INTERNATIONAL STANDARD

ISO 14644-5

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Cleanrooms and associated controlled environments —

Part 5: Operations

Salles propres et environnements maîtrisés apparentés —

Partie 5: Exploitation

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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

ISO 14644-5 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: Test methods*

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

— *Part 5: Operations*

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

— *Part 8: Classification of airborne molecular contamination*

The following part is under preparation:

— *Part 6: Terms and definitions*

Introduction

Industries and organizations of all kinds utilize cleanrooms. Operational procedures have a profound effect on the cleanliness levels achieved during the operation of the cleanroom and equipment. Consistent quality is cleanliness dependent. Operational cleanliness can only be attained and maintained through a deliberate programme established to specify, measure and enforce defined operational procedures. Regulatory agencies that have authority over processes and products produced in the cleanroom may require additional procedures and measures of cleanliness not covered in this general operating standard.

This part of ISO 14644 addresses normative and informative operational requirements related to:

a) providing a system that defines policies and operational procedures;

b) clothing used to isolate human-generated contamination from the cleanroom environment;

c) training of personnel inside the cleanroom and monitoring their compliance to specified procedures and disciplines;

d) transfer, installation and maintenance of stationary equipment (selection criteria is not discussed);

e) selection and use of materials and portable equipment in the cleanroom;

f) maintaining the cleanliness of the cleanroom through systematic cleaning and monitoring procedures.

Cleanrooms and associated controlled environments —

Part 5: Operations

1 Scope

This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference is made to ISO 14644-2 and ISO 14644-3 for monitoring particles and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

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

ISO 14698-1:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

ISO 14698-2:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

1) To be published.

3 Terms and definitions

For the purposes of this part of ISO 14644, the following terms and definitions apply.

3.1 General Terms

3.1.1
biocleanroom
cleanroom used for products and processes that are sensitive to microbiological contamination

3.1.2
changing room
room where people entering or leaving a cleanroom put on or take off cleanroom clothing

NOTE Adapted from ISO 14644-4:2001, 3.1.

3.1.3
cross-over bench
bench that is used as an aid to changing of cleanroom clothing and which provides a barrier to the tracking of floor contamination

3.1.4
disinfection
removal, destruction or de-activation of micro-organisms on objects or surfaces

3.1.5
fibre
particle having an aspect (length-to-width) ratio of 10 or more

[ISO 14644-1:1999, 2.2.7]

3.1.6
operator
person working in the cleanroom performing production work or carrying out process procedures

3.1.7
particle
minute piece of matter with defined physical boundaries

NOTE For classification purposes refer to ISO 14644-1:1999.

3.1.8
personnel
persons entering the cleanroom for any purpose

3.1.9
separative device
equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and the outside of a defined volume

EXAMPLES Some industry-specific examples of separative devices are clean air hoods, containment enclosures, gloveboxes, isolators and minienvironments.

3.1.10
unidirectional airflow
controlled airflow through the entire cross-section of a clean zone with a steady velocity and approximately parallel airstreams

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

[ISO 14644-4:2001, 3.11]

3.2 Occupancy states

3.2.1
as-built
condition where the installation is complete with all services connected and functioning but with no production equipment, materials or personnel present

[ISO 14644-4:2001, 2.4.1]

3.2.2
at-rest
condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present

[ISO 14644-4:2001, 2.4.2]

3.2.3
operational
condition where the installation is functioning in the specified manner, with the specified number of personnel present and working in the manner agreed upon

[ISO 14644-4:2001, 2.4.3]

4 Specification of requirements

4.1 Operational systems

4.1.1 A system of operational procedures shall be established and documented that will provide a framework for producing the quality products and processes for which the cleanroom was designed.

4.1.2 A set of risk factors, appropriate for the use of the cleanroom, shall identify the areas where there is a risk of contamination to the process. A method for monitoring these risks shall be instituted so that action can be taken when conditions violate the contamination limits for the cleanroom classification.

NOTE Although not covered in detail in this part of ISO 14644, it is important to routinely monitor the operation of a cleanroom. Guidance for monitoring particles is given in ISO 14644-2 and ISO 14644-3. Guidance for monitoring biocontamination is given in ISO 14698-1 and ISO 14698-2.

4.1.3 A system for training personnel in cleanroom procedures shall be instituted. A method for monitoring compliance to those training procedures shall be specified.

4.1.4 A documentation system shall be maintained to provide evidence that all personnel have received suitable levels of training for their assignments.

4.1.5 A set of procedures shall be documented to describe how the cleanroom mechanical systems are to be operated, maintained, repaired and monitored (see ISO 14644-4).

4.1.6 All activities that modify, supplement or enlarge the cleanroom shall be planned and include all relevant personnel. Any significant change of operational use may be subject to re-qualification of the installation in compliance with ISO 14644-2.

4.1.7 A system shall be documented that encourages and enforces safety for personnel in the cleanroom that may influence aspects of contamination control.

NOTE Informative guidance concerning the operational systems requirements listed in 4.1.1 to 4.1.7 can be found in Annex A.

4.2 Cleanroom clothing

4.2.1 Cleanroom clothing shall protect the environment and products from contamination generated by the personnel and their everyday clothing. To maximize this containment, the choice of barrier fabric, the clothing style and extent of coverage of personnel by the cleanroom clothing shall be established.

4.2.2 Cleanroom clothing shall be made of fabrics and materials that will resist breakdown (minimal linting) and therefore not shed contamination.

4.2.3 The frequency of changing into fresh cleanroom clothing before entering the cleanroom shall be determined in accordance with the product and process cleanliness requirements.

4.2.4 Reusable cleanroom clothing shall be processed at regular intervals to remove contamination.

4.2.5 The necessary cleaning, processing (including sterilization or disinfection where required) and packaging of clothing shall be defined.

4.2.6 Cleanroom clothing shall be transported and stored in a specified manner to minimize contamination.

4.2.7 Cleanroom clothing (clean packaged or dirty) shall not be removed beyond the confines of the storage area and cleanroom except for laundering, repair or exchange purposes.

4.2.8 Cleanroom clothing shall be put on and taken off in such a way that the spread of contamination is avoided or minimized.

4.2.9 If clothing is to be reused, it shall be removed and stored to ensure that contamination is minimized.

4.2.10 Cleanroom clothing shall be checked at regular intervals to ensure that it retains acceptable contamination control characteristics.

4.2.11 Consideration shall be given for the comfort of personnel wearing the cleanroom clothing.

4.2.12 Consideration shall be given to special (e.g. chemical, physical or microbiological) properties of the clothing that may be necessary for specific applications.

4.2.13 Consideration shall be given to special concerns for cleanroom clothing during and after emergency evacuations.

NOTE Informative guidance concerning cleanroom clothing requirements listed in 4.2.1 to 4.2.13 can be found in Annex B.

4.3 Personnel

4.3.1 Personal and other items not intended for cleanroom use shall not be allowed inside the cleanroom, unless approved.

4.3.2 Personnel shall be instructed in hygiene-related issues that will prepare them for properly working in the cleanroom environment.

4.3.3 A policy concerning jewellery, cosmetics and similar materials that can cause contamination problems shall be determined.

4.3.4 Cleanroom personnel shall be trained to conduct themselves in a manner that minimizes generation of contamination which can be transferred or deposited on or into the product.

4.3.5 Personnel shall be protected against hazards. Personnel shall receive safety training for all known health and safety risks associated with their work.

NOTE Informative guidance concerning personnel requirements listed in 4.3.1 to 4.3.5 can be found in Annex C.

4.4 Stationary equipment

4.4.1 All equipment, with its associated moving and rigging equipment, shall be thoroughly cleaned or decontaminated, or both, before being transported into the cleanroom environment.

4.4.2 Procedures relating to the entry of equipment into a controlled environment shall be specified to ensure that all equipment undergoes the necessary cleaning and decontaminating.

4.4.3 Installation of equipment shall be planned and carried out to minimize the impact on the cleanroom environment.

4.4.4 Equipment maintenance, repairs and calibration procedures shall be performed in such a way as to control and minimize contamination of the cleanroom.

4.4.5 Documented procedures relating to maintenance work and repairs shall be specified to control contamination.

4.4.6 Preventive maintenance schedules shall be established and timed to renew and replace components before the components become contamination sources.

NOTE Informative guidance concerning stationary equipment requirements listed in 4.4.1 to 4.4.6 can be found in Annex D.

4.5 Materials and portable and mobile equipment

4.5.1 All materials, as well as portable and mobile equipment, shall be appropriate for the level of cleanroom cleanliness, and in use, shall not compromise the product and process.

4.5.2 Procedures shall be established to ensure materials and portable and mobile equipment entering the cleanroom are not contaminated.

4.5.3 Procedures shall be established to minimize the quantities of materials stored in the cleanroom. Consideration shall be given to shelf-life limitations, if applicable.

4.5.4 Materials stored in the cleanroom shall be subject to defined procedures and, where necessary, shall be held in protective storage or isolation. The risk of contamination arising from the storage and subsequent use of materials and portable and mobile equipment in the cleanroom shall be considered.

4.5.5 All used and waste materials shall be collected, identified and removed in accordance with defined procedures. Waste materials shall be removed frequently and in a manner that does not compromise the cleanliness of the product or process. Procedures for hazardous materials must conform to statutory requirements set by local and other regulatory agencies.

NOTE Informative guidance concerning materials and portable equipment requirements listed in 4.5.1 to 4.5.5 can be found in Annex E.

4.6 Cleanroom cleaning

4.6.1 Cleaning methods and procedures shall be specified and routinely followed to maintain cleanroom surfaces at acceptable cleanliness levels.

4.6.2 Personnel responsible for the cleaning operation shall be designated and receive specific training for accomplishing the task.

4.6.3 Cleaning schedules shall be defined and carried out at effective frequencies to ensure that specified cleanliness levels are maintained.

4.6.4 Appropriate contamination checks shall be carried out on a routine basis to ensure the cleanroom is maintained at specified levels.

4.6.5 An assessment shall be made to identify any cleaning procedures that will place products or processes at risk during the performance of such cleaning tasks. Preparations should be made to remove or cover work-in-process before cleaning begins.

4.6.6 Special cleaning procedures and techniques shall be defined for unavoidable accidents or system failures that create contamination that places the cleanroom, products, processes or personnel at risk.

NOTE Informative guidance concerning cleaning requirements listed in 4.6.1 to 4.6.6 can be found in Annex F.

Annex A
(informative)

Operational systems

A.1 General

It is essential that management provides leadership that will focus the attention of its staff on generating and maintaining systems that will encourage good cleanroom practices. A management structure should be defined and published to ensure all parties are aware of their responsibilities. Good cleanroom practices will have a significant impact on the quality of products being produced and the processes performed in the cleanroom. This annex is provided to assist management in identifying those systems.

A.2 Assessing contamination risks

A.2.1 Methods for assessing risks

A risk assessment should be made to determine any relevant contamination control factors that may affect the products or processes performed in the cleanroom.

Some examples of methods used for determining and managing these factors include:

a) HACCP (Hazard Analysis Critical Control Point)[1];

b) FMEA (Failure Mode Effects Analysis)[2][3];

c) FTA (Fault Tree Analysis)[4].

A.2.2 Determining operational risks

A.2.2.1 General

Improper control of the critical elements of an operational cleanroom can pose a risk to the cleanliness of the cleanroom and the quality of the product. A list of these critical elements and some of the associated risks can be found beginning in A.2.2.2 to A.2.2.6. An assessment of these risks should be carried out and plans formulated by each organization to remedy non-compliant situations. In this assessment, it is especially important to consider the following:

a) concentration of contamination in or on the risk factor;

b) distance from the risk to the product;

c) importance of the method used to protect product from the risk[5].

Information concerning cleanroom support parameters and factors including heating, ventilation and air conditioning functions, pressure, temperature, humidity, air change failure and filter failure are discussed in ISO 14644-2, ISO 14644-3 and ISO 14644-4.

A.2.2.2 Cleanroom clothing

Risk factors that may influence the operation or environmental quality of the cleanroom include:

a) required human containment (coveralls, frocks, hoods, gloves, boots, masks, etc);

b) material performance (weave characteristics, filament types, sterility, antistatic, calendering, etc);

c) design and construction (special tailoring requirements);

d) comfort;

e) usage (launderable versus disposable);

f) choice of personal clothing worn under cleanroom clothing;

g) time interval or number of wearings before laundering is required;

h) choice of cleanroom clothing laundry;

i) renewing, packaging, storage and distribution.

A.2.2.3 Personnel

Risk factors that may influence the operation or environmental quality of the cleanroom include:

a) selection of personnel;

b) education and training;

c) safety (including emergency procedure);

d) personal attire, hygiene and behaviour, (including behaviour prior to entering the cleanroom);

e) chronic and acute medical conditions;

f) personnel who shed significantly more contamination than other personnel;

g) who is allowed to enter;

h) special procedures for visitors;

i) maximum occupancy;

j) entry and exit procedures;

k) movement and activity of personnel within the cleanroom.

A.2.2.4 Stationary equipment

Risk factors that may influence the operation or environmental quality of the cleanroom include:

a) entry and exit procedures;

b) installation;

c) cleaning techniques;

d) contamination generation;

e) generation of heat, humidity and electrostatic charge;

f) maintenance and repair;

g) cleanliness of process material and utilities delivery systems;

h) potential equipment failures.

A.2.2.5 Materials and portable and mobile equipment

Risk factors that may influence the operation or environmental quality of the cleanroom include:

a) compatibility and selection;

b) entry, exit and movement procedures;

c) storage factors while in the cleanroom;

d) contamination factors during use;

e) generation of electrostatic charges;

f) liquid and gas purity supplied by delivery systems;

g) waste disposal;

h) packaging.

A.2.2.6 Cleanroom cleaning

Risk factors that influence the operation or environmental quality of the cleanroom may include:

a) routine environmental contaminating factors (airflows, airborne particles, out-gassing, hazardous gas, micro-organisms, vibration, electrostatic charges, molecular contamination, etc.);

b) personnel and material flow;

c) service, maintenance and repair;

d) cleaning methodology;

e) emergency and planned shutdown;

f) facility expansion and modification;

g) frequency for monitoring the results of cleaning.

A.3 Monitoring and corrective action

A routine monitoring programme should be followed that encompasses personnel, cleaning and other operational systems. Monitoring should be sufficiently frequent and comprehensive to detect actual or emerging unacceptable conditions in a timely manner. Exceeding specified action levels should result in a prompt response, including investigative and corrective action. Investigative and corrective action should include the effect on product quality as a potential result of the non-compliant condition. Further information can be found in ISO 14644-2 and ISO 14644-3 for particle monitoring. Information on microbiological monitoring can be found in ISO 14698-1 and ISO 14698-2.