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norm

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Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004,IDT)

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- ISO 14644-5:2004,IDT

Normcommissie 301 003 "Cleanrooms and associated controlled environments"

NEN

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Nederlands voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

vermelde norm	Nederlandse norm	titel
ISO 14644-1:1999	NEN-EN-ISO 14644-1:1999	Stof- en kiemarme ruimten en omgevingen - Deel 1: Indeling van luchtreinheid (en)
ISO 14644-2:2000	NEN-EN-ISO 14644-2:2000	Stof- en kiemarme ruimten en omgevingen - Deel 2: Specificaties voor het beproeven en controleren om de continue overeenkomst met ISO 14644-1 aan te tonen (en)
ISO 14644-3:	-	-
ISO 14644-4:2001	NEN-EN-ISO 14644-4:2001	Stof- en kiemarme ruimten en omgevingen - Deel 4: Ontwerp, constructie en opstarten (en)
ISO 14698-1:2003	NEN-EN-ISO 14698-1:2003	Stof- en kiemarme ruimten en omgevingen - Controle op biocontaminatie - Deel 1: Algemene principes en methoden (en)
ISO 14698-2:2003	NEN-EN-ISO 14698-2:2003	Stof- en kiemarme ruimten en omgevingen - Controle op biocontaminatie - Deel 2: Evaluatie en interpretatie van gegevens van biocontaminatie (en)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14644-5

August 2004

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English version

Cleanrooms and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)

Salles propres et environnements maîtrisés apparentés - Partie 5: Exploitation (ISO 14644-5:2004)

Reinräume und zugehörige Reinraumbereiche - Teil 5: Betrieb (ISO 14644-5:2004)

This European Standard was approved by CEN on 29 July 2004.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Foreword

This document (EN ISO 14644-5:2004) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

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

Endorsement notice

The text of ISO 14644-5:2004 has been approved by CEN as EN ISO 14644-5:2004 without any modifications.

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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.

A.4 Education and training

A.4.1 Involvement

General personnel activity within the cleanroom has a profound effect on the integrity of the clean environment. Failure to properly train anyone entering, using or maintaining the facility will compromise the effectiveness of the cleanroom. Management is therefore responsible for implementing a comprehensive programme to train all personnel with regard to their responsibilities and how those responsibilities interact with the clean environment. Certification should be based on successful completion of testing to demonstrate understanding and compliance. The programme should ensure each of the following groups of personnel is educated and trained appropriately:

a) operators;

b) technicians;

c) engineers and scientists;

d) quality assurance personnel;

e) supervisors and managers;

f) facilities personnel;

g) contractors;

h) field service personnel;

i) visitors.

A.4.2 Training course contents

Subjects that can be included in the training course include:

a) how the cleanroom works (design, airflow and air filtration);

b) cleanroom standards;

c) sources of contamination;

d) personal hygiene;

e) cleaning;

f) cleanroom clothing procedures;

g) maintenance procedures;

h) how a cleanroom is tested and monitored;

i) how to act in a cleanroom;

j) explanation of the work process, technologies or sciences employed and how the process can become contaminated;

k) safety and emergency response.

A.4.3 Monitoring of cleanroom personnel and corrective action

The cleanroom training programme provides an explanation of requirements and actions that minimize the risk factors important to the cleanroom, identified in A.2.2.3. The ability of personnel to incorporate all elements of

cleanroom training into practice is essential to the continuous, effective operation of the cleanroom. Personnel, although properly trained, may not fully comprehend all requirements or may lapse into poor procedural habits. Therefore, actions of personnel listed in A.4.1 should be monitored to ensure personnel carefully comply with correct cleanroom disciplines. Consideration should be given to a system that will monitor cleanroom personnel. Monitoring programmes can be formal or informal depending on the level of empowerment given to each person that is part of the cleanroom staff. Internal auditors can monitor the actions of those in the cleanroom based upon the written procedures. Reports can be issued to management on a regular basis detailing unsatisfactory behaviour and can be used for determining corrective action[6].

An effective programme should be a positive influence on all personnel to follow proper cleanroom procedures.

A.4.4 Training documentation

A concise, comprehensive system that documents the training progression and level of each individual associated with cleanroom operation and maintenance should be used. The management team should identify each job and set of jobs or responsibilities. This documentation system should be easily accessible to management and periodically reviewed. Basic documentation should include course contents, personnel identification information, training and certification dates, and schedules for retraining that may be required at future intervals.

A.5 Cleanroom support services

A.5.1 General overview

Management is responsible for ensuring cleanroom support services consistently function as designed on a day-to-day basis. Support services may include clean and conditioned air systems, compressed air and gasses, water and other utilities, and other aspects required for standard cleanroom operation. Failure of any mechanical support system can seriously affect the cleanliness and operation of the cleanroom. Records and procedures documenting the operation of the systems that provide and maintain the cleanroom should be readily available. Some of the information required to establish such systems is given in A.5.1 to A.5.6. More thorough coverage of the subjects listed in A.5.2 to A.5.6 is found in ISO 14644-4.

A.5.2 Record of the installation

This record should contain installation drawings, cleanroom classification including acceptance test results to original specifications, and recommended spare parts lists.

A.5.3 Operating and maintenance instructions

Operating and maintenance instructions should include an explanation of how the systems work and their influence on room cleanliness. The mechanical and electrical systems within the installation should have a clear set of operating and maintenance instructions. These instructions should describe procedures used to check and inspect all critical components prior to start-up. Emergency shutdown procedures and start-up procedures after unplanned shutdowns should be documented.

A.5.4 Performance monitoring

Performance monitoring of the installation is essential to demonstrate satisfactory operation. Documented schedules and procedures that specify the required tests and the frequency of testing are needed to demonstrate specified cleanroom classifications. Action plans for non-compliant situations should be defined.

A.5.5 Maintenance procedures

Unplanned downtime can adversely affect productivity and introduce contamination to the cleanroom. Ongoing performance checks and preventive maintenance should be performed to minimize contamination

that may be caused by unanticipated equipment failures. Repair and maintenance procedures should contain precautions that will help minimize and contain contamination. Tests may also be necessary to ensure that reactivated equipment is clean and in specification before being accepted for reuse.

A.5.6 Maintenance records

Evidence of effective maintenance requires a documented record involving all maintenance activities. Problem diagnoses, parts replaced, dates, times and personnel performing the maintenance should be documented. Preventive maintenance schedules and charts should be updated as required. Periodic analysis of such records may help in making improvements to the programme and help optimize preventive maintenance schedules.

A.6 Upgrading and modifying the cleanroom

All upgrades or modifications, including the addition of stationary equipment and changes to floor plans, can affect the cleanliness of the cleanroom. Management should make certain these changes are planned and carried out in a controlled and thorough manner and that requalification of the installation is in compliance with ISO 14644-2 and ISO 14644-4. A record of all changes or modifications should be documented after requalification. All appropriate personnel with responsibilities affected by these changes should be involved and kept informed of progress. Such personnel may include but are not limited to:

a) facility engineers;

b) manufacturing engineers;

c) equipment engineers;

d) contamination control engineers;

e) process engineers and scientists;

f) quality assurance engineers and scientists;

g) manufacturing managers;

h) contractors.

A.7 Safety

Normal operation of cleanroom facilities often includes the use of hazardous, toxic or infectious materials. Preventive measures required by statutory regulations must be observed to protect personnel from exposure to these agents. Management should implement and monitor effective systems for protecting the health and welfare of personnel. Good programmes should include the following:

a) centralized, readily-available safety data sheets that describe hazardous materials;

b) evacuation plans and practice evacuations;

c) accident reporting system;

d) feedback suggestion systems for personnel;

e) appropriate monitoring of potentially hazardous conditions or materials;

f) rapid response to emergencies by trained personnel;

g) documentation that supports improvements and corrections to safety-related issues.

Annex B
(informative)

Cleanroom clothing

B.1 Function of cleanroom clothing

Personnel disperse fragments from their skin and particles from their indoor, non-cleanroom clothing. This airborne dispersion will vary from person to person and from time to time but can be several million particles per minute and several hundred bacteria-carrying particles per minute. The prime function of cleanroom clothing is to act as a barrier filter that protects product and process from human contamination. Therefore, cleanroom clothing should be made from a fabric that filters the dispersed contamination. Cleanroom clothing should also be designed to envelop a person and not allow significant amounts of unfiltered body emissions to be dispersed into the cleanroom. An effective cleanroom undergarment in combination with cleanroom clothing can provide an additional reduction in dispersion.

Although the majority of contamination originates from the skin and non-cleanroom clothing, contamination is also dispersed from the surface of cleanroom clothing fabrics. The fabric used to manufacture cleanroom clothing should not add to the contamination burden.

Personnel also emit inert and microbe-carrying particles from the mouth through sneezing, coughing and talking. Therefore, cleanroom clothing should be made from a fabric that filters the contamination dispersed. Touching will transmit contamination from the hands to surfaces in the cleanroom. Depending on the cleanroom function and class, it may be necessary to wear face masks, helmets and gloves to minimize transmission of these types of contamination. The choice of cleanroom clothing will vary according to the product cleanliness and process requirements but will normally, but not exclusively, consist of hoods, caps, helmets, coveralls, overboots, face masks and goggles or safety glasses.

B.2 General choice of cleanroom clothing

The best design of cleanroom clothing will completely envelop the person and have good closures at the wrist, neck and ankle. The choice will depend on the class of cleanroom but cleanrooms with higher cleanliness requirements are typified by a one-piece coverall, overboots and a hood with yoke or skirt that tucks under the neck of the garment.[8] Increasing technical requirements on cleanroom clothing may result in increasing personal restrictions or discomfort. Therefore, consideration should be given to what is necessary for the standard of room cleanliness. Where cleanliness and process requirements permit, clothing of lesser coverage may be acceptable[7] [8] [9] [10]. Certain separative devices with built-in clean air systems (e.g mini-environments or isolators) may allow for the simplification of required cleanroom clothing.

There are two broad categories of clothing used in cleanrooms: 1) disposable (or limited use) and 2) reusable. In general, disposable or limited use clothing usually is made from a non-woven materials and is used either once or a few times, and then discarded. Reusable cleanroom clothing is processed at regular intervals and usually made from tightly woven synthetic fabrics, constructed with lint-free, continuous filament materials (such as polyester or polyamide). Natural fabrics made from fibres, such as cotton, would not normally be used in cleanrooms as they easily break up and disperse contamination. More critical applications may require the use of membrane barrier technology, which may be either disposable or reusable.

B.3 Properties of fabric

B.3.1 Barrier properties

The fabric used in cleanroom clothing should prevent personnel-generated contamination from being dispersed into the cleanroom. Woven fabric acts as a filter; effectiveness is related to the tightness of the weave of the fabric. In the case of barrier-type fabrics such as non-wovens and laminate membranes, the effectiveness to contain contamination is a function of the barrier characteristics. Fabric effectiveness can be assessed by a measurement of air permeability, particle retention and pore size [8] [10] [11] [12]. As air permeability decreases, there is a corresponding increase in pressure within the garment as personnel move about. This can result in an outward pumping action of unfiltered air through the closures of the cleanroom clothing.

B.3.2 Durability

Cleanroom clothing should be resistant to breakdown and tearing. The fabric should disperse the minimum of particles. Information is available on tests used to assess these types of fabric properties [7] [10] [13] [14].

B.3.3 Electrostatic properties

In some types of cleanrooms (e.g. microelectronics or rooms with flammable or explosive chemicals), the electrostatic charges that build up on the surface of clothing will be harmful to the components being manufactured or hazardous to operators. Fabrics are available with woven-in, static-dissipative threads to discharge any induced voltage potentials on the fabric surface. The effectiveness of a fabric to dissipate an electrostatic charge can be indirectly measured by checking the fabric's surface resistivity. Such methods are described in other sources [10] [15] [16]. In a more effective test, a static charge of known voltage level is applied to the fabric. Static dissipative performance can then be determined by the time it takes for the voltage to decrease by a given percentage of the original voltage. Such methods are described in other sources [10] [15] [16].

B.3.4 Other physical properties

The effectiveness of a fabric will deteriorate due to aging, wear, washing, drying, sterilization, etc. This deterioration should be monitored. Another physical property that should be considered is the resistance of the fabric to chemicals, such as those used during the manufacturing process and in the cleaning and disinfection of the cleanroom and clothing.

NOTE The tests referenced in B.3.1 to B.3.4 will help to verify that the clothing remains effective.

B.4 Design and construction of cleanroom clothing

B.4.1 Construction of clothing

Cleanroom clothing should be constructed to minimize contamination in the cleanroom. Cutting the fabric prior to sewing produces raw edges that will generate particles if left unfinished. Methods used to finish these edges are as follows: all raw edges of the fabric should be covered, interlocked and heat seared or laser cut to prevent fraying. Seams should be double-needle stitched, bound or taped to provide a good barrier and not produce fibres. Threads should be synthetic continuous filament. Zippers, clips and fasteners, and shoe soles should not shed, chip or corrode, and should stand up to multiple launderings and where necessary, sterilization [8].

B.4.2 General design

The selection of the design of clothing should be considered with respect to the type of cleanroom [8] [9] [10]. Cleanroom clothing should incorporate a large selection of sizes to provide comfort and fit. To minimize the retention of contamination, pockets, pleats, darts, hook and pile fasteners, and action backs should not be

used. Elasticized or knitted cuffs should not trap or shed contaminants and should not build up electrostatic charges. Cleanroom clothing closures should provide a tight yet comfortable closure. Other design parameters that should be considered are:

a) zipper material (e.g. covered plastic zip-fasteners), type and location;

b) placement and effectiveness of snap adjusters and stays;

c) sleeve construction (set-in or raglan);

d) cuff closures (elasticized, knit or snap)

e) collar style;

f) ability to put cleanroom clothing on over various shoe or boot styles;

g) hood style (open or closed face, snap or pull-over);

h) passive or active adjustment and fit of hoods;

i) type and placement of straps on boots.

B.4.3 Dispersal chamber (body box)

This simulation procedure can be used to demonstrate the combined effect of fabric, construction and design of clothing. A person will enter the box, which is ventilated at a known flow rate of filtered air, and exercise to a given routine. The number of particles or bacteria dispersed can be measured. Different types of clothing that have to be assessed can be compared. A description of this test is available [8].

B.5 Thermal comfort

Whenever possible, the comfort of people working in the cleanroom should be considered when choosing cleanroom clothing materials [17]. Air and water vapour permeability specifications of the fabrics under consideration can help in this determination [8] [18] [19]. A simple but effective approach is to obtain a selection of suitable clothing of different fabrics and try them in the cleanroom. Feedback, solicited from personnel who will be expected to wear the clothing, may provide valuable information that will aid in the selection process.

The use of relevant personnel parameters and environmental parameters (air temperature, velocity, turbulence, mean radiant temperature, and humidity within the cleanroom) can be used to derive theoretical clothing comfort level according to ISO 7730 [20] which provides guidance and tables that will assist in making this determination.

B.6 Cleanroom clothing cleaning process and frequency of change

During use, cleanroom clothing will become contaminated. If it is to be reused it should be cleaned. Suggestions as to how this cleaning process should be carried out are available in other sources [8] [21]. Final treatment and packaging operations for cleanroom clothing should be carried out in cleanroom conditions that are compatible with the standards of the cleanroom in which they will be used. Clothing similarly becomes contaminated with bacteria. In cleanrooms where bacteria are an important consideration, the processing cycle in the cleanroom laundry should include, as appropriate:

a) disinfection;

b) hot water cycles;

c) sterilization.

Cleaning procedures should include sample testing at the laundry for the appropriate type and level of contamination. The frequency of clothing change will vary according to the intended use of the cleanroom. The more sensitive the process is to contamination, the more frequently the clothing should be changed and cleaned. However, increasing the cleaning frequency will cause additional stress to the cleanroom clothing, contributing to premature breakdown of the fabrics. Guidance is also available to help in the decision-making process [8].

B.7 Gloves

Cleanroom gloves are required in most cleanrooms. They cover that part of the human body that is often closest to the product and critical surfaces. Consideration should therefore be given to whether gloves are necessary. If they are used, consideration should be given to what properties are best suited, as well as how often they should be changed or cleaned (and where appropriate, disinfected).

Properties of cleanroom gloves that should be considered with respect to the type of cleanroom in which they will be used are as follows: surface contamination, outgassing, sterility, tactility, strength, comfort, fit as well as the method of packaging. Various tests can be performed to help in selecting the proper gloves for each particular cleanroom application.[22]

Gloves can be constructed of latex, vinyl, polyurethane, or other materials such as nitrile rubber. The choice of construction should be considered with respect to the required properties and application of the glove, and the cost. Undergloves, made from non-linting materials, may also be needed by some employees to provide a level of comfort or isolation from inner glove surfaces that can cause or aggravate contact dermatitis.

The cleanliness of outer surfaces of cleanroom is extremely important. A method should be devised for storing and removing gloves from their packaging and putting them on so as to minimize contaminating the outer glove surfaces.

B.8 Face masks and other headgear

Face masks and exhaust headgear provide a barrier against saliva and contamination dispersed from the mouth, nose, face and, in the case of headgear, the head. Masks and veils are passive barrier elements commonly used in cleanrooms. The masks can be surgical-style masks with tie straps, elasticized straps or loops. Face veils have headbands or snaps or can be permanently sewn into cleanroom hoods at manufacture. Materials used are washable and disposable fabrics. Care should be taken to select the proper material and style that is appropriate to the risk from emissions from the mouth. This selection should also consider the acceptability of the face mask to the personnel.

Headgear is available that provides an active barrier to contamination from the mouth and head. A helmet with hood and clear face-shield encloses the head and is provided with a filtered exhaust system that prevents contamination from escaping into the cleanroom.

Glasses or goggles can help provide an additional barrier to help retain skin flakes and eyelashes and keep them from falling onto critical surfaces. Glasses or goggles should be constructed from materials that are cleanroom compatible and should conform to accepted personal safety standards.

B.9 Storage of clothing

B.9.1 If the cleanroom clothing is to be reused, it should be stored or hung using appropriate techniques that will maintain the cleanliness of the clothing. Clothing elements may require physical separation when stored. Launderable or disposable bags can be used to help avoid cross-contamination. Several methods are effective for storing clothing. These may include:

a) clothing racks with high-efficiency, self-contained, filtered air supply;

b) fixed and portable racks utilizing hangers;

c) locking and non-locking hooks mounted to walls or frames in the changing area or room (either in a locker or in the room);

d) bins or storage slots.

B.9.2 The space required to temporarily store cleanroom clothing used by personnel currently working in the cleanroom is dependent upon the number of people working in the cleanroom and the frequency at which the cleanroom clothing is changed.

B.9.3 An area large enough to contain the total inventory of packaged cleanroom clothing should be set aside for storage purposes. Lockers can be obtained for this purpose. These lockers should be placed on the cleaning schedule to ensure that they do not contribute to contamination.

B.9.4 Cleaned clothing should be packaged in clean, non-shedding bags to avoid contamination during handling, storage and distribution.[8] The shelf life for sterilized products should be defined. It is recommended that storage should be in a controlled environment that is adjacent to or in the changing area. This allows better control of the inventory and reduces the risk of clothing being removed from the cleanroom environment and becoming soiled.

Annex C
(informative)

Personnel

C.1 Training

Only trained personnel should be allowed to enter and work in a cleanroom. All personnel should be given an introductory course when initiated into the cleanroom and further periodic retraining (see A.2).

C.2 Access by personnel

People generate contamination. Therefore, only essential personnel should enter the cleanroom. If the total number of people allowed in the cleanroom is controlled, access should be documented and enforced. Visitors and maintenance people can be allowed into the room by permission and under supervision. They should be given an appropriate level of training.

C.3 Clothing and personal items

The type of clothing worn under cleanroom clothing will affect the dispersion of airborne particles and fibres. Personal indoor clothing manufactured from natural fibres such as wool or cotton and worn underneath cleanroom clothing will shed contamination. The provision for special cleanroom undergarments should be considered. If underclothing is provided, they should be made from closely woven, artificial fibres such as polyester for effective filtration of body contaminants. Personal items should be left outside the cleanroom in a secure area. Jewellery, such as rings, watches, and chains, can puncture cleanroom gloves or dangle outside face masks, hoods or sleeves of the clothing, and should be avoided. Cosmetics, talcum powder, hair sprays, nail polish or similar materials are undesirable in a cleanroom. An assessment should be made of the risk to the product or process from these types of items. Cosmetics can generate particles that contaminate cleanroom clothing, the cleanroom and products being produced and may be prohibited.

C.4 Hygiene

Cleanroom personnel are expected to have good personal hygiene. Personnel should keep dandruff controlled, and, as necessary, use specially formulated skin lotion to replace skin oils after washing and showering.

Personnel arriving for work should report problems that might increase contamination in the cleanroom, including the following:

a) conditions such as flaking skin, dermatitis, sunburn or bad dandruff;

b) cold, flu or chronic coughing;

c) allergic conditions that cause sneezing, itching or scratching;

d) in a biocleanroom — high microbial bioburden on personnel.

Depending on the seriousness of the condition with respect to the process or product being produced, it may be necessary to reassign personnel with such conditions to work outside the cleanroom until the condition is in abeyance. In some cleanrooms, it may be required that personnel refrain from smoking for a defined period of time before entering.

C.5 Cleanroom clothing changing procedures

Cleanroom personnel will change into cleanroom clothing before proceeding into a cleanroom. A method should be adopted to put on and remove clothing to minimize contamination of the outside of the cleanroom clothing and to ensure contamination is not spread from the changing area. Several methods are acceptable depending on the design of the changing area and the standard of cleanliness of the cleanroom. Further information is described in other sources. [5] [6] [23]

Usually the process begins at the head and proceeds downward to the feet:

1) Remove contamination from shoes by use of a shoe cleaner, cleanroom mat or cleanroom flooring.

2) Remove unnecessary street clothing.

3) Remove jewellery, etc. if required.

4) Remove cosmetics and put on moisturizer, if required.

5) Put on hair cover, if applicable.

6) Wash hands and put on suitable moisturizer, if applicable.

7) Put on cleanroom underclothing, if applicable.

8) Put on cleanroom-dedicated under-shoes, or shoe covers.

9) Select cleanroom clothing.

10) If required, put on gloves for handling cleanroom clothing.

11) Put on face and head covering.

12) Put on coverall or gown.

13) Put on shoe coverings or special cleanroom shoes, using a crossover bench.

14) Using a full-length mirror, ensure that all items of clothing are properly adjusted.

15) Gloves used for putting on cleanroom clothing can now either be removed, or left on, so that process gloves can be put on.

16) Enter the cleanroom.

NOTE The previous list of steps outlines one typical procedure that is commonly used, but many variations exist to comply with contamination control needs for certain types of cleanrooms.

The way cleanroom clothing should be taken off when leaving the cleanroom will depend on whether fresh clothing is used on each entry or whether the clothing is to be reused. Methods for removing cleanroom clothing that will be reused are described in other sources [17]. Special storage methods can be used if the clothing is to be reused and are described in other sources. [5] [6] [17]. Cleanroom clothing should not be removed from the controlled environment except for transfer to the laundry for cleaning.

C.6 Discipline and conduct

Cleanroom personnel should conduct themselves in a cleanroom in such a way as to minimize the possibility of contaminating the product. The following are minimum disciplines that should be considered (more information can be found in other sources. [6]

— Doors should not be opened and closed quickly, nor left open.

— When using a transfer area, the entry door should be allowed to close and the air to purge or stabilize for a predetermined period of time before the exit door is opened into the next area.

— Personnel should not position themselves between clean air supplies and product or process surfaces. Doing so will increase the risk of dispersing particles onto product or process surfaces. In general, the correct positioning sequence should be: air supply to exposed product to personnel and then to the general cleanroom area and the air return or exhaust.

— Methods should be devised for moving or manipulating the product. “No-touch” techniques should be used where appropriate.

— Personnel should not support material against their bodies or contamination may be transferred.

— Personnel should not talk when working close to the product.

— Personnel should not allow anything to trail over the product.

— Nose blowing should be done outside the cleanroom. Gloves should always be changed afterwards.

— Personnel should also refrain from touching, scratching or wiping any skin areas while in the cleanroom. Doing so may require personnel to return to changing area to obtain and put on fresh gloves.

— Glove and cleanroom clothing surfaces can easily become contaminated. Personnel should not touch contaminated surfaces that will transfer contamination to critical areas. Each cleanroom must have a policy that instructs personnel to return to the changing area to change into clean gloves or cleanroom clothing. Some cleanrooms may allow gloves to be changed in the cleanroom.

— A cleanroom wipe should be used as specified and then discarded in the proper waste receptacle.

— All personnel movements should be deliberate and methodical. Rapid walking and movements or over-exuberant behaviour should not be allowed since it will disrupt the airflow. This will both generate contamination and allow it to be included in the air stream.

— The room should be kept neat and tidy.

— Products stored or left standing in a cleanroom should be protected from contamination and kept in an identifiable closed cabinet, container or unidirectional cabinet.

— Waste material should be placed into easily identifiable containers and not allowed to collect unnecessarily.

C.7 Safety

C.7.1 Preventive measures required by statutory regulations must be implemented to protect personnel from hazards that may occur or may be in use in the cleanroom, such as microbes, radioactivity and chemicals. The use of containment cabinets, cupboards or isolators may address these concerns. Information on preventive methods is discussed in ISO 14644-4 and ISO 14644-7. Suitable protective clothing such as eye splash shields, gloves and aprons may be required. Local regulatory authorities may recommend or require additional measures to protect the safety of personnel in cleanrooms.

C.7.2 Emergency situations may arise and emergency response personnel, trained in all aspects of potential emergencies, can minimize the effects of mishaps that may occur. All employees should be trained for an orderly evacuation. If an evacuation is necessary, provisions should be made for the orderly return to the cleanroom once the situation is cleared. An emergency procedure for supplying fresh cleanroom clothing should be implemented.

C.8 Personnel initiatives

Elements for formal monitoring and corrective action programmes are described in A.7. However, personnel should understand that they could have a positive influence on the effectiveness of the cleanroom. Helpful coaching of one to another can have a positive effect on conformance to personnel procedures. Personnel should be encouraged and empowered to immediately report any observed deficiencies, whether personnel or facility related, to individuals responsible for cleanroom integrity. Such action will allow otherwise unnoticed contamination sources to be corrected before the problem becomes serious enough to place products or process at risk.

Annex D
(informative)

Stationary equipment

D.1 General

Equipment that is large enough to be stationary or relatively immovable, once located within the cleanroom, is discussed in this section. Stationary equipment often surrounds, envelopes, or encloses the products or processes for which the cleanroom was provided. Stationary equipment may be in the form of automated and mechanical processing equipment, separative devices, and exhaust hoods as well as other large equipment. Usually, extensive efforts are required to remove or relocate this equipment once installation is completed.

When possible, equipment to be used in the cleanroom should be manufactured under clean conditions and packaging procedures should be adapted for the requirements of the intended cleanroom.

D.2 Clean entry process

D.2.1 Planning

The process of bringing equipment into the cleanroom should not add contamination. Equipment entering a cleanroom that is “as-built” or “at-rest” should be properly unpacked and cleaned. Failure to do so will require extensive cleanup afterwards. However, special considerations should be made before bringing equipment into an “operational” cleanroom. Failure to do so will expose not only the cleanroom to contamination risks but may affect products in process. This will also necessitate additional cleaning and may require the cleanroom to be requalified under ISO 14644-2. An appropriate strategy should be developed to avoid problems. Guidance is given in D.2.2 and D.2.3 and in other sources. [6]

D.2.2 Inspection and removal of non-cleanroom packaging

All equipment should be checked for damage in transport. Suspected or damaged goods should be isolated or protected outside the cleanroom pending appropriate actions. Whenever possible, shipping crates and packaging should be removed in the uncontrolled environment adjacent to the cleanroom. All cardboard and heavily shedding materials should be removed before being transported into the controlled environment. When not pre-packaged, all surfaces of the equipment should be pre-cleaned prior to entry of the equipment into a cleanroom area. This cleaning is best carried out within the specific transfer area used for equipment entry If the equipment is so large that special installation procedures are required, the area should be isolated from surrounding cleanrooms or other controlled environments through the use of temporary walls.

D.2.3 Removing cleanroom packaging

Unpacking of equipment should be done in steps to control contamination entering the cleanroom. A controlled transfer room, or a temporary room built for this purpose and attached to the cleanroom, can be used for the removal of exterior film packaging materials and surface cleaning before cleanroom entry.

The following is an example of the steps that should be taken during unpacking:

1) The outer protective covering should be vacuumed, beginning at the top surface and then proceeding to the sides.

2) The protective cover should be wiped, using the appropriate cleaning agent.

3) The outer layer of packaging film should be slit at the top in an "I" form and peeled from the top to the bottom edge. The bottom edge of the packaging film should then be lifted and joined to the sides of the packaging film.

4) The unpacking procedures in steps 2 and 3 should be repeated for each additional layer. All exterior surfaces of the equipment should be thoroughly cleaned.

5) All personnel should be wearing the proper cleanroom clothing prior to entering the transfer area from the cleanroom.

6) All moving and handling equipment should also be cleaned, in accordance with procedures described in D.3.

7) The transfer area should be cleaned before opening the doors to the cleanroom for transferring the equipment inside.

D.3 Transporting equipment

Large equipment should be dismantled (if possible) to a size that will enable safe entry, minimizing risk to personnel and the existing cleanroom. Physical damage and contamination can result when these large units come into contact with fixed surfaces and other tools.

Any special equipment used for lifting, hauling or positioning large equipment should be thoroughly cleaned before being allowed into the cleanroom. Often, this equipment may not be designed or maintained for cleanroom use and should be thoroughly inspected for chipping and flaking surfaces or for materials unsuitable for transfer into the cleanroom. These tools can often be made acceptable by means such as wrapping and sealing the tool with cleanroom-compatible plastic films and tape. Soft rubber wheels can be coated with cleanroom tape to avoid leaving trails of rubber or plastic particles on the flooring.

D.4 Installation procedures

The method used to install equipment will depend on how the cleanroom has been designed and used. Ideally, the cleanroom should be closed down during the installation and a sufficiently wide door or pre-engineered access panel provided to bring the new equipment into the cleanroom. Preventive measures should be taken to avoid contaminating the adjacent cleanroom area during the installation period. This will simplify the subsequent cleaning and testing needed to ensure that the cleanroom is within its cleanliness specification.

If work within the cleanroom must continue during installation, or structural demolition is required, then the rest of the operational cleanroom must be effectively isolated from the work area. Surrounding the equipment with a temporary isolation wall or partition can do this. An area should be left around the equipment to complete the installation unhindered.

a) Access to the isolation area should be from a service aisle or other non-critical area, if possible. If access is not possible, measures should be taken to minimize the effects of construction-generated contamination. Airflow to this isolation area should be maintained at a neutral or negative pressure to reduce the possibility of contamination being forced outside the work area.

b) A completely sealed isolation area should not be pressurized from within or the possibility of contaminating the surrounding cleanroom exists if a penetration of the barrier should occur. The clean-air supply inside the isolated area should be blocked to avoid pressurizing the surrounding cleanroom. When entry to the isolated area is only accessible through an adjacent cleanroom, sticky mats should be installed to remove shoe-borne contamination. Once inside, disposable boots or shoe covers and coveralls may be required to avoid contaminating cleanroom clothing. These disposables should be taken off before leaving the isolated area.

c) A method and frequency for monitoring the areas surrounding the isolated area should be instituted to ensure that any contamination that may leak into the adjacent cleanroom areas is detected.

d) All facility services, such as electricity, water, gas, vacuum, compressed air and waste piping, will then be attached. Care should be taken to ensure fumes and debris generated by this operation are controlled and contained as completely as possible to avoid inadvertent release to the surrounding cleanroom and facilitate effective cleaning before removal of the isolation barriers.

e) Accepted cleaning procedures (see Annex F) should then be used to decontaminate the entire isolation area. All surfaces should be vacuumed, wiped and mopped, including all walls (both fixed and portable), equipment and floors.

f) Special care should be taken to clean areas behind equipment panels and under equipment.

g) Some internal preparation and preliminary performance testing of the equipment is now possible, but final acceptance may require full cleanroom conditions before final testing can be completed.

h) The isolation walls can now carefully be removed and filtered air sources returned to service if deactivated. This step should be scheduled to minimize interruptions in the regular operation of the cleanroom. Particle measuring or testing may also be required.

i) Equipment interiors and critical processing chambers should be cleaned and prepared for use under normal cleanroom conditions.

j) All appropriate inner chambers and all surfaces coming into contact with the product or involved in the handling of the product should be wiped to achieve a desired cleanliness level. The cleaning procedure should be carried out, by working from the top to the bottom of the equipment, as once particles are disturbed, gravity will force larger particles to fall to the bottom of the equipment or to the floor.

k) Clean the outer surfaces of the equipment, working from the top to the bottom surfaces.

l) If necessary, surface particle checks should be performed in areas critical to product or process requirements.

D.5 Maintenance and repair

With time, equipment wears out and becomes dirty or emits contamination unless it is maintained. Preventive maintenance should be carried out to ensure equipment is not allowed to become a source of contamination. Maintenance and repair of equipment should proceed without contaminating the cleanroom. [24] [25] Successful completion of such repairs should include decontamination of external surfaces. Decontamination of internal surfaces may also be needed, if required by the process. The equipment should not only be in working condition, but steps should be taken to decontaminate internal and external surfaces consistent with processing requirements.

The following measures can help to control contamination generated by maintenance of stationary equipment.

a) Equipment being repaired should be removed from the area whenever possible before making repairs to reduce the possibility of generating contamination.

b) If necessary, stationary equipment should be suitably isolated from the surrounding cleanroom operations before proceeding with major repairs or maintenance. Alternatively, steps should be taken to ensure that all products under manufacture have been removed to a suitable location.

c) Adjacent cleanroom areas near the equipment being repaired should be suitably monitored to insure that contamination is being effectively controlled.

d) Maintenance personnel working in the isolated areas should not come into contact with personnel performing manufacturing or processing procedures.

e) All personnel repairing and maintaining equipment in cleanrooms should follow the appropriate practices defined for the area, including wearing appropriate cleanroom-approved protective clothing, and cleaning the area and equipment after repairs are completed.

f) A determination of conditions should be made before technicians lie or crawl under equipment to make repairs. Conditions caused by chemicals, acids or biohazards should be effectively neutralized before proceeding.

g) Steps should be taken to protect the cleanroom clothing from undue contact with contamination from lubricating oils or processing chemicals. Rips and tears from sharp edges should also be avoided.

h) All tools, boxes and carts used for maintenance or repair work should be thoroughly cleaned before being exposed to the cleanroom environment. No rusted or corroded tools should be allowed. Sterilization or disinfection may be necessary in a biocleanroom.

i) Technicians should refrain from setting tools; spare, damaged parts; or cleaning materials on adjacent or nearby work surfaces used for product and process materials.

j) Care should be taken to clean as repairs proceed so that contamination does not build up.

k) Gloves should be changed regularly so they do not deteriorate and permit bare skin to touch clean surfaces.

l) When gloves other than cleanroom gloves (e.g. acid-, heat- or cut-resistant types) are required, they should be either cleanroom compatible or covered with a pair of cleanroom gloves.

m) Vacuum cleaners should be used during all drilling or sawing operations. Maintenance and construction operations often require drilling or sawing. Special shrouds can be used to contain the tool and area being drilled or sawn.

Open spaces remaining after holes are drilled in floors, walls, sides of equipment or other such surfaces should be properly sealed afterwards to prevent contamination from entering the cleanroom. Methods for sealing may include use of caulks, adhesives and specially fabricated plates. When maintenance is complete, it may be necessary to verify the surface cleanliness of the equipment that was repaired or maintained

D.6 Equipment removal

Removing stationary equipment from the cleanroom often stirs up or loosens contamination from internal or other inaccessible surfaces that have not been routinely cleaned. This is especially true when the equipment must be disassembled before removal. Steps should be taken to isolate, clean, and contain such equipment before and during removal to avoid contaminating the surrounding cleanroom.

Regulatory considerations may be involved if the contamination is of a hazardous nature.

Annex E
(informative)

Materials and portable equipment

E.1 General

Items that can easily be transported into and out of the cleanroom can compromise the cleanliness of the cleanroom if they are not properly selected, handled and stored in the correct quantities. This includes consumable and disposable supplies, and production and cleaning materials, as well as hand tools and portable equipment. The ability to sterilize or disinfect reusable materials and portable equipment should be considered in biocleanroom applications.

E.2 Criteria for selection

E.2.1 Characteristics

To protect a cleanroom from contamination, materials should have the following characteristics:

— surfaces and moving parts that shed or generate as little contamination as possible;

— unbroken, impervious and clean surfaces, although there are necessary exceptions, such as cleanroom wipers;

— properties that minimize generation of contamination by shedding and cutting;

— suitable cleanroom packaging;

— compatibility with the cleanroom environment.

E.2.2 Other criteria

The following additional criteria should be determined according to the purpose and usage within a cleanroom:

— free from undesirable chemicals (e.g. acid, alkali, organic);

— acceptable anti-static properties;

— low outgassing properties;

— free from micro-organisms;

— compatible with sterilization or disinfection procedures in biocleanrooms.

E.3 Preliminary testing

Preliminary testing and auditing should be performed as agreed upon between customers and suppliers. Testing procedures performed by the supplier may be deemed sufficient for entry and use in the cleanroom. However, certain applications may require that additional testing be performed before some materials are brought into or used in the cleanroom. Incoming inspection criteria and sampling methods should be fully documented.

A secure storage location may be necessary to avoid unauthorized use while materials are waiting for acceptance. Strict quarantine measures may be necessary for biologically sensitive materials. Test equipment and methods should be fully documented. Acceptance limits and authorized personnel should be identified for final approval or disposition of non-conforming materials.

A procedure for communicating problems to the supplier should be instituted. The supplier should be expected to react with plans to improve its quality and avoid further shipment of non-conforming materials. The supplier should notify the customer prior to making critical changes to approved materials or supplies used in the cleanroom. Evaluation methods and technologies should be reviewed periodically. Some incoming inspections may be eliminated when data show that the supplier has a proven quality record.

E.4 Entry and exit procedures

E.4.1 Unpacking and entry procedures

Carrying materials into the cleanroom should not contribute contamination to the cleanroom. Materials and supplies that are carried into the cleanroom are subject to procedures similar to those described in Annex D.

Only materials and portable equipment that are compatible with the cleanroom classification and use should be brought into the cleanroom. Outer contamination-generating packaging, such as wood, cardboard, paper and other materials, should be removed before entry to any part of the controlled or cleanroom environments. Inner plastic wrappers should not be removed at this time. Any interior packaging should be wiped with appropriately moistened cleanroom wipers to remove any gross contamination from the outer packaging before being carried into the controlled environment or specific area used for removing cleanroom packaging. Various types of non-wrapped portable equipment require careful cleaning before entering the cleanroom and are discussed in E.5. A designated transfer area, adjacent to the cleanroom, should be used for final wiping procedures. The changing area should be avoided for this purpose to avoid contaminating cleanroom clothing. A working surface and wiping materials should be readily available in this location for the task of cleaning all outer surfaces of the object to be transported into the cleanroom. The outer wrappers of double-wrapped packaging can now be removed and placed in an appropriate rubbish receptacle. Final packaging should only be removed prior to use of the material or object.

Any wheeled, portable equipment, including carts and trolleys, should be thoroughly cleaned before being allowed to enter the cleanroom. Cleaning efforts should not overlook the surfaces of wheels that can transfer excess contamination directly onto the cleanroom floors. Sticky mats or flooring will help prevent this from occurring.

Cleanroom personnel, correctly dressed in cleanroom clothing, may enter the transfer area from the cleanroom side and carry such items into the cleanroom. A clean cart or trolley should be used to transfer numerous or large items into the cleanroom.

E.4.2 Entry of materials through pipes

Materials such as bulk chemicals, compressed gasses and water generally enter the cleanroom through pipes. Such materials are subject to the procedures that govern the introduction and intended use of those materials to the facility.

E.4.3 Exit procedures for materials and portable equipment

E.4.3.1 Personal and small equipment

Many items used by personnel are routinely removed when personnel leave the cleanroom. These items may include notebooks, pens, hand tools and other types of small portable equipment. These items should be protected from becoming contaminated through the use of approved plastic bags or other suitable means. This procedure will facilitate re-entry to the cleanroom at a future time.

E.4.3.2 Waste Materials

Certain waste materials and portable equipment may have a higher risk of transferring contamination to personnel and their clothing. Steps should be taken to completely contain any such materials before transport and arrangements made to thoroughly clean such areas before personnel or processing is allowed to continue. Such objects should preferably leave the cleanroom (after being packaged) via transfer areas for material rather than via changing rooms for personnel.

E.5 Types of materials and portable equipment

E.5.1 General

Materials designated for use in the cleanroom should conform to desired cleanliness levels. Considerations vary according to the desired use in the cleanroom and should be selected to control cleanroom contamination and protect the process during use. Many items typically used in cleanrooms are listed in E.5.2 to E.5.18.

E.5.2 Cleanroom clothing materials

Cleanroom clothing materials are described in Annex B.

E.5.3 Solutions and finishes used in cleaning

Cleaning solutions are used to aid in the removal of contamination from surfaces in the cleanroom. Some particles are floated off by the cleaning solution and others are pushed off through use of a wiper. After cleaning, certain finishes are also used to protect or preserve characteristics of surfaces in the cleanroom. These solutions and finishes should be as clean as required to meet the particle requirements of the cleanroom. The filtration of pre-packaged solutions should be considered. The following are types of cleaning solutions and finishes:

a) Clean-filtered, distilled or deionized water has many desirable properties but such water can corrode certain types of surfaces and may be ineffective in cleaning without the addition of a surfactant or disinfectant.

b) Surfactants and detergents are the most reasonably priced, non-toxic, non-flammable and effective cleaning agents. However, non-ionic surfactants are generally preferred for cleaning cleanrooms as this group is the least reactive and does not contain metallic ions.

c) Organic solvents can also be used for removing contamination on hard surfaces. Organic films are best removed with organic solvents or detergents. (Detergents tend to leave behind a film.)

d) Disinfectants are used to kill micro-organisms. Care should be taken to select an appropriate material that will not contaminate the process or become harmful to personnel or equipment [26].

e) Synthetic sealers that are highly resistant to wear can be used on certain cleanroom floors. Antistatic floors require special care and sealers should not compromise the surface or electrical characteristics. Any sealing operations should only be done when cleanroom manufacturing is stopped or during general maintenance periods.

E.5.4 Wipers

Wipers are used to remove contamination from surfaces in the cleanroom. Unfortunately, there is no single perfect wiper that suits every application within the cleanroom. Some wipers are absorbent but shed particles or fibres; others don't shed but do not absorb. Information on the selection of wipers is described in other sources. [10] [27] [28] The needs of the application should be considered and an appropriate evaluation should be performed. The following characteristics should be considered when selecting wipers for cleanroom use:

a) wiper material;

b) solution or solvent compatibility;

c) absorption rate of liquids;

d) particle generation (both wet and dry);

e) extractable molecular contamination;

f) sterilization compatibility, if necessary;

g) packaging.

E.5.5 Vacuum cleaners, hoses and handles

The selection and use of cleanroom-compatible vacuum cleaning equipment is important for an effective contamination control programme.

a) Portable vacuum cleaners are constructed of stainless steel or plastic. All outlet air must flow through a terminal HEPA or ULPA filter before being allowed to escape to the surrounding environment. Vacuum cleaners capable of handling damp and liquid materials are also available for the cleanroom.

b) Built-in vacuum cleaner systems employ a large, centralized vacuum pump, usually in a service area outside the cleanroom environment, which is connected by a system of plastic piping to wall outlets in each area of the cleanroom.

c) Hoses, handles and tools should be matched to the application and constructed of cleanroom-compatible materials.

d) Arrangements should be made for routine inspection and maintenance of all equipment used in the vacuum cleaning process. The HEPA or ULPA filters of the vacuum cleaning equipment should be tested and/or replaced on a regular basis to ensure that they do not become a source of airborne contamination in the cleanroom.

E.5.6 Mops

Standard commercial or industrial grade mops and handles should not be used within the cleanroom environment (including changing and other controlled areas). Mops should be carefully selected to resist shedding of fibres and the effects of sterilization, if so required. Floor mop heads should be constructed of polyester fibres or open-celled hydrophilic (synthetic) materials. Block or sponge mop heads should be constructed of open-celled hydrophilic (synthetic) sponge material. Handles and fittings should be made of stainless steel, anodized aluminium, fiberglass coated with polypropylene, or other non-shedding plastics and should be compatible with the operation of the cleanroom mops. Roll mops (similar to paint rollers) with a slightly sticky surface may be used when appropriate for removing contamination from wall surfaces without applying any moisture. Roll mops are available in both renewable and disposable forms.

When purchasing synthetic mops or handles, one should be cognizant of the intended cleaning application. Polyvinyl acetate (or equivalent) mop heads are acceptable when used with aqueous cleaning solutions. However, the mop heads will prematurely deteriorate when used with cleaning agents containing high levels of isopropyl alcohol. Some materials used in handles or mop heads are not compatible with steam sterilization. Polyester offers better resistance to autoclaving than polyvinyl acetate.

E.5.7 Buckets and wringers

Buckets or containers with wringers that are compatible with the cleanroom operation are required for wet or damp cleaning operations. The buckets or containers should be constructed of plastic or stainless steel (not galvanized). Stainless steel buckets can be repeatedly autoclaved. The wringer system used in mopping should be compatible with the style and material of the mop head.

E.5.8 Floor scrubbers, buffing and waxing machines

Standard commercial floor scrubbers or buffers should never be used within an operating cleanroom, as the process would contaminate the environment. Special machines designed for scrubbing cleanroom floors are available. These machines have special shrouds and built-in HEPA or ULPA filtered vacuum cleaners to control contamination redistribution. They also have HEPA or ULPA filtered exhaust casings for the motor chambers. Careful evaluation for cleanroom and flooring compatibility should precede the use of such equipment. Waxes and other non-permanent sealers flake off and cause contamination with traffic and therefore any equipment used to apply or buff such finishes are never recommended.

For specific types of flooring refer to ISO 14644-4.

E.5.9 Stepladders

Stepladders should be of stainless steel, anodized aluminium or reinforced fibreglass and should not leave the cleanroom-controlled area. They should be thoroughly cleaned (disinfected or sterilized if necessary) before entry.

E.5.10 Brooms or brushes

Brooms, brushes, or similar tools should not be used in an operational cleanroom, as they will cause gross particle generation. The bristles themselves are very large fibres that are also a contaminant.

E.5.11 Receptacles for rubbish and recycling

Used materials, by-products and other waste generated inside the cleanroom should be removed as soon as possible. A means for the collection, containment and storage of wastes should be provided to protect the cleanroom from these contamination sources while waiting for removal. Removal procedures are discussed in F.4.10.

The following criteria should be considered when selecting receptacles for collection of these materials:

a) nature of the materials to be discarded or recycled;

b) safety requirements;

c) environmental hazards;

d) lining materials and how they will be installed;

e) floor space available;

f) size required, based on frequency of collection;

g) material of construction;

h) cleanroom compatibility.

E.5.12 Cleanroom mats and sticky flooring

Cleanroom mats and sticky flooring can be used as a barrier to help control foot-borne contamination from entering the cleanroom. The size (particularly the length) and location of the mats/flooring are the major factors governing the effectiveness for the removal of foot-borne contamination. Two major varieties of available mats/flooring are:

a) Disposable — Multiple layers of adhesive, plastic film with the sticky surface facing up. Layers are removed and discarded as they get dirty.

b) Reusable — Resilient polymeric mat with a naturally sticky surface, to be cleaned when it becomes dirty.

E.5.13 Clean containers and packaging

Clean containers can be used for transporting or isolating sensitive materials and products to and from the cleanroom while waiting to be used or processed. Surface cleanliness and isolation characteristics should be consistent with the intended use of the enclosed materials. Entry and exit procedures as stated in E.4 should be followed. Frequent cleaning may be necessary to avoid contamination buildup during use. Special cleaning and verification of cleanliness may be required before reuse.

Materials that may be used to protect or package finished products made in the cleanroom should be clean and compatible with the cleanroom. Selection should be based on particle generation, microbial contamination, electrostatic properties, outgassing and other concerns. Tapes that are used within the cleanroom should have adhesives that leave minimal residues when removed.

E.5.14 Hand tools, boxes and maintenance equipment

Hand tools should be compatible with the cleanroom classification, products, stationary equipment and processes with which they will come into contact. They should be kept clean and free from contamination of all kinds.

Boxes or cases that contain tools and other repair or diagnostic equipment are often overlooked sources of contamination. They should be made of stainless steel or synthetic materials that resist or protect against the generation or transfer of contamination. Any use of moulded inserts or dividers that can generate contamination such as open-cell foam, vinyl-covered wood or pressboard (wood-chip board) should be avoided. Boxes should be thoroughly cleaned on a regular and scheduled basis (with tools and instruments removed) to ensure cleanliness. Tools and instruments should be cleaned before being replaced inside the toolbox or case. Toolboxes and cases should remain inside the cleanroom whenever possible. If removed from the environment, toolboxes and cases should never be opened outside the cleanroom. Thorough external cleaning should be required before being allowed back inside the cleanroom.

Carts and trolleys routinely used for transferring maintenance and other supplies into and out of the cleanroom must be thoroughly cleaned before re-entry.

NOTE Initial and routine sterilization or disinfection of the above items may be required when used in the biocleanroom.

E.5.15 Safety equipment

Safety goods and equipment used in the cleanroom such as chemical gloves, aprons, face and arm shields, self-contained breathing apparatus, chemical absorbing pads and fire extinguishers should be selected for their intended safety requirements as well as compatibility with the intended cleanroom.

E.5.16 Written documentation

Contamination from documents, within the cleanroom, should be controlled. Methods for documentation will depend largely on the use and classification of the cleanroom.

Paper and paper products will contaminate the cleanroom. All documents should be printed on lint-free, cleanroom-compatible media or thermally laminated between plastic films. Information on the selection of such substrates is given in other sources. [28] Use of such media in the form of labels, log sheets, equipment repair manuals, reports and notebooks should be controlled and kept to a minimum. Label adhesives should leave minimal residues when removed from surfaces.

Writing instruments can become sources of contamination to the cleanroom, products or processes. Pencils, rubber erasers and felt-tipped and retractable pens should be avoided. Pens should be of the non-retractable, ballpoint style with inks that are permanent and compatible.

E.5.17 Electronic documentation

The use of computers for work in progress will eliminate the need for many sources of contamination such as log books, log sheets, process documentation and others. Installation and use of computers and peripherals should be compatible with the classification of and intended location inside the cleanroom.

Computers often employ internal cooling fans. Consideration should be given to how the exhaust air may affect the cleanroom and critical surfaces surrounding the computer. Methods may need to be devised to duct such exhaust directly to air returns or through portable filtration units, depending on cleanliness requirements.

Keyboards have recesses around the pushbuttons that may trap and release particles. Use of flexible continuous films or covers placed over the keyboard will facilitate cleaning and reduce contamination.

Printers interfaced with such computers should be appropriately contained or isolated and exhausted in a similar manner. Printer maintenance should be performed carefully to avoid dispersal of residual contamination generated by the printing operation.

E.5.18 Other materials

Other materials, including those directly used in the production process, are taken into the cleanroom. They should exhibit the lowest possible contamination properties for the application intended and the classification of the cleanroom. They should enter and be controlled in an appropriate manner as described above and be compatible with products and processes.

E.6 Storage

Materials can become contaminated or ineffective if improperly stored while waiting to be used. Proper storage and controlled storage methods are critical to preserve their effectiveness. They should be stored in an environment that protects them from degradation and contamination. If not properly stored, the accumulation of unused materials in the cleanroom presents a risk of contamination.

Certain classes and types of waste materials are stored in the cleanroom until specified limitations are reached. Often, these limits are regulated by agencies or by recycling programmes set up for the cleanroom. The use of specialized containers may also be required.

Annex F
(informative)

Cleanroom cleaning

F.1 Overview

Cleanrooms are designed to be as free from contamination as possible. Facility and maintenance operations, manufacturing processes, the presence and activity of personnel and other factors may cause contamination to be generated and dispersed on surfaces in the cleanroom. Therefore, all surfaces should be cleaned frequently enough to prevent this from becoming a risk to the manufacturing process. Procedures should be specified to ensure that thorough and complete cleaning operations are performed in a manner that is consistent with recommended cleanroom practices for the facility. When feasible, cleaning should be avoided during manufacturing operations. If this is not possible, special cleaning procedures should be devised to minimize risks. Information is available in a number of documents that will assist in effective cleaning of a cleanroom [29] [31] [32].

NOTE Some processes generate contamination as a by-product. It is better to identify and attempt to contain contamination from such operations than to rely on cleaning to control the contamination.

F.2 Surface classification

F.2.1 General

The cleanliness of areas and surfaces should be classified and designated based upon how they may affect the products and processes performed in the cleanroom. Effective application of this classification will be useful in developing the proper cleaning strategy for the cleanroom.

F.2.2 Critical surfaces

Surfaces classified as critical are located at and around the point of manufacture or production where contamination can gain direct access to the product or process. These surfaces should be kept the cleanest. Separative devices, including unidirectional airflow equipment, clean benches or workstations, usually help control the cleanliness of these surfaces.

F.2.3 General cleanroom surfaces

All surfaces within the cleanroom that are not at the point of production or localized by unidirectional airflow are considered “general”. They should be cleaned on a regular basis to prevent transfer of contamination onto critical surfaces.

F.2.4 Surfaces of changing rooms and transfer areas

Surfaces of changing rooms and transfer areas can become highly contaminated due to the high level of activity. Frequent cleaning is necessary to minimize the level of contamination and to reduce the transfer of contamination into the cleanroom.

F.3 Basic cleaning

F.3.1 General

Maintaining the cleanliness of a cleanroom is a meticulous set of tasks. Cleaning levels should be defined and basic methods for attaining those levels should be developed. Approved methods can then be applied to every surface within the cleanroom to achieve the desired result. [10] [29] [30] [31] [32].

F.3.2 Basic cleaning categories

The act of cleaning can be divided into three different categories depending on the current state and desired cleanliness of the surface once cleaning is completed. These are **gross**, **intermediate** and **precision**, and are described as follows:

— **Gross cleaning** involves the removal of large particles of contamination usually greater than 50 µm in diameter. Contamination of this size is usually found on floors and is typical of the type carried into changing and transfer areas. Broken or spilled materials resulting from the production operation or process are additional sources of contamination that end up on work surfaces and floors. Construction and equipment maintenance activities also can often generate gross particle contamination.

— **Intermediate cleaning** involves the removal of smaller particles of contamination, typically ranging from 10 µm to 50 µm in diameter. Performed on general cleanroom surfaces, intermediate cleaning is usually associated with walls, benches and clean hallways. This size of contamination remains after gross cleaning methods are used. Intermediate cleaning provides the next level of cleanliness.

— **Precision cleaning** is needed to remove remaining particulate contamination that is generally less than 10 µm in diameter. Precision cleaning is generally employed on or near critical surfaces where product is stored and processed.

F.3.3 Vacuum cleaning

Vacuum cleaning can be used in gross and intermediate cleaning operations as a basic first step to cleaning both general and critical areas. Vacuum cleaning is a prerequisite, not an alternative, to mopping or wet wiping. Vacuum cleaning is effective in removing larger particles and other debris such as glass fragments. Vacuum cleaning should be performed in deliberate, unidirectional strokes to minimize air turbulence at the floor level and at operator height.

The use of HEPA/ULPA vacuum cleaners or in-house central vacuum systems is employed in vacuum cleaning. Systems that can accommodate wet materials are helpful for removing excess water and suspended particles during and after the mopping process. Vacuum cleaning can also be useful in helping to speed the drying process once mopping is completed.

F.3.4 Wet cleaning

Wet cleaning methods where liquid is applied to a surface and removed through wiping or vacuuming methods can be employed in all stages of cleaning. Methods for wet cleaning include:

— **Scrubbing** is a gross cleaning method that employs machine or manual methods to remove stains or heavily soiled areas. Care should be taken to control any contamination that may be generated by the equipment or materials used in scrubbing. Mopping or wet vacuuming procedures follow scrubbing.

— **Mopping** is an effective method in gross or intermediate cleaning for removing contamination. Mopping can also be used for removing residues from spilled liquids left after wet vacuuming is completed. Wet wipers may be used in small or localized areas. Mops are used for floors and other large areas. The mop bucket should be filled with clean-filtered de-ionized or distilled water and changed frequently to avoid recontamination. The more critical the surface, the more frequently the water should be changed. Water coloration indicates the need for the bucket to be emptied, cleaned and refilled for use in the gross

cleaning mode. Intermediate and critical areas should show little or no coloration throughout specified use, so cleaning procedures for these areas should define the allowable surface area to be cleaned before changing the water. Two (or multiple) bucket systems can be used to reduce the frequency of rinse water changes. Non-ionic detergents or surfactants can be added if necessary. Mops should be well squeezed to avoid puddles. A damp mop will produce a damp surface that will dry more quickly. A systematic method, using overlapping strokes should be employed to ensure complete cleaning of floor surfaces. Frequent rinsing and turning of mop surfaces help to avoid recontamination of previously cleaned sections of the floor. Mop heads should be rinsed frequently to avoid recontamination of the mop head. Specialty mops are also available for removing intermediate-sized contamination from walls, and floors (see E.5.6).

F.3.5 Damp cleaning

Wiping techniques are used in most phases of cleaning. Wiping produces results that support intermediate and precision cleanliness for general and critical surfaces. The chosen wiper should be dampened with the appropriate cleaning solution. The solution is dependent upon the type of contaminant being removed. Wiping should always be done in unidirectional, overlapping strokes, proceeding from most critical to least critical areas, following the direction of unidirectional airflow. As wiping proceeds, wipers should be folded to provide an unused surface area. The wiper should be replaced as frequently as needed to avoid transferring contaminants to other parts of the cleanroom surface.

F.4 Cleaning specific surfaces

F.4.1 Identifying surfaces to be cleaned

All surfaces within the cleanroom can become contaminated and should be cleaned at some identified interval. It is important that all surfaces be identified according to how critical the cleanliness of the surface is to the product or process performed in the cleanroom. Cleaning techniques can then be developed and specified to ensure that the required level of cleanliness is attained.

F.4.2 Floors and subfloors

Gross contamination can be removed first by vacuum cleaning e.g. glass or product fragments. Areas with stubborn stains should then be identified and addressed with predetermined scrubbing procedures. The floor should be wet or damp mopped according to predetermined procedures. Water or cleaning solutions should be changed frequently enough to minimize the spread of dissolved or suspended contamination as the cleaning process continues. Larger floor areas should be divided into manageable segments so that work can proceed in an orderly manner. Cleaning should begin in critical areas and proceed through general areas, but certain cleanroom applications may require a different routine. Repeating the mopping procedure will produce cleaner surfaces if greater cleanliness levels are required.

During operational hours, it may be necessary to cordon off the area and redirect traffic flow to avoid dangerous falls by unwary personnel. Damp mopping or wet vacuuming after mopping will speed the drying process.

Wet washer/scrubber systems, followed by wet vacuum cleaning, can be used to remove stubborn stains and floor stains. These systems are described in E.5.8 and should be thoroughly cleaned before and after each use.

F.4.3 Walls, doors, return grilles, windows and vertical surfaces

In unidirectional flow cleanrooms, surfaces upstream from product exposure should never be cleaned in the operational state. Upstream surfaces should only be cleaned in the at-rest state or after products have been removed from the area or covered. Contamination should be removed using wiping methods or special purpose or roll mops. Choice of method should be determined based on state of cleanliness desired and configuration of the area being cleaned. In non-unidirectional flow cleanrooms, surfaces should not be cleaned during normal operations.

F.4.4 Ceilings, diffusers and lamp fixtures

Ceilings and other fixtures upstream or close to work areas should not be cleaned in the operational state but should wait for at-rest conditions. Diffuser and ceiling grids should be carefully wiped using damp cleaning techniques. Some diffusers may require removal for washing or replacement. Lamp fixtures should be thoroughly wiped whenever bulbs are changed.

F.4.5 Tables and other critical horizontal surfaces

Tables and other critical horizontal surfaces should be cleaned using appropriate wiping techniques described above. Acceptable cleaning solutions may be used to aid in contamination removal. Damp wipers can be used to remove contamination, working in unidirectional strokes from most to least critical areas.

F.4.6 Cleanroom chairs, furniture and ladders

Wipe chairs, furniture and ladder surfaces from top to bottom. Include cushions, supports, and wheels if equipped.

F.4.7 Stationary equipment

Surfaces of stationary equipment should be cleaned according to the risk presented to the cleanroom and products. It is important to note that fluid piping, electrical wires and connections often supply stationary equipment. Extreme care must be taken to avoid damaging or disconnecting piping or wires during the cleaning operation.

Stationary equipment often contains surfaces that are critical to the product or process cleanliness. These surfaces should be classified so that an appropriate cleaning programme can be established for each type of surface. A careful assessment of the following surfaces should be made to assure effective cleaning.

a) Exterior surfaces of stationary equipment are common to the cleanroom environment. These surfaces should be cleaned according to procedures determined appropriate for walls, horizontal and vertical surfaces.

b) Interior surfaces are made up of the inner walls of the stationary equipment and the machinery contained within the equipment. Inner walls often surround the critical product or process areas. Cleaning of these surfaces often may not proceed until products or process components are removed from the equipment. These surfaces may also become contaminated with product or process residues, requiring special safety considerations prior to cleaning. Machinery contained within stationary equipment should be maintained and cleaned on a periodic basis and in accordance with manufacturers specifications and as described in D.5.

c) Critical surfaces of stationary equipment are the closest to products or processes that are enclosed or surrounded by the equipment and cannot be done in the presence of product or process. Procedures and schedules for cleaning should be developed and specified and carried out in accordance with product and process cleanliness requirements.

F.4.8 Carts and trolleys

Carts and trolleys should be vacuumed or wiped down, or both, using wipers and starting from the top and working downward using acceptable cleaning solutions in an appropriate transfer area or other non-critical area. Special care should be taken to assure that the rolling surfaces of the wheels are free from debris that may be deposited on the cleanroom floor. Rolling carts or trolleys over sticky mats can help in the removal of such debris from the wheels.

F.4.9 Hazardous processing surfaces

Procedures should be developed to neutralize existing hazards before beginning normal cleanroom cleaning procedures. Use the appropriate cleaning technique for the surface involved and described in F.3.1 to F.3.5.

F.4.10 Cross-over benches, supply and cleanroom clothing supply cabinets, lockers and other compartmented surfaces

Vacuum cleaning followed by wiping will effectively remove contamination from exposed surfaces. Compartments should be periodically emptied so that the interiors can be cleaned.

F.4.11 Rubbish bins and containers

Rubbish bins and containers can be lined with plastic bags to facilitate removal of refuse and protect container surfaces. Rubbish should be removed before it collects in excess. Plastic bags or liners should never be removed from bins in the vicinity of critical areas. All bins should be removed to general, non-critical areas before any rubbish is removed. This can be done as required or at the end of each shift. They should be emptied, cleaned and re-lined, if required, before being returned to service.

F.4.12 Cleanroom mats and sticky flooring

Cleanroom mats and sticky flooring should be cleaned or maintained on a regular basis during the normal workday.

Cleanroom mats and sticky flooring should be serviced according to the manufacturer's instructions as frequently as needed. Mats with renewable surfaces should be cleaned frequently. After wet mopping, a rubber squeegee is used to pull contamination and water to the edge to be mopped dry. A wet vacuum with a squeegee head can also be used for this purpose.

Mats with removable, sticky surfaces are cleaned by slowly peeling each of the four corners and rolling the film towards the middle of the mat until the layer is removed.

F.5 Surface treatment

F.5.1 General

Specific cleanroom applications require that certain surface treatments or finishes are applied to cleanroom surfaces, to provide characteristics that normally would not exist. These treatments may protect the products being produced in the cleanroom, but should be carefully considered. The use of surface treatments and finishes, after cleaning, should be avoided if at all possible. These treatments deteriorate with time and will compromise the cleanliness of the cleanroom. In addition, these treatments can pose the risk of process or product contamination if not used or maintained properly. Surfaces that receive these treatments should be inspected or tested on a periodic basis to ensure they do not compromise the cleanroom. Steps can then be taken to remedy the situation.

F.5.2 Anti-static treatment

Anti-static materials can be applied to surfaces to minimize static charge buildup. Treating surfaces with anti-static agents should be done carefully. Improper use will result in non-uniform, anti-static characteristics and residues that can become a source of contamination. The coating should be thick enough to be effective but thin enough to avoid flaking and generation of contamination. Anti-static surface characteristics can often be achieved simply by changing the humidity of the air supplied to the cleanroom.

F.5.3 Disinfection

Thorough cleaning programmes help to control micro-organisms. However, certain industries and regulatory agencies may require disinfection procedures in addition to normal cleaning procedures. The effectiveness of the disinfectants and the methods used for disinfection should be determined in each cleanroom. In general, disinfectant efficacy is a function of the type of disinfectant, the concentration of the disinfectant, the temperature of the solution and its contact time on the surface being disinfected. Some disinfectants can damage cleanroom surfaces (e.g. chlorine-based compounds on stainless steel) if they are not properly removed, and may be toxic if they are deposited on products. Furthermore, disinfectants may be toxic not only when in direct contact with the product, but also when a residue remains on surfaces. Therefore, it may be appropriate to remove such residues by properly rinsing the surfaces. Disinfectants can have harmful effects on personnel if used improperly.

F.6 Cleaning personnel

A specific training program should be provided for any personnel performing the cleaning operation. Specific personnel should be designated for each part of the cleaning programme. It is quite common to assign cleanroom cleaning to specialized cleaning personnel. Operators with proper training are often assigned to clean the work surfaces.

F.7 Cleaning programme

F.7.1 Preparing a cleaning programme

The classification of different kinds of cleanroom surfaces and the rate at which they become contaminated should be understood when setting up a cleaning programme. Schedules should be specified to ensure cleaning is performed frequently enough to maintain the required cleanliness of the cleanroom. Testing and evaluation of the surface contamination will assist in drawing up schedules. The process and product requirements within the cleanroom should determine which cleaning tasks need to be accomplished on a daily, weekly or other periodic basis. [29]

The following steps should be followed in preparing a cleaning programme.

a) Classify all surfaces into critical, general or other surfaces.

b) Determine the best cleaning and surface treatment method for achieving the desired cleanliness level.

c) Determine the cleaning frequency required to maintain the desired cleanliness levels for each surface type.

d) Determine which cleaning operations can be accomplished during normal operating hours.

e) Prepare the cleaning schedules.

f) Decide which part of the cleaning schedule operators will execute and which part cleaning staff will execute.

g) Choose the correct materials, machines, cleaning solutions and surface treatments for the specified methods.

h) Train all personnel for the expected level of involvement in the cleaning programme.

i) Provide adequate storage facilities for the required cleaning materials.

j) Decide how to monitor the cleaning results and react to discrepancies.

k) Organize all documents and schedules so that they can be reviewed and managed effectively.

F.7.2 Scheduling the cleaning programme

Most cleaning operations should be performed on a regularly scheduled and frequent basis. Other cleaning operations are performed on a scheduled basis but infrequently. Some cleaning operations must be done in reaction to events that create contamination and are not subject to normal scheduling. The frequencies, listed below, can be used as guidelines but should be adjusted to the needs of the cleanroom as based on a risk assessment and cleaning evaluation.

F.7.3 Regular cleaning

Regular cleaning includes all tasks that are carried out frequently enough to reduce the risk of contamination from being transferred to critical surfaces. Tasks associated with regular cleaning of the cleanroom may be performed several times per day, once per day, or every several days depending on the risk assessment. Many tasks may be allowed during working hours, such as trash removal, vacuuming, mopping floors, and wiping surfaces in changing areas, transfer areas and common areas such as hallways. Each room within the cleanroom may need a special written cleaning programme depending on criticality of cleanliness to product or process concerns.

Changing areas and transfer areas should be cleaned at least once per day. These areas can harbour high contamination levels, due to the high level of personnel activity. Therefore, cleaning is required more frequently than in manufacturing cleanrooms to control the cleanliness level and reduce the opportunity for contamination transfer. Regular cleaning will enhance the level of cleanliness within the general cleanroom areas. Thorough vacuum cleaning and mopping procedures described in F.3.3 and F.3.4 should be implemented. Cleanroom mats and sticky flooring should be serviced (described in F.4.12) but with greater frequency to prevent the migration of contamination into the cleanroom.

F.7.4 Periodic cleaning

Surfaces not cleaned on a regular basis should be cleaned periodically. Special precautions may need to be taken to ensure product integrity during cleaning procedures.

Many surfaces should be cleaned on a weekly basis (i.e. at least once during a seven-day period). Product may need to be covered or removed from areas where weekly service is performed.

Surfaces that present less of a risk can be scheduled for less frequent cleaning. This type of less frequent cleaning should be performed once per month or extended time interval. Schedules should reflect these less frequent intervals.

Arrangements should also be made to thoroughly clean the entire cleanroom facility, from top-to-bottom, on a scheduled basis. Thorough cleaning should include storage areas, service areas, pipes and fittings. Thorough cleaning is often best accomplished during extended facility shutdowns or during weekends, holidays or other planned facility shutdowns. Continuously operating cleanrooms are only shut down sporadically and may only have certain times when thorough cleaning can be accomplished. Intensive cleaning efforts should be taken at these times to accomplish the task.

F.7.5 Cleaning during and after construction or maintenance

Effective cleaning during cleanroom construction is essential to control and eliminate contamination sources that might later affect the operational cleanroom. Annex D provides guidance for maintenance activities. A sample 10-stage cleaning schedule in F.9 can be used to aid in planning, executing, and documenting efforts.

F.7.6 Cleaning during emergency situations

Procedures should be instituted to ensure that work-in-progress, the process and the cleanroom environment are not compromised in the case of a gross contamination event. Special tools and materials should be readily available to neutralize or control any hazardous situations that may arise. Work should be suspended in the area deemed at risk until acceptable levels of cleanliness are attained. Events that may trigger special cleaning include:

a) environmental incident (e.g. utility failure, spill, major equipment failure, broken product, biological hazard, etc.);

b) failure of routine cleaning procedures resulting in contamination rising to unacceptable levels;

c) monitoring that reveals the occurrence of unacceptable contamination of the facility.

F.8 Monitoring cleaning effectiveness and testing

F.8.1 Particle contamination

Cleanroom equipment, apparatus or surfaces may require cleanliness testing and monitoring after cleaning. Users are responsible for selecting appropriate cleanliness verification methods. An acceptable degree of cleanliness should be determined for each element or characteristic that will affect the products or processes in the cleanroom. The user should specify limits for tests performed. It is recommended that, when possible, limits be determined from actual measurements, using the test methods. Routine surface contamination checks should be defined and carried out to ensure that the specified levels are being maintained [24] [31] [34].

Visual inspection techniques can be used to determine surface cleanliness. Visual-clean surfaces demonstrate an absence of contamination that can be seen without magnification. Visual inspection may be accomplished with or without the aid of angled, high-intensity white light or ultraviolet light sources. Wiper-clean surfaces can be demonstrated by passing a clean wiper over a clean surface. This inspection aid detects visual contamination that may adhere to the wiper surface indicating further cleaning is needed. Coloured wipers are available from some suppliers and may be helpful in detecting some forms of contamination. Other methods that may be considered include:

a) tape lift method [33];

b) surface particle detector method [30].

NOTE Additional methods for measuring surface cleanliness in critical areas are discussed in other sources [10] [30] [31] [34] [35] [36].

F.8.2 Microbiological contamination

A variety of methods and sampling schemes exists for detecting microbiological contamination in the cleanroom. These are described in other sources. [26] [32] The following methods are the most common:

a) contact plates (for flat surfaces);

b) surface swabbing (for uneven surfaces).

F.9 Construction-related cleaning programme

Depending on the user requirements, the following 10-stage programme can be used effectively to schedule, assign and document cleaning procedures that are needed during different phases of construction operations (see also ISO 14644-4, Annex E).

Table F.1 — Stages of construction-related cleaning programme

Stage	Purpose	Responsible party	Method	Standard
Stage 1 — Clean during demolition or preliminary construction such as framing for wall installation.	Preventing unnecessary dust concentration in places that will be difficult to reach during later construction.	Contractor. If the construction contractor has no relevant experience in cleanroom cleaning, it is advisable to hire a professional cleaning contractor specializing in cleanroom cleaning.	Vacuum clean upon completion.	Visual-clean.
Stage 2 — Clean during utility installation.	Removing local contaminants caused by installing electricity, gas, water, etc.	Installation engineer.	Vacuum clean; wipe-down piping and fixtures with moistened wipers upon completion. The use of vacuum cleaning and/or other cleaning materials is necessary.	Visual-clean.
Stage 3 — Clean during early construction.	Cleaning all visible contamination from ceilings, walls, floors, (filter mountings), etc. after completion of construction and installation activities.	Cleaning contractor.	Vacuum clean; wipe-down piping and fixtures with moistened wipers. Application of protective floor sealants is generally a particle generating activity. If this is necessary, it should be applied at this time.	Visual-clean.
Stage 4 — Prepare for air conditioning ductwork installation.	Cleaning any dust from ductwork sections before installing using a vacuum cleaner and wipers. Meanwhile, a positive pressure should be introduced to the cleanroom.	Installation engineer and cleaning contractor.	Vacuum clean; wipe down with moistened wipers.	Wiper-clean.
Stage 5 — Clean before mounting all air filters into the system.	Removing deposited or settled dust, or both, from ceilings, walls, and floors.	Cleaning contractor.	Wipe down with moistened wipers.	Wiper-clean.
Stage 6 — Mount the (HEPA/ULPA) filters into the air systems	Removing possible contamination caused by the mounting operation.	Cleanroom HVAC filter engineer/ technician.	Clean all surface edges on all sides.	Wiper-clean.
Stage 7 — Adjust the air conditioning equipment.	Removing suspended dust from the airflow and creating over-pressure installation, including the filters.	Cleanroom HVAC filter engineer/ technician.	Air conditioning air flushing operation.	Wiper-clean.
Stage 8 — Upgrade the room into prescribed classification.	Removing all deposited and clinging dust from every surface (in order: ceilings, walls, equipment, floors).	A professional cleanroom cleaning by personnel specially instructed on regulations, routing and behaviour.	Wipe down with moistened wipers.	Wiper-clean.

Table F.1 (*continued*)

Stage	Purpose	Responsible party	Method	Standard
Stage 9 — Approve installation.	Verifying the cleanroom to the prescribed design specifications. Customer acceptance.	Installation engineer and certification engineer.	Monitor airborne and surface particles, air velocities, temperature and humidity.	Wiper-clean. Results should conform to agreed design criteria.
Stage 10 — Clean daily and periodically	Maintaining the cleanroom in long-term compliance with designed classification. Microbiological cleaning and testing begins in biocleanrooms.	Cleanroom manager/cleaning contractor.	Listed in F.1 to F.8.	A tailor-made cleaning programme for the cleanroom, accounting for the specific demands of the production process and the customer. Routine testing of critical operation parameters.
NOTE 1 During Stages 4 to 10, all high-efficiency and ultra-high-purity components, such as filters, ducts, etc., should arrive on site protected by plastic or foil covers on both ends. Covers should only be removed when ready for use.				
NOTE 2 During Stages 6 to 10, all activities should be done wearing prescribed cleanroom clothing.				

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