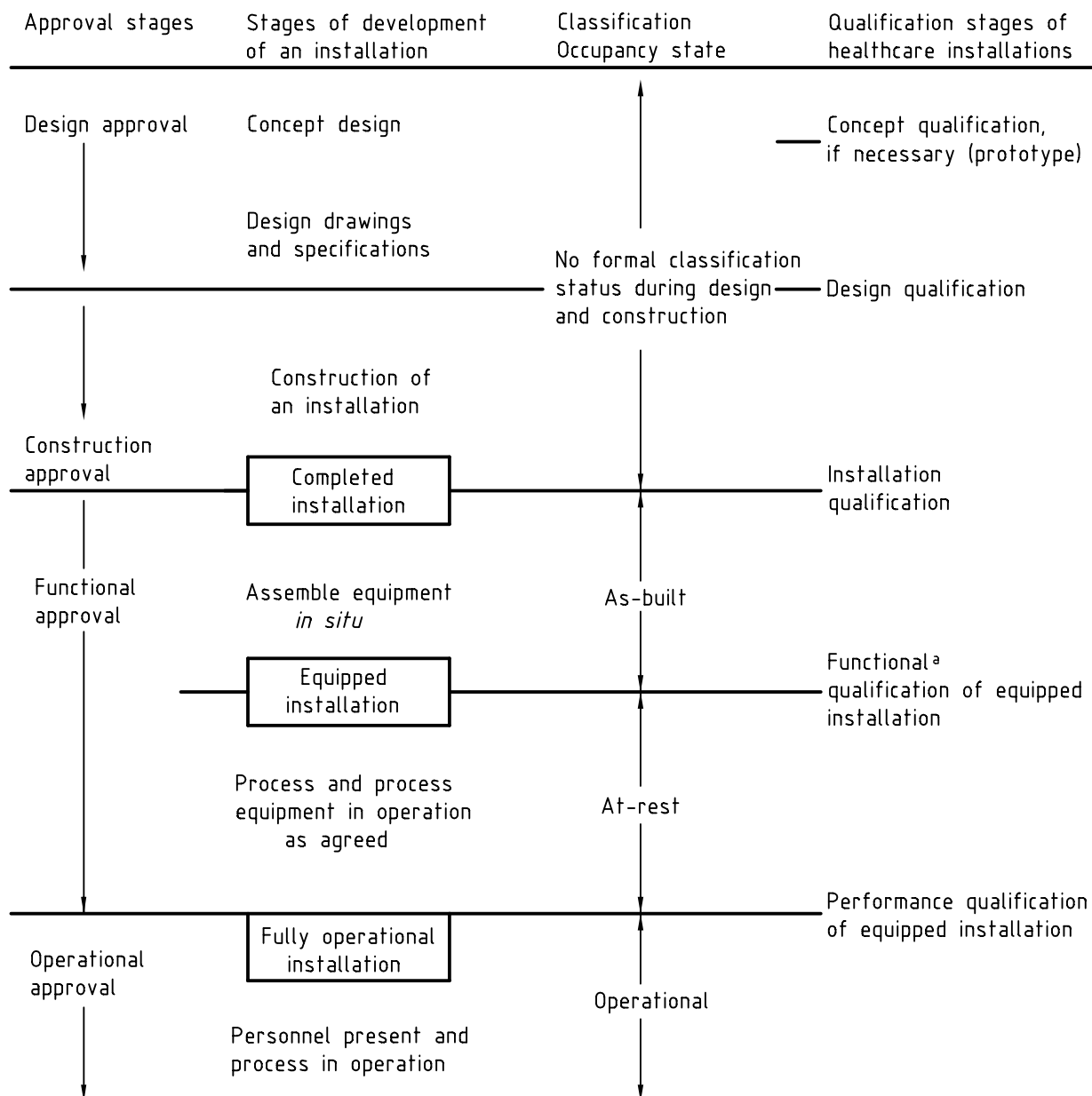
- d) where appropriate, determine particulate surface cleanliness and microbiological contamination levels;
- e) check the completeness of documentation according to clause 8.

For compliance-related issues, refer to ISO 14644-2; for microbiological-related issues, refer to ISO 14698-1, ISO 14698-2 and ISO 14698-3; for testing-related issues and for operational-related issues, refer to other relevant parts of this International Standard.

C.3 Reports

The reports of the tests should be presented in a documented manual. This manual should include:

- a) supplier's test documentation;
- b) calibration certificates of instrumentation used;
- c) relevant drawings and as-installed details;
- d) witnessed verification of compliance with specification.



^a Often used: operational.

Figure C.1 — Approval of an installation

Figure C.1 indicates a logical sequence for and relationship between approvals, stages of development and the formal classification occupancy state of an installation. Terminology may vary in specific industries, through established usage or regulatory requirement. Figure C.1 shows the qualification sequence frequently used in healthcare industry applications, in relation to the stages of construction and approval.

Annex D **(informative)**

Layout of an installation

D.1 General considerations

D.1.1 Size

The size of a cleanroom should be kept to the minimum practicable, allowing for any future requirements. In general, if a large amount of space is required, it should be divided into several zones or rooms, with or without physical barriers.

NOTE It is recognized that the presence of people, and activity, within a cleanroom can generate both contamination and disturbance of airflow. Annex B provides examples of installation configurations to control these phenomena. Annex A discusses contamination control concepts in which airflow and the physical configuration of a workstation or other critical discrete areas are managed to obviate or minimize exchange of contamination between product and its environment, including people in the immediate proximity.

D.1.2 Workstation siting and organization

Within the cleanroom, critical workstations or areas of risk should be sited away from entries and exits, major traffic pathways and other features which may cause disruption of the airflow pattern and higher levels of contamination.

In horizontal-flow cleanrooms, the siting of workstations should be such that the clean work which is to be performed receives clean air from the appropriate source, without flow disturbance or contamination from personnel movements or adjacent work.

When operations that require different degrees of cleanliness are to be carried out in an area swept by horizontal unidirectional airflow, less clean operations should be sited downstream of cleaner operations, insofar as it can be determined that this arrangement will not compromise the maintaining of target conditions for any critical points.

D.1.3 Ancillary areas and adjacent cleanrooms

Consideration should be given to the location and integration of ancillary areas such as service and utility, cleaning, preparation, toilet and refreshment facilities, in order to avoid compromise of the critical conditions maintained within the cleanrooms. Pressure or flow differentials, access and communication arrangements (such as airlocks, speech panels and intercoms), enclosure sealing (notably material joints, equipment and utility penetrations) should be executed so that cross-contamination from less clean zones does not compromise the cleaner zones. Layout should combine with effective training and management of personnel behaviour to minimize disturbance and cross-contamination due to movement between ancillary areas and cleanrooms.

D.1.4 Utility services and ancillary equipment

D.1.4.1 General

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 may present problems for adequate cleaning, and may be sources of damage by contact with cleanroom garments, wipes, etc. This should be balanced against the potential for contamination within protective housings, covers, etc., which may also hinder disinfection or fumigation. Where possible, consideration should be given to the routing of such services

in external service areas or ducts. Means should be provided for the effective removal of waste and contamination generated within such spaces.

Power take-off points, 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, maintenance activities should be performed outside the cleanroom. Pressure or flow differentials, access arrangements (notably airlocks and transfer hatches), enclosure sealing (notably material joints, equipment and utility penetrations) should be executed so that cross-contamination from ancillary areas does not compromise the cleanroom.

The number, type and location of utility services should be agreed between the purchaser and supplier.

D.1.4.2 Vacuum-cleaning equipment

Vacuum-cleaning equipment, either portable or built-in, should be provided to ensure that particulate contamination can be removed during periodic cleaning, and to ensure that contamination generated by any operation that cannot reasonably be conducted outside the cleanroom can be removed efficiently, and with appropriate frequency.

Where a permanent vacuum-cleaning system is provided, the exhaust and fan should be sited outside the cleanroom. The connection sockets in the cleanroom should be blanked off when not in use. The airflow through the vacuum chamber should not compromise the differential pressure or the airflow configuration of the cleanroom.

When portable vacuum equipment is used, it should be fitted with an exhaust filter of at least the same efficiency as that filtering the environmental air supply, and care should be taken to consider the influence upon air patterns in the cleanroom.

D.1.4.3 Sprinkler systems

Fire control systems present special problems, notably in the routing of supply piping containing a fire suppressant medium, whether water, chemical substance or gas, which is a potential contaminant of the cleanrooms, and a potential source of damage to the components of the installation, in the event of accidental or deliberate release.

When sprinkler piping is to run above ceilings, careful consideration should be given to its routing, in relation to the equipment and operations sited in the cleanroom below. Adequate access should be provided for maintenance and modification, and consideration should be given to provision of means to collect and evacuate fluid leaked or released above the ceiling.

Penetration of walls or ceilings for supply to sprinkler points should be sealed as appropriate, like all other penetrations of the cleanroom. The sprinkler heads themselves should be situated and shaped for minimum intrusion into the cleanroom, and for minimal disturbance of clean airflow, insofar as this is compatible with their primary safety function. Where disturbance is inevitable, appropriate measures should be taken to avoid any undesirable effect upon the required integrity of the cleanroom conditions.

D.1.5 Communication systems

Wherever practical, communication systems should be provided in order to minimize movement of personnel into and out of the cleanroom. Windows, speech panels, intercoms, data links and telephones are suitable means of communication. They should be selected to be compatible with the cleanroom class and application considerations.

D.1.6 Glazing

Where windows to the outside are a requirement, care should be taken, in design and fitting, to avoid undue heat loss, solar gain and condensation. The use of windows to adjoining inside spaces should be considered, to allow observation of activity within the room, without entry. Windows should be non-opening and sealed. Double glazing can be used to achieve flush fitting, and also enables provision of interstitial shutters or blinds. The use of exposed blinds within a cleanroom should be avoided.

D.2 Access

D.2.1 General

The number of openings connecting the cleanroom to outside, or adjoining, areas should be minimized.

Effective means should be taken to minimize the contamination arising from the entry or exit of personnel or material, or from air movement. Normal (non-emergency) access to or from the cleanroom should be through airlocks for both personnel and material.

D.2.2 Airlocks

In order to maintain pressure differential and integrity of the controlled space during entry and exit, airlocks or transfer hatches (pass-throughs) are normally required.

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

Barrier benches or other clear demarcation systems, together with appropriate decontamination devices and procedures, should be employed within an airlock system for the passage of material. The passage of material and personnel can be segregated.

D.2.3 Emergency exits

Emergency exits should be provided with means to show that they have been opened.

D.2.4 Changing rooms

D.2.4.1 General

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, depending on the cleanroom quality, facilities for donning and removing specialized garments, and may include washing, disinfection facilities, etc. Special contamination control equipment such as air showers, shoe cleaners and adhesive floor materials may be provided at the point(s) of entry and exit to the cleanroom.

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, or by providing physically separate entry and exit routes.

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

D.2.4.2 Changing room control and configuration

Changing rooms should be provided with a level of contamination control and environmental control that ensures the integrity of the cleanroom. 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 of the changing room:

- a) at the changing room entry: access from ancillary areas (either directly or via an airlock) appropriate 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/access zone: area where inspection of the completed gowning process is accomplished and which provides access to the cleanroom either directly or via an airlock.

The three functional zones may be separated by a physical barrier (e.g. a stepover bench or airlock) 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.

D.2.4.3 Facilities in changing rooms

The features provided in the changing room are particular to the cleanroom that the changing room serves.

The following requirements should be defined:

- number of people passing through the gowning procedure, both in the absolute, and at any one 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 to avoid cross-contamination);
- the frequency of garment replacement.

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

- a) storage and disposal of garments;
- b) storage before use, provision and disposal of consumable items and accessories (e.g. gloves, masks, protective glasses, overshoes);
- c) storage of personal items;
- d) hand-washing and -drying or other decontamination processes;
- e) prominent display or posting of gowning sequence, with clear instructions;
- f) full-length mirrors to check effective fit.

Annex E **(informative)**

Construction and materials

E.1 Selection of materials

E.1.1 General

The materials used in the construction of the installation should be selected and applied to meet the requirements of the installation, and should take into account the following:

- a) the cleanliness class;
- b) effects of abrasion and impact;
- c) cleaning and disinfection methods and frequencies;
- d) chemical/microbiological attack and corrosion.

Materials which may tend to break down or to shed particles should only be used when they are effectively encapsulated and protected.

Consideration should be given to the chemical compatibility of all materials used with the operating requirements of the installation. This may, for instance, influence the choice of adhesives and sealing mastics for surface-finishing work, or of materials used for filter assembly and sealing.

All surfaces which come into contact with air supplied to the interior of the cleanroom or clean zone may 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 air-handling system should be critically assessed and specifically approved for this purpose.

All exposed surfaces of equipment, furnishings and material present within the cleanroom or clean zone should meet the same criteria as the exposed structural elements of the installation.

Further details of specific performance criteria follow.

E.1.2 Surface cleanliness and cleanability of materials of construction

All exposed materials should be suitable for effective and frequent cleaning and disinfection, and offer no surface asperities or porosity which are likely to allow retention of particulate and chemical contamination, or the development of microbiological contamination. Methods for selecting, applying and controlling suitable procedures for cleaning and disinfection are indicated in ISO 14698-1 and ISO 14698-3, and other relevant parts of this International Standard. Appropriate methods for assessing and monitoring surface cleanliness (for instance in terms of releasable particulate, biological and chemical contamination) should be selected and approved for the application. Exposed materials should be selected with due consideration of their resistance to the mechanical and chemical effects of the intended methods of cleaning and disinfection, in order to remain smooth, non-porous, abrasion- and stain-resistant (see also E.1.4 and E.3.3).

Walls, floors and ceilings in cleanrooms and in clean zones should be designed and constructed in such a way that the surfaces are accessible for cleaning. In a room, this generally includes the walls, floors, ceilings and doors, the inlet side of air diffusers and floor drain, etc. (see examples in annex G).

When it is necessary to wipe down or wash walls, floors or ceilings on a frequent basis, consideration of the selection of materials should include careful evaluation of the junction and intersection details, and in particular the avoidance of places where moisture can be trapped or lie on surfaces.

E.1.3 Control of electrostatic charging and discharge

Accumulation of electrostatic charge, and subsequent electrostatic discharge, can present a risk of hazards 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 the above risks cause concern, materials used in the construction of installations should neither generate nor hold a significant static charge. This significant value will be specific to each application, and should be clearly specified by the purchaser. Certain processes may require particular conditions in terms of environmental humidity, in order to minimize the generation of electrostatic charge. Annex F provides further guidance on this technique. It should be noted that the most favourable humidity conditions for avoidance of electrostatic charge accumulation may conflict with other requirements of the process, or project objectives. A solution should be agreed, which achieves an acceptable compromise. Certain applications may require the use of conductive or static dissipative materials in order to minimize the influence of any induced static charge.

To protect electrostatically sensitive components the resistance to earth should be in the range of $R_E = 10^4 \Omega$ to $10^7 \Omega$. Care should be taken to protect the personnel against risk of electrocution. Earthing should be considered, with a site transition resistance $R_{ST} = 5 \times 10^4 \Omega$. The "ideal" range of resistance is therefore between the site transition resistance $R_{ST} = 5 \times 10^4 \Omega$ and the mass resistance $R_E = 10^7 \Omega$.

The required electrical characteristics for flooring are valid for the entire structure or composite of materials used as a floor, and should be measured regularly to monitor potential loss of performance through ageing. Limit values of 2 kV (applicable to accumulated surface charge) should not be exceeded. Monitoring of wall conductivity should be carried out regularly and after modifications or repairs.

E.1.4 Internal finishes, durability and maintainability

In the completed installation, all internal surfaces should be finished suitably smooth, non-porous and free from cracks, cavities, steps and ledges. The design and construction should be such that the number of steps, ledges, cavities and similar features where contamination could collect is minimized. The number of corners should also be kept to a minimum, particularly internal corners. Corners and junctions may be radiused, especially at floor-to-wall and wall-to-wall junctions, so that effective cleaning is facilitated. The finish should be compatible with the mechanical and chemical effects of the intended methods of cleaning and disinfection.

Materials used for internal finishes should be maintained to ensure that they consistently retain the performance qualities consistent with the cleanliness class of the installation. This may require regular maintenance procedures and repairs. Consideration of maintenance and repair methods and disruption impact should form part of the material selection criteria. Full lifecycle cost and contamination risk analysis procedures should be considered.

E.2 Considerations for specific components

E.2.1 Ceilings, walls and floors

E.2.1.1 Basic requirements

Wall, ceiling and floor elements should comply with all relevant regulations concerning fire protection, sound and thermal insulation. Surface finish and assembly details should be compatible with the specified cleaning methods. In order to avoid glare, consideration should be given to the interaction of surface colour and finish with the intended lighting conditions. Airlocks, gowning rooms and material passage points should normally have at least the same requirements as the cleaner of the zones they serve. In the case of equipment and material transfer airlocks, decontamination and "cleandown" procedures may impose special requirements.

NOTE There are many acceptable methods and materials for constructing cleanrooms ranging from *in situ* construction to fully prefabricated site-assembled systems. The basic options are summarized as follows:

a) Prefabricated site-assembled systems and *in situ* construction:

- 1) wet construction with applied surface finish,
- 2) dry construction with applied surface finish.

b) *In situ* assembly:

- 1) pre-finished engineered components,
- 2) modular pre-finished panel system.

Combinations of these basic construction options can also be used.

The choice of method of construction of an installation should take into account not only the contamination control and operational requirements, but also matters relating to the construction location (e.g. construction and finishing skills available); considerations influenced by the available building envelope in which the installation is located, such as available height, load-bearing capability, deflection of structures; maintenance constraints and requirements such as "walk-on-ceiling" capability, etc.

E.2.1.2 Ceilings

Ceilings should be sealed, to prevent ingress of air bearing 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 kept to the minimum required, and be sealed. Consideration should be given to the location and configuration of components such as lights and sprinklers to avoid disturbance of the intended airflow.

E.2.1.3 Walls and wall systems

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

Some applications may require that walls or wall panels be sealed to prevent exchange of contaminants with surrounding areas. Cover strips or seals between panels should be smooth, with rounded edges (some applications require flush fitting) to facilitate efficient cleaning and limit retention of contaminants. Particular attention should be paid to smoothness and effective sealing of utility services or other penetrations.

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. If blinds or shutters are required, these should be fitted outside the clean zone, or between the glazed elements of double glazing. Glazing frames should be smooth. Where flush fitting is not required, rounded edges or sloping surfaces should be considered.

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 handles, where required, should be smooth, non-snagging and easy to clean. Consideration should be given to the use of push plates, automatic openings, or appropriate door-swing direction where contamination transfer is a concern.

E.2.1.4 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 durability. The floor complex should provide the appropriate electrostatic characteristics.

E.2.2 Air-handling systems

Attention should be paid to minimizing the contamination generated, retained and released throughout the air-handling system, in all components and surfaces in contact with the system air, in order that an excessive load is not placed on the filtration system. Ducts should be manufactured from materials with corrosion-resistant and non-flaking properties, or should be given suitable surface treatment to prevent release of contaminants from the duct to the air passing through. If there is no terminal filter outlet provided, the quality and integrity of the system downstream of the final filter is more important. The effects of leakage from air-handling systems should be considered.

E.2.3 Fittings in airlocks

Fittings in airlocks and gowning rooms should present as few horizontal surfaces as possible. For example consideration should be given to the use of hanging rails and perforated shelf boards rather than closed lockers. Exposed surfaces should satisfy criteria similar to those specified for the interior of the cleanroom and clean zone, and may require additional specifications to ensure durability in this application.

E.2.4 Ancillary areas

These should have no direct connection to the cleanroom, except for emergency exits. Exposed surfaces in these areas should be chosen with a particular concern for durability and ease of maintenance.

E.3 Construction and assembly

E.3.1 General

Construction work should comply with the drawings and specifications, and the agreed quality plan. Any changes required during the construction phase should be checked for acceptance, approved and documented prior to their implementation (see also examples in annex C).

E.3.2 Material management during construction

All components and materials for use in the construction and subsequent maintenance of the installation should be manufactured, packed, transported, stored and inspected before use in such a manner as to ensure their suitability for their intended use.

E.3.3 Cleanliness and cleaning during construction and start-up

Many tasks involved in construction and assembly intrinsically generate contamination. A clean construction protocol should be developed and enforced to satisfy and achieve the specified contamination control objectives. Particular attention should be paid to the scheduling of tasks which are the greatest sources of contamination, such that those tasks are accomplished before tasks which are lesser sources of contamination or more contamination-sensitive.

During construction, measures should be taken to ensure that contamination generated in the course of assembly and construction work is contained and removed, so as to limit undue contamination of surrounding areas. Appropriate means of containment may include the use of temporary screens and walls, and pressurization of critical zones, with provisional use of temporary "sacrificial" filters in the air-handling system(s). Such filters, installed to protect clean volumes (clean environment and air-handling systems) from outside contaminants, and to permit their initial pressurization and operation, are intended to be removed and replaced by filters of the appropriate grade at the agreed stage or stages of start-up, before construction approval and subsequent operational use of the installation.

Continual or frequent cleaning should be planned, undertaken and controlled as specified, with the aim of preventing undue build-up of contaminants in any part of the installation, and so facilitating the essential final cleaning before start-up (see also clause 6 and E.1.2).

It may be useful to effect initial cleaning of components, and those preparation or assembly tasks which it is not absolutely necessary to perform as part of definitive construction *in situ*, in a separate or intermediate zone between the point of reception on-site, and the final point of construction. Such procedures can contribute significantly to the reduction of contamination in all parts of the installation, though they are of special value where subsequent access and cleaning would be difficult or impossible.

E.4 Materials of construction

Typical surface materials are:

a) For walls and ceilings:

- sheets of stainless steel;
 - anodized aluminium;
 - polymer sheets or coating.
- } mounted on appropriate substrates or construction

b) For floors:

- polymer coating or sheets;
- tiles with appropriate sealed joints.

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.

Annex F (informative)

Environmental control of cleanrooms

F.1 Design

F.1.1 Requirements for environmental control vary with each application. Therefore the purchaser should state which criteria are important when specifying a cleanroom. The lists given in this annex are not exhaustive and should be supplemented as required.

F.1.2 The design of the environmental systems should take into account the following:

- a) the contamination control concept chosen;
- b) product quality requirements;
- c) capital and operating costs (life cycle costing);
- d) energy conservation;
- e) safety;
- f) health and comfort of personnel;
- g) needs and constraints imposed by equipment and processes;
- h) reliability, ease of operation and maintenance;
- i) environmental issues (e.g. handling of waste and packaging);
- j) regulatory requirements.

F.2 Temperature and humidity

F.2.1 The set point and variation limits of temperature (in degrees Celsius) and relative humidity (in percent saturation) which may depend on special process requirements should be specified for the performance of the cleanroom.

F.2.2 Temperature control should be provided for:

- a) processes;
- b) equipment and materials;
- c) stable conditions for personnel wearing cleanroom garments selected to suit the class of cleanliness specified.

In general terms, heat loads from lighting are high and stable; personnel loads vary; the heat generated by process operations (e.g. heat-sealing, soldering, welding, heat-treating and heating pressure vessels) is usually high and variable.

F.2.3 The large quantities of air required for contamination control facilitate the offsetting of internal heat gains at an acceptable rate of response from the temperature control system. However, areas of concentration of heat-

producing equipment and supply-air patterns should be analysed to determine the acceptability of resulting temperature gradients and contamination control.

F.2.4 Humidity control should be provided for:

- a) manufacturing processes;
- b) equipment and materials;
- c) the reduction of electrostatic charges;
- d) personnel comfort in conjunction with temperature control mentioned above.

F.2.5 In cleanroom installations, humidity control is affected more by external influences (such as weather changes) than by variations in moisture generation within the space. If processes involving evaporation should take place within the cleanroom installation, they should be confined within ventilated enclosures. Precautions should be taken to control static electricity effects. Some manufacturing processes (such as vacuum tube manufacture and tabletting) require relative humidities (R.H.) lower than 35 %. As indicated in annex E, consideration should be given also to selection of materials which minimize electrostatic effects. If the humidity in a confined space is low, static charges may be higher than in an area with higher humidity.

F.2.6 Temperature and humidity levels for personnel comfort should be defined for these specific installations. A typical set range for relative humidity is < 65 % R.H. to > 30 % R.H. Outside this range, suitable measures should be considered to meet process and personnel requirements. Specific guidance to adjust temperature specifications to cleanroom garments used is given in ISO 7730.

F.2.7 The locations at which temperatures and relative humidities require to be measured should be specified.

F.2.8 The outside conditions under which the system is required to operate should be specified taking into account the intended operational mode.

F.2.9 The amount of heat and moisture generated in the cleanroom, the location of sources and the nature of their dynamic variation should be specified.

F.3 Lighting

F.3.1 The lighting levels and uniformities required within the various parts of the installation should be specified, together with the methods used to assess them.

F.3.2 The colour rendering of light should be specified by the purchaser, as it has a significant effect on the comfort of personnel and, in many cases, the processes being carried out, especially photosensitive processes.

F.3.3 The lighting system should be consistent with the effective operation of the cleanroom. Light fittings should have no areas from which contamination may be released. The use of sealed or flush fittings should be considered. For unidirectional airflow applications, the design and positioning of the light fitting and associated diffuser should be such as to minimize or negate turbulence. The light fittings should be serviceable in a manner such that the integrity of the cleanroom is not violated and excessive contamination is not produced. The effect of glare should be considered within the context of the work being carried out.

F.4 Noise and vibration

F.4.1 General

Noise and vibration limits should be specified, if required, according to a specific process or other requirements. Consideration should be given to

- a) site selection: vibration, soils, and future site developments;
- b) structural design: cleanroom floor support, stiffness, isolation joints;
- c) mechanical design: equipment selection, system design, performance specifications, vibration isolation systems, noise control systems (internal and external);
- d) architectural layout: building and installation layout, plant areas, service systems.

F.4.2 Sound pressure level

The selected sound pressure level should be based on the requirements with regard to both the comfort and safety of the personnel and consideration of the background sound pressure level created in the environment (e.g. other equipment). A typical A-weighted sound pressure level range for cleanroom installations lies between 55 dB and 65 dB. Some applications may require lower levels or may tolerate higher levels. Noise control measurements should be carried out in accordance with ISO 3746.

F.4.3 Mechanical vibration

F.4.3.1 Vibration is an important consideration in cleanroom installations, since it can have an adverse influence on processes, human comfort and service life of equipment and systems.

F.4.3.2 Vibration in cleanrooms should be minimized, or the source isolated, using methods such as high quality fans and vibration control equipment.

F.4.3.3 When vibration control is required, the permissible levels should be defined using ISO 1940-1 and ISO 10816-1.

F.5 Energy conservation

Consideration may be given to incorporating in the design energy conservation considerations, such as provisions to reduce or close down temperature and humidity control and to reduce airflow during periods in which there is no activity. The ability to recover operating conditions in a defined recovery period should be demonstrated.

Annex G **(informative)**

Control of air cleanliness

G.1 Air filtration systems

Air filtration systems including filter elements, mounting frames, housings, gaskets, sealants and clamping systems should be selected to suit both the cleanliness level required and the conditions associated with their use and installation test requirements in the system. Specific air filtration standards should be used for filter selection. Three basic stages of air filtration are recommended:

- a) prefiltering of the outside air to ensure adequate quality of air supply to the air conditioning plant;
- b) secondary filtering in the air conditioning plant to protect the final filters;
- c) final filtering before cleanroom supply.

G.2 Secondary filtration

It should be understood that unless adequate secondary filtration is provided before the final filters supplying cleanrooms, several problems may arise. These problems include the following:

- a) the desired class of air cleanliness may not be achieved;
- b) the high frequency of final filter changing may become unacceptable;
- c) undesirable particulate and microbiological contamination of the product may occur.

G.3 Application

The designer should evaluate the performance of the primary and secondary air filters used in cleanroom air conditioning systems to suit each application. Consideration should be given to the use of filters for chemical and molecular decontamination (e.g. activated carbon) and configurations for exhaust air filtration to protect the outdoor environment.

G.4 Energy conservation

For energy conservation reasons, airflow of the ventilation systems may be reduced to low levels during non-operating periods. If, however, they are turned off, the potential for unacceptable room contamination to occur should be considered.

G.5 Temporary filters

The installation of temporary filters should be considered to protect the air cleanliness of air-handling systems during construction and commissioning.

G.6 Packaging and transportation

High-efficiency air filters should be packaged in a manner that adequately protects the element from mechanical damage during handling and transportation from the supplier. The filters should be inspected and be free from damage prior to fitting into the installation.

G.7 Fitting

The fitting of high-efficiency filters should be delayed until they are required for commissioning purposes. Whilst awaiting fitting, filters should be stored in accordance with the supplier's instructions. Immediately prior to fitting, the air ducting system should be visibly clean and free from contamination. The filters should be fitted in accordance with the manufacturer's instructions.

G.8 Testing

All air filtration equipment installed in an installation should allow for leak-testing of the final filters and integrity-testing of the seals between filter and mounting arrangements. Consideration should be given to the materials used for such testing to ensure that materials themselves do not become contaminants or cause contamination.

Annex H (informative)

Additional specification of requirements to be agreed upon between purchaser/user and designer/supplier

H.1 General

This annex is intended to assist the purchaser/user and designer/supplier to communicate and agree on additional requirements. It is intended that the checklist be used to define known requirements and identify aspects where further development is required.

H.2 Checklists

Checklists are given in the form of tables.

Table H.1 suggests a check for process requirements which affect the installation.

Table H.2 suggests a check for contaminants which detrimentally affect the process.

Table H.3 suggests a check for all pieces of equipment to be utilized in the process.

Table H.4 suggests a check for all external factors affecting the process.

Table H.5 suggests a check for environmental requirements affecting the process.

Table H.6 suggests a check to identify requirements for safe operation.

Table H.7 suggests a check to evaluate the requirements for systems redundancy (standby/backup).

Table H.8 suggests a check for the scope of equipment maintenance required.

Table H.9 suggests a check for miscellaneous requirements not previously defined that affect design, construction, operation and maintenance.

Tables H.10, H.11 and H.12 suggest checks for factors affecting future developments, cost requirements and scheduling, respectively.

Table H.1 — Process requirements

Number	Item	Description	Specified value	Achieved performance
1	Direct processes	Those which directly affect the end product or service.		
2	Indirect processes	Those which support or indirectly affect the end product or service.		

Table H.2 — Process contaminants

Number	Item	Description	Specified value	Achieved performance
1	Matter as contaminant	Non-viable or viable matter		
1.1	Particulate	Particles of different shape		
1.1.1	Class	In accordance with ISO 14644-1		
1.1.2	Size(s)	Particle size(s), M- and U-Descriptors (see annex E in ISO 14644-1:1999)/Basic, ultrafine, macroparticles and fibres		
1.1.3	Recovery time			
1.2	Chemical	Molecular, ionic, gaseous, condensable, metallic		
1.2.1	Amount	Quantity of chemical contamination/weight, layer(s), concentration		
1.2.2	Class	In accordance with ISO 14644-1 or other standard		
1.2.3	Recovery time			
1.3	Biological	Viable, aerobic or non-viable pathogenic organisms/organisms capable of reproducing		
1.3.1	General type	Bacteria, fungi, other		
1.3.2	Contamination type	Aggressive to surfaces, resistant to disinfection, pathogenicity		
1.3.3	Propagation	Duration from upset to steady state		
2	Energy as contaminant	Energy sources which interfere		
2.1	Vibration	Extent of motion		
2.1.1	Amplitude	Greatest displacement		
2.1.2	Frequency	Rate of motion		
2.2	Magnetic	Electromagnetic fields		
2.2.1	Field strength			
2.3	Radio frequency			
2.3.1	Field strength			

Table H.3 — Process equipment specification

Number	Item	Description	Specified value	Achieved performance
1	Input utilities	Matter and energy required to be delivered to each process equipment		
1.1	Solids — Supply requirements	List equipment solids to be utilized in the process		
1.1.1	Solids supply purities/ Concentrations	List, for each piece of equipment, for purities/concentrations required for all solids to be utilized in the process		
1.1.2	Solids supply quantities	List, for each piece of equipment, the quantities of all solids to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		
1.2	Gases — Supply requirements	List, for each piece of equipment, all gases to be utilized in the process		
1.2.1	Gases supply purities	List, for each piece of equipment, the purities required for all gases to be utilized in the process		
1.2.2	Gases supply quantities	List, for each piece of equipment, the quantities of all gases to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		
1.2.3	Pressures	List, for each piece of equipment, the pressures of all gases to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		
1.3	Liquids — Supply requirements	List, for each piece of equipment, all liquids to be utilized in the process		
1.3.1	Liquids supply purities/ Concentrations	List, for each piece of equipment, the purities/concentrations required for all liquids to be utilized in the process		
1.3.2	Liquids supply quantities	List, for each piece of equipment, the quantities required for all liquids to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		

Number	Item	Description	Specified value	Achieved performance
1.3.3	Liquids supply pressures	List, for each piece of equipment, the pressures for all liquids to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		
1.4	Electric power requirements	List, for each piece of equipment, the electric power requirements		
1.4.1	Voltage			
1.4.2	Phase			
1.4.3	Frequency			
1.4.4	Load			
1.4.5	Allowable electrical power fluctuation requirements	List, for each piece of equipment, the maximum allowable fluctuation in electrical service that can be accepted without electrical power filtration		
2	Output utilities			
2.1	Solid waste requirements	List, for each piece of equipment, all solids to be rejected in the process		
2.1.1	Solids waste purities/ Concentrations	List, for each piece of equipment, the purities/concentrations of all solids to be rejected in the process		
2.1.2	Solids waste quantities	List, for each piece of equipment, the quantities of all solids to be rejected in the process, including the maximum, minimum, and nominal rates of rejection		
2.2	Exhaust flow requirements	List, for each piece of equipment, all types of exhaust to be utilized in the process		
2.2.1	Exhaust flow characteristics	List, for each piece of equipment, the types of exhaust flows (e.g. acid, solvent, heat, general, etc.) to be utilized in the process and their respective concentrations, and temperatures		
2.2.2	Exhaust flow quantities	List, for each piece of equipment, the quantities of all exhaust flows to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		

Number	Item	Description	Specified value	Achieved performance
2.2.3	Exhaust flow pressures	List, for each piece of equipment, the pressures of all exhaust flows to be utilized in the process, including the maximum, minimum, and nominal rates of introduction and utilization		
2.3	Liquid waste requirements	List, for each piece of equipment, all liquids to be rejected in the process		
2.3.1	Liquid waste quantities	List, for each piece of equipment, the quantities of all liquids to be rejected in the process, including the maximum, minimum, and nominal rates of introduction and utilization		
3	Environmental parameters	To allow intended use of the process equipment		
3.1	Temperature requirements	List, for each piece of equipment, the maximum, minimum, and optimum temperature requirement, both internal and external to the equipment. Further list by equipment component separately, as required.		
3.1.1	Rate of temperature rise	List, for each piece of equipment, the maximum allowable rate of temperature rise		
3.1.2	Rate of temperature fall	List, for each piece of equipment, the maximum allowable rate of temperature fall		
3.2	Humidity requirements	List, for each piece of equipment, the maximum, minimum, and optimum humidity requirement, both internal and external to the equipment components as required separately		
3.2.1	Rate of humidity rise	List, for each piece of equipment, the maximum allowable rate of humidity rise		
3.2.2	Rate of humidity fall	List, for each piece of equipment, the maximum allowable rate of humidity fall		
3.3	Vibration requirements/ Limitations	List, for each piece of equipment, the maximum, minimum, and nominal vibration energy level		
3.4	Physical barrier applied	Are they required?		

Number	Item	Description	Specified value	Achieved performance
4	Physical attributes	Equipment dimensions and mass		
5	Installation considerations	How to install		
6	Operational considerations	How to operate		
7	Maintenance considerations	How to maintain		
8	Pre-process	Status of incoming product or starting materials		
9	Post-process	Description of subsequent manufacturing steps		
10	Process throughput	The amount of product passing through the equipment over time		
11	Communication considerations	Describe		
12	Ergonomic considerations	Describe		

Table H.4 — External factors

Number	Item	Description	Specified value	Achieved performance
1	Regulatory requirements	List all regulatory factors affecting site selection and operations, including local zoning laws and ordinances, local tax structures, and permitting requirements		
2	Utility resources and factors	List utility resources, including availability, quality, and quantities		
2.1	Site water supply	List the characteristics of local ground or municipal water supply, including toxicity, turbidity, etc.		
2.2	Site air quality	List existing site air quality characteristics		
2.3	Site electrical power factors	List the local electrical power supply characteristics, i.e. capacity, voltage, number of phases, frequency, and intensity and frequency of fluctuations, etc.		
2.4	Site waste systems factors	List the local waste system characteristics		

3	Site vibration characteristics	Evaluate the ambient site vibration level and its variations. Evaluate for potential impacts on planned processes and facilities		
4	Proximity factors	List all proximate and adjacent site structures, processes, pollutants, etc. Evaluate for potential impacts on planned processes, facilities, and personnel		
5	Site geotechnical factors	List all geotechnical factors, i.e. soils toxicity, soils expansion, characteristics, etc. Evaluate affect on planned installation		
6	Security and access factors	List all security and accessibility factors. Evaluate for affect on installation.		

Table H.5 — Environmental requirements

Number	Item	Description	Specified value	Achieved performance
1	Ambient requirements	Consider for process, equipment, and personnel requirements. List initially by cleanliness hierarchy. List each process area by cleanliness classification only if the design process is substantially developed.		
1.1	Cleanliness	Required cleanliness classification		
1.2	Air pattern type	List the cleanroom air pattern type, i.e. unidirectional, non-unidirectional, or mixed		
1.3	Airflow direction	List the cleanroom airflow direction, i.e. vertical or horizontal		
1.4	Air velocity	List the cleanroom air velocity within the process area		
1.5	Air circulation system and configuration	Evaluate the cleanroom air circulation system configuration. Consider process, regulatory, personnel and budgetary factors		
1.6	Dry bulb temperature	Evaluate the cleanroom dry bulb temperature requirement, including the maximum, minimum and nominal value		
1.6.1	Rate of dry bulb temperature rise	List the cleanroom maximum allowable rate of dry bulb temperature rise		

Number	Item	Description	Specified value	Achieved performance
1.6.2	Rate of dry bulb temperature fall	List the cleanroom maximum allowable rate of dry bulb temperature fall		
1.7	Humidity	Evaluate the cleanroom humidity requirement, including the maximum, minimum, and nominal value		
1.7.1	Rate of humidity rise	List the cleanroom maximum allowable rate of humidity rise		
1.7.2	Rate of humidity fall	List the cleanroom maximum allowable rate of humidity fall		
1.8	Pressurization	List the cleanroom pressure		
1.8.1	Pressurization differential	List the cleanroom pressurization differential from zone of higher space pressure to adjacent zone of lesser pressure		
1.8.2	Pressurization rate of change	List the cleanroom maximum allowable rate of change in space pressure		
2	Sound pressure level (noise)	List the cleanroom maximum allowable and nominal sound pressure levels		
3	Vibration	List the cleanroom maximum allowable and nominal vibration energy level		
4	Lighting	List the minimum and nominal cleanroom lighting requirements, and any wavelength restrictions		
5	Physical geometry	List the dimension/size requirements		
5.1	Ceiling-to-floor height	List the cleanroom ceiling-to-floor height requirement		
5.2	Floor area requirement	List the cleanroom floor area requirement, i.e. length and breadth		
5.3	Floor loading	Maximum mass loading		
6	Ionization	Charge balance (air)		

Table H.6 — Safety requirements

Number	Item	Description	Specified value	Achieved performance
1	Cleanroom life-safety requirements	Identify all safety codes and regulations that affect the installation		
2	Separation of air circulation zones	Evaluate specific requirements for individual zone control and segregation		
3	Storage and transport of toxic, flammable and hazardous materials	Evaluate specific process and overall storage requirements		
4	Exiting requirements	Evaluate maximum exit distance requirements		
5	Physical requirements	Evaluate requirements for fire resistive materials and assemblies		
6	Purge system	Is one required?		
6.1	Flowrate	At what rate?		

Table H.7 — Standby/backup requirements

Number	Item	Description	Specified value	Achieved performance
1	System duplication	100 % replacement capability		
2	System oversizing	More available than required		
3	Largest component backup	Replace 100 % of single		
4	Alternative source	Switch over to alternative		
5	Failure detection and reporting			
6	Change-over methodology	Manual or automatic		

Table H.8 — Operations and maintenance factors

Number	Item	Description	Specified value	Achieved performance
1	MTBF	Mean time between failures		
2	MTTR	Mean time to repair		
3	Maximum time to repair	How long to fix?		
4	Spare parts availability	How many, what type?		

Table H.9 — Personnel factors affecting people and productivity

Number	Item	Description	Specified value	Achieved performance
1	Personnel and materials flow requirements	Evaluate product and process flow requirements and personnel flow requirements. Evaluate distances between individual processes and their functional interdependencies. Evaluate personnel communications and access needs.		
1.1	Airlocks	Required?		
1.2	Gowning requirements	What type of gown(s)		
2	Operating frequency	List the operating frequency of the cleanroom, i.e. continuous versus intermittent. If intermittent, specify frequency of operation, e.g. 5 days per week, 8 h per day		
3	Ergonomics	Any requirements		
4	Aesthetics	Any requirements		

Table H.10 — Future developments

Number	Item	Description	Specified value	Achieved performance
1	Future	Planning to consider now?		
2	Flexibility	Planning to consider now?		

Table H.11 — Cost requirements

Number	Item	Description	Specified value	Achieved performance
1	Capital cost	First cost		
2	Operating cost			
2.1	Energy use	Identify ways to reduce operating costs		
2.2	Maintenance costs			
3	Life cycle cost	Owning cost		

Table H.12 — Schedule

Number	Item	Description	Specified value	Achieved performance
1	Task definition	Project tasks shall be agreed between the user and supplier		
2	Identify milestones	Identify or define key project milestones and the acceptance criteria		

H.3 Specification checklist of basic requirements for cleanroom projects

Purpose: The purpose of this form is to help the user and supplier of the cleanroom project to document the essential and non-essential aspects of the cleanroom project. This form should be used in conjunction with the normative and informative clauses of this part of ISO 14644.

Project Name: _____ Project Location: _____

Customer Name: _____ Supplier Name: _____

Customer Contact: _____ Supplier Contact: _____

Customer Phone No. _____ Supplier Phone No. _____

Date: _____

H.4 Relation to clause 4

Table H.13 — Relation to clause 4

Clause 4 reference	Description of requirement	Response, requirement, specification
4.2	What is the number of the International Standard being referenced?	
4.2	What is the date of publication of this International Standard?	
4.4	What is the general purpose for which the controlled space is to be used?	
4.4	What are the operations to be carried out in the cleanroom?	
4.4	Are there any constraints imposed by the operating criteria (see examples in annexes A, B and D)?	
4.5	What are the required classes or demands for cleanliness in accordance with the relevant parts of this International Standard (ISO 14664-1, ISO 14698-1, ISO 14698-2, ISO 14698-3) (see examples in annex F)?	
4.6	What environmental parameters will be measured for validation purposes? What are the allowable variations, measurement method(s), and calibration method(s) (ISO 14644-2 and ISO 14644-3) (see examples in annex F)?	
4.7	Describe the contamination control concept to be used to achieve the required cleanliness level (including operating and performance criteria) (see examples in annex A for description of control concepts).	
4.9	What is the material flow through the cleanroom (see examples in annex D)?	
4.10	What are the occupancy state(s) under which the required conditions shall be achieved and maintained, including variations with time, and the methods of control of occupants, including e.g. gowning, sanitation techniques, personnel flow and access control to all clean areas (see examples in annex C)?	
4.11	Provide layout and configuration drawings of the installation (see examples in annex D).	
4.12	Provide all critical dimensions and mass restrictions, including those related to available space (see examples in annex D).	
4.13/4.14	The process and product equipment to be installed in the cleanrooms or clean zones, including usage, method of gaining access for construction and maintenance, emissions, size and mass, and utility requirements (see examples in annexes B, D, E, G and H).	

Clause 4 reference	Description of requirement	Response, requirement, specification
4.15	The maintenance requirements of the system components creating the cleanroom or clean zone shall be supplied in a timely manner (see examples in annexes D and E).	
4.16	Provide the definition of all responsibilities for statement of criteria, basis of design, detailed design, construction, testing, commissioning and qualification (including the performance and witnessing) of tests (see examples in annexes E and G).	
4.17	Identify all external environmental influences, such as chemical and particle contamination, noise and vibration (see examples in annex H).	

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- [1] ISO 1940-1:1986, *Mechanical vibration — Balance quality requirements of rigid rotors — Part 1: Determination of permissible residual unbalance.*
- [2] ISO 3746:1995 + Technical Corrigendum 1:1995, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane.*
- [3] ISO 7730:1994, *Moderate thermal environments — Determination of the PMV and PPD indices and specification of the conditions for thermal comfort.*
- [4] ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*
- [5] ISO 9001:2000, *Quality management systems — Requirements.*
- [6] ISO 9004-1:1994, *Quality management and quality system elements — Part 1: Guidelines.*
- [7] ISO 10816-1:1995, *Mechanical vibration — Evaluation of machine vibration by measurements on non-rotating parts — Part 1: General guidelines.*
- [8] ISO 14001:1996, *Environmental management systems — Specification with guidance for use.*
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- [10] EN 779:1993, *Particulate air filters for general ventilation — Requirements, testing, marking.*
- [11] EN 1822-1:1998, *High efficiency air filters (HEPA and ULPA) — Part 1: Classification, performance testing, marking.*
- [12] EN 1822-2:1998, *High efficiency air filters (HEPA and ULPA) — Part 2: Aerosol production, measuring equipment, particle counting statistics.*
- [13] EN 1822-3:1998, *High efficiency air filters (HEPA and ULPA) — Part 3: Testing flat sheet filter media.*
- [14] EN 1822-4:1997, *High efficiency air filters (HEPA and ULPA) — Part 4: Testing filter elements for leaks (scan method).*
- [15] EN 1822-5:1996, *High efficiency air filters (HEPA and ULPA) — Part 5: Testing the efficiency of the filter element.*
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- [21] US Pharmacopeia 23-NF 18 (1995) Supplement 8 (May 15, 1998) P4426 (1116), *Microbiological evaluation of cleanrooms and other controlled environments*.
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- [23] VDI 2083 part 4:1996, *Cleanroom technology — Surface cleanliness*. Berlin: Beuth Verlag GmbH.

Major multi-national cleanroom relevant standards/recommendations

- [24] *EC Guide to GMP for medicinal products*. Brussels: European Commission, 1995.
- [25] ISO 13408-1:1998, *Aseptic processing of health care products — Part 1: General requirements*.

Surveys of contamination control standards/recommendations

- [26] IEST-RD-CC009.2:1993, *Compendium of standards, practices, methods, and similar documents relating to contamination control*. Mount Prospect, Illinois: Institute of Environmental Sciences and Technology.

Major contamination control handbooks

- [27] TOLLIVER, D.L. (ed.): *Handbook of contamination control in microelectronics*. Park Ridge (New Jersey): Noyes Publications, 1988, 488 pp.
- [28] WHYTE, W. (ed.): *Cleanroom design*. Wiley, Chichester, 1991, 357 pp.
- [29] HAUPTMANN-HOHMANN (eds.): *Handbook of cleanroom practice*. Ecomed Verlag, Landsberg, 1992.
- [30] LIEBERMANN, A: *Contamination control and cleanrooms*. Van Nostrand Reinhold, New York, 1992, 304 pp.

Dictionaries for contamination control terms

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 14644-1	1999	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness	EN ISO 14644-1	1999
ISO 14644-2	2000	Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	EN ISO 14644-2	2000