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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 environements — 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

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[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.

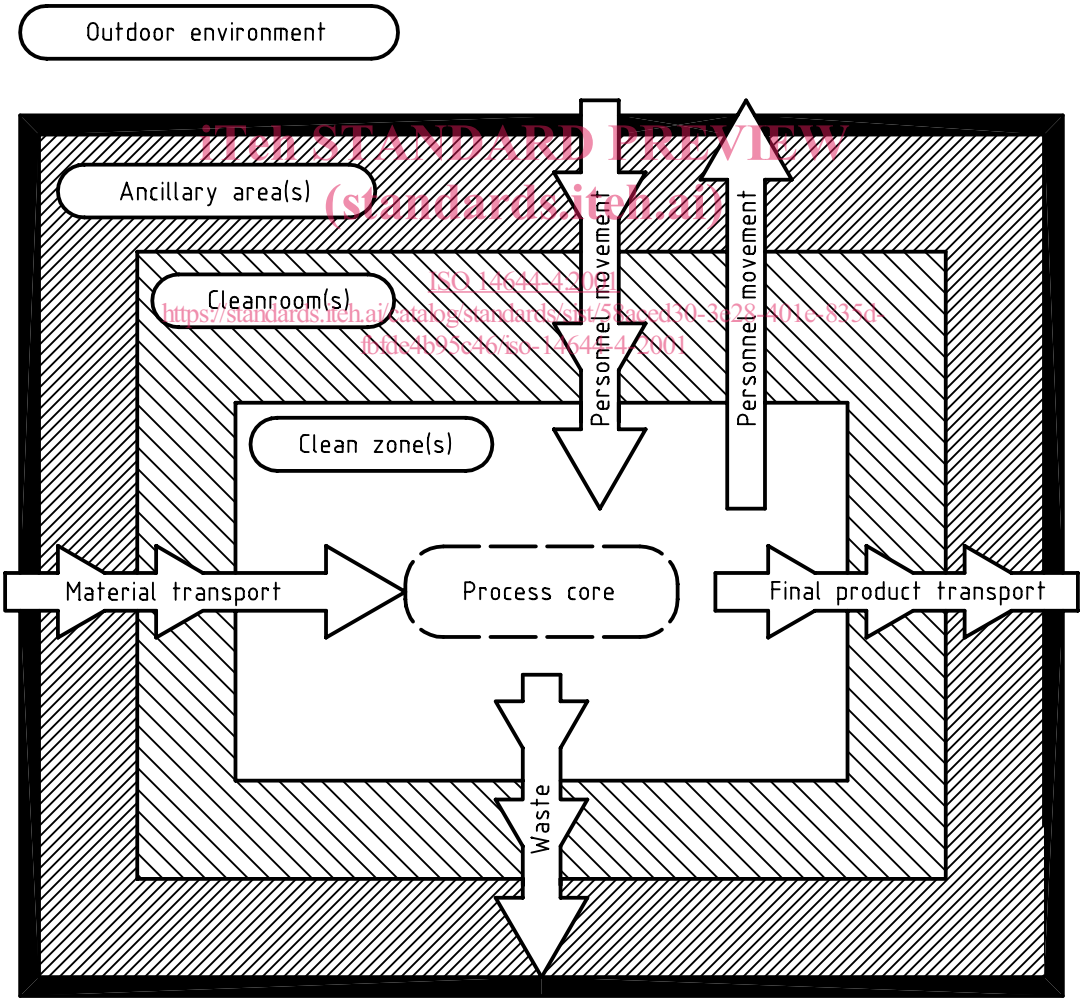

Figure A.1 — Shell-like contamination control concept