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Cleanrooms and associated controlled environments — Biocontamination control —

Part 1: General principles and methods

Salles propres et environnements maîtrisés apparentés — Maîtrise de la biocontamination —

Partie 1: Principes généraux et méthodes

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Foreword

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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 14698-1 was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

ISO 14698 consists of the following parts, under the general title *Cleanrooms and associated controlled environments — Biocontamination control*:

— *Part 1: General principles and methods*

— *Part 2: Evaluation and interpretation of biocontamination data*

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Introduction

The principles described here are intended to promote appropriate hygienic practices. This part of ISO 14698 is one of a number of standards considering factors important for the creation of clean, controlled environments.

Hygiene has become increasingly important in many areas of modern society. In such areas, hygiene or biocontamination control methods are, or will be, used to create safe and stable products. International trade in hygiene-sensitive products has greatly increased. At the same time, the use of antimicrobial agents has been reduced or forbidden, creating a need for increased biocontamination control.

This part of ISO 14698 is the first general International Standard for biocontamination control. However, many factors besides cleanliness must be considered in the design, specification, operation and control of cleanrooms and associated controlled environments.

In some circumstances, relevant regulatory agencies could impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures might be required.

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Cleanrooms and associated controlled environments — Biocontamination control —

Part 1: General principles and methods

1 Scope

This part of ISO 14698 establishes the principles and basic methodology of a formal system of biocontamination control (Formal System) for assessing and controlling biocontamination when cleanroom technology is applied for that purpose. This part of ISO 14698 specifies the methods required for monitoring risk zones in a consistent way and for applying control measures appropriate to the degree of risk involved. In zones where risk is low, it can be used as a source of information.

Application-specific requirements are not given. Neither are fire and safety issues addressed; for these, see regulatory requirements and other national or local documentation.

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

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

3 Terms and definitions

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

3.1 General

3.1.1
action level
level set by the user in the context of controlled environments, which, when exceeded, requires immediate intervention, including investigation of cause, and corrective action

3.1.2
alert level
level set by the user in the context of controlled environments, giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention to the process

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3.1.3
bioaerosol
dispersed biological agents in a gaseous environment

3.1.4
biocontamination
contamination of materials, devices, individuals, surfaces, liquids, gases or air with viable particles

3.1.5
cleanroom
room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters e.g. temperature, humidity, and pressure, are controlled as necessary

[ISO 14644-1:1999, 2.1.1][1]

3.1.6
contact device
specially designed appliance holding an appropriate, sterile, culture medium with an accessible surface used for surface sampling

3.1.7
contact plate
contact device where the container is a rigid dish

3.1.8
control point
point in a controlled environment at which control is applied and a hazard can be prevented, eliminated or reduced to acceptable levels

3.1.9
controlled environment
defined zone in which sources of contamination are controlled by specified means

3.1.10
corrective action
action to be taken when the results of monitoring indicate that alert or action levels are exceeded

3.1.11
Formal System
system of biocontamination control with established and documented procedures

3.1.12
hazard
potential source of harm

[ISO/IEC Guide 51:1999, 3.5][2]

3.1.13
impact sampler
device designed to sample particles in the air, or other gas, through a collision with a solid surface

3.1.14
impingement sampler
device designed to sample particles in the air, or other gas, through a collision with a liquid surface and the subsequent entering into the liquid

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3.1.15
qualification
process of demonstrating whether an entity — activity or process, product, organization, or any combination thereof — is capable of fulfilling specified requirements

3.1.16
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51:1999, 3.2][2]

3.1.17
risk zone
defined and delimited space where individuals, products or materials (or any combination of these) are particularly vulnerable to contamination

3.1.18
settle plate
suitable container (e.g. a Petri dish) of appropriate size, containing an appropriate, sterile, culture medium, which is left open for a defined period to collect viable particles depositing from the air

3.1.19
swab
sterile collection device, non-toxic and non-inhibitory to the growth of the microorganisms being sampled, consisting of a specific matrix of suitable size, mounted on an applicator

3.1.20
target level
defined level set by the user as a goal for routine operations, for the user's own purpose

3.1.21
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[ISO 9000:2000, 3.8.5][3]

3.1.22
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[ISO 9000:2000, 3.8.4][3]

NOTE Monitoring and auditing methods, procedures and tests, including random sampling and analysis, can be used in the verification of the Formal System.

3.1.23
viable particle
particle that consists of, or supports, one or more live microorganisms

3.1.24
viable unit
VU
one or more viable particles which are enumerated as a single unit

NOTE When viable units are enumerated as colonies on agar media, it is common usage to name them colony forming units (CFU). One CFU might consist of one or more VU.

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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 14644-1:1999, 2.4.1][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 14644-1:1999, 2.4.2][1]

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 14644-1:1999, 2.4.3][1]

4 Principles of biocontamination control

4.1 A formal system of biocontamination control (Formal System) shall be established, implemented and maintained within cleanrooms and associated environments. The Formal System will assess and control factors that can affect the microbiological quality of the process and product.

There are a number of accepted methods for achieving this goal by risk assessment[4], [5]. The hazard analysis critical control point (HACCP) system[6], [7], [8], [9] is commonly used. Fault tree analysis (FTA)[10], or the failure mode and effect analysis (FMEA)[11], or any other validated equivalent system can be used.

In many such methods, any type of hazard can be considered. Within this part of ISO 14698, only microbiological hazards are addressed.

4.2 To assess and control the microbiological hazards, any selected system shall address the following principles:

a) identification of potential hazard(s) to the process or product, assessment of the likelihood of occurrence of these hazard(s), and identification of measures for their prevention or control;

b) designation of risk zones and, in each zone, determination of the points, procedures, operational steps and environmental conditions that can be controlled to eliminate the hazard(s) or minimize the likelihood of their occurrence;

c) establishment of limits to ensure control;

d) establishment of a monitoring and observation schedule;

e) establishment of corrective actions to be taken when monitoring results indicate that a particular point, procedure, operational step or environmental condition is not under control;

f) establishment of procedures, which may include supplementary tests and procedures, to verify that the chosen Formal System is working effectively;

g) establishment of training procedures;

h) establishment and maintenance of appropriate documentation.

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5 Establishing the Formal System

5.1 General requirements

It is the responsibility of the user to develop, initiate, implement and document a Formal System for biocontamination control that allows detection of adverse conditions in a timely fashion. It is imperative that such a programme be tailored to the field of application, to the specific facility and to specified conditions, and that this system be an integral part of a quality management system. The quality management system shall include an appropriate training programme for the selected Formal System.

In addition, it is essential that a monitoring programme (see 5.3) be designed and implemented in a manner that minimizes the possibility of the sampling activities themselves contributing to the contamination of the product or risk zone or both.

Risk zones shall be classified according to relevant guidelines, regulations (where these exist) and the chosen Formal System. Risk zones may also be classified according to the level of aerial and surface biocontamination, for example, low, medium, high or very high risk.

NOTE The first two parts of a Formal System, as given in 4.2 a) and b), are not discussed in detail in this part of ISO 14698, but information on how to identify, assess and control hazards is given in other sources. See, for example, [12].

5.2 Alert, action and target levels

The user of a cleanroom or controlled environment shall set microbiological alert and action levels. These levels shall be appropriate to the field of application, to the classification of the risk zones and to what is achievable using current technology. Microbiological target levels may be used as an alternative to microbiological alert and action levels in some specific fields of application.

During initial start-up and at intervals established according to the Formal System, data on biocontamination levels should be reviewed to establish or confirm a baseline for the determination of alert and action levels. Alert and action levels may be related to the target levels in any specific applications where these are set. Alert and action levels should be reviewed and adjusted as appropriate.

5.3 Monitoring of biocontamination

5.3.1 General

Detection and monitoring of biocontamination in risk zones shall be carried out by sampling and enumerating viable units with appropriate methods in accordance with a sampling plan.

Examples of sources of biocontamination that can constitute a hazard are air, surfaces, textiles and liquids (see Annexes A, C, D and F).

Microbiological sampling may be useful for providing baseline data as new installations are constructed and commissioned, including, as relevant, in the as-built state. Monitoring in risk zones shall be performed when the installation is in the as-built and at-rest states. Monitoring shall also be performed routinely in the operational state according to the selected Formal System.

5.3.2 Sampling

5.3.2.1 General

The appropriate sampling method and related procedures shall be selected and performed to reflect the complexity and variety of situations. Sampling shall be carried out using a device and method selected in accordance with the written procedure and in accordance with the instructions provided by the device manufacturer.

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5.3.2.2 Sampling device

A sampling device shall be selected according to the area being monitored. The selection for a particular application shall take into consideration the following factors:

a) type of viable particles for which to sample;

b) sensitivity of the viable particles to the sampling procedure;

c) expected concentration of the viable particles;

d) indigenous microbial flora;

e) accessibility of the risk zones;

f) ability to detect low levels of biocontamination;

g) ambient conditions in the risk zone being sampled;

h) time and duration of sampling;

i) sampling method, material and properties of the sampling medium;

j) effect of the sampling device on the process or environment to be monitored;

k) collection accuracy and efficiency;

l) incubation and viable particle detection and evaluation method;

m) type of information to be obtained (e.g. qualitative or quantitative aspects);

n) efficiency of extraction/rinse fluids, where appropriate.

5.3.2.3 Sampling plan

A sampling plan shall be developed through the selected Formal System and shall be documented. A documented sampling plan is essential for accurately assessing and interpreting biocontamination data.

Sampling shall be carried out when the area is in the operational condition and during periods of greatest stress in the system, for example, before the end of a shift or when the greatest amount of activity is taking place. Sampling in the at-rest condition may also provide useful information about the facility design and performance.

The sampling plan shall comprise the following:

a) initial sampling plan to provide a reference point or baseline within the framework of the chosen Formal System;

b) routine sampling plan resulting from the implementation of the chosen Formal System.

5.3.2.4 Design of the sampling plan

The sampling plan shall take into account the cleanliness level of the risk zone and the degree of biocontamination control required for the activity being conducted, to protect individuals, the environment, the process and the product. The following are examples of elements to be considered:

a) choice of the sampling location, taking account of the location and function of the risk zone;

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b) number of samples (limited or small sample volumes may not provide representative results, although, in some cases, large numbers of samples may compensate for the size of the sample volumes);

c) frequency of sampling;

d) methods of sampling, including whether the tests will be qualitative or quantitative;

e) volume to be taken or the area that should be covered to constitute a sample;

f) diluents, rinse fluids, neutralizers, etc.;

g) factors pertinent to a particular situation that could affect culturing results;

h) impact of operations, personnel and equipment in risk zones which contribute to biocontamination, such as

   1) compressed gases,

   2) room air,

   3) manufacturing equipment,

   4) monitoring/measuring devices,

   5) storage containers,

   6) number of persons present in zone,

   7) unprotected surfaces of personnel,

   8) personal attire,

   9) protective clothing,

   10) walls/ceilings,

   11) floors,

   12) doors,

   13) benches,

   14) chairs, or

   15) air admitted from other sources.

5.3.2.5 Frequency of sampling

The frequencies of sampling shall be developed using the selected Formal System and shall be confirmed or modified as necessary in the following cases:

a) when alert or action levels are exceeded consecutively;

b) after prolonged shut-down of activities;

c) on detection of infectious agents in risk zones;

d) after any significant maintenance work has been undertaken on the ventilation system;

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e) after changes to the process that affect the cleanroom environment;

f) after recording of unusual results;

g) after changes to the cleaning or disinfection procedures;

h) after unplanned incidents that could contribute to biocontamination.

5.3.2.6 Sampling sites

Sampling sites shall be determined through the selected Formal System, and included in the sampling plan.

More than one sample may be taken at each site and different numbers of samples may be taken at different locations.

Sampling shall be carried out at the microbiological control points defined in a written procedure.

5.3.2.7 Identification of samples

The labelling of each sample shall carry the following information or a coding that provides traceability of the information:

a) collection site;

b) date and time of collection;

c) person collecting the sample;

d) current activity at the time of sampling;

e) culture medium type;

f) any deviations from the sampling plan.

5.3.3 Validation

The selected monitoring system shall be used as part of the qualification and validation process for cleanrooms and associated controlled environments in accordance with ISO 14698-2 and ISO 14644-4:2001, Annex C.

NOTE Information on the validation of some microbiological methods is given in ISO 14698-2.

5.4 Processing of samples

The collection, transport and processing of samples shall not affect the viability and number of the collected organisms. Factors to be considered are

a) transport/storage conditions and duration,

b) use of neutralizing agents, and

c) use of osmotic solutes.

Samples shall be collected in a manner and in containers such as not to add to, or inhibit, biocontamination.

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5.5 Culturing of samples

5.5.1 General

Culture media and incubation conditions (e.g. temperature, duration, oxygen tension, relative humidity) shall be selected according to the types of microorganisms expected. This selection will also depend upon the sampling environment and the procedure and equipment used.

5.5.2 Culture media

Culture media shall, if not otherwise indicated, be non-selective. Appropriate additives shall be included to overcome, or minimize, the effects when residual antimicrobial activity at the sampling point is expected.

When culture media are used within cleanrooms or associated environments, the external surface of their containers shall be maintained in a state of cleanliness appropriate to their use.

NOTE The adoption of double- or triple-wrapping may be necessary to maintain the state of cleanliness.

Appropriate quality control procedures for the culture media shall be ensured[13], [14].

5.5.3 Incubation

When selecting a suitable incubation temperature and time for the inoculated culture media, conditions that favour the growth of the types of organisms expected to enter the clean environment shall be considered whenever possible.

Total incubation periods of two to five days for bacteria and five to seven days for fungi are generally acceptable, especially when the number of VU is low. When anaerobic, thermophilic, micro-aerophilic, or nutritionally deficient or fastidious bacteria, and fungi, are of concern, specific atmospheric conditions and incubation times could be necessary. Plates should be observed at appropriate intervals over the incubation period.

5.6 Evaluation of sampling data

5.6.1 General

The evaluation of biocontamination data shall provide sufficient information for effective corrective actions. Further information on the evaluation of biocontamination data is given in ISO 14698-2.

NOTE Monitoring of microbial contamination may be performed by the measurement of indirect indicators, e.g. adenosine triphosphate (ATP) measurements. However, it should be noted that there may be no direct relation between the presence of such indicators and biocontamination. It is therefore essential when the Formal System is being verified or the monitoring system is being validated, that there be a direct estimation of biocontamination.

5.6.2 Enumeration

It is generally accepted that, as with other microbiological counts, the estimation of biocontamination can be influenced by instruments and procedures used to perform these counts. Therefore the enumeration of viable particles from the samples shall be performed only by appropriate validated methods.

NOTE 1 Information on enumeration of viable particles is given in other sources[15], [16].

NOTE 2 This part of ISO 14698 does not imply or accept any direct constant or causal link between concentrations of viable and non-viable particles. Control levels for those parameters can be set separately as required.

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5.6.3 Characterization

Microbial monitoring cannot identify and quantify all the microbial species found in controlled environments. Evaluation of results shall include choice of an appropriate level of characterization.

NOTE The level of characterization will depend upon the criticality of the area involved and whether investigation warrants further identification. Broad categories based on cell morphology, staining properties and other characteristics may be sufficient. When required, identification, at least to the genus level, can be carried out using established laboratory methods. Information gathered through characterization can help in the evaluation of cleaning and disinfecting procedures and in determining a source of contamination or an appropriate corrective action. Identification of isolates from critical areas will usually take precedence over identification from non-critical areas.

6 Expression, interpretation and reporting of results

Quantitative results are expressed as viable units (VU) or as colony-forming units (CFU), depending on the method used, using appropriate SI units [17]. Information on data evaluation is given in ISO 14698-2.

To assist in interpretation, results shall be reviewed over extended periods to determine trends. Based on the review of these investigations and specific testing results, decisions shall be made on the significance of unusual results, and the acceptability of the operations or products processed under those conditions.

The test report shall include or make reference to the following:

a) type of sample;

b) method(s) used and, where appropriate, the number and title of the standard;

c) collecting device used;

d) sampling site;

e) type of activity underway at the time of sampling, including occupancy state;

f) number of persons within the sampling area, where appropriate;

g) sampling date and time of sampling;

h) sampling duration, where appropriate;

i) time of examination of samples;

j) conditions and duration of incubation;

k) variations from the described test method, as well as any factor that may have influenced the results;

l) test results from the examination of the collected samples after initial and final reading;

m) when quantitative tests have been performed, the results, expressed using appropriate SI units;

n) description of the isolate(s), if characterized;

o) name of the organization responsible for the test report and the date of completion of the test;

p) name and signature of the individual(s) responsible for performing the test.

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7 Verification of the Formal System

The results of monitoring biocontamination shall be examined periodically in order to confirm that the system chosen is functioning in accordance with the established procedures and the specified requirements have been fulfilled [see 4.2 f)].

NOTE This examination could require use of monitoring and auditing methods, procedures and tests, including random sampling and analysis. It could also require the systematic verification of all working steps and equipment to ensure the proper functioning of the Formal System.

If verification indicates deviations from the established limits or a change in the microbiological status of the controlled environment, corrective action shall be initiated. If appropriate, the Formal System shall be modified.

8 Training

A training programme shall be implemented (see Annex G).

9 Documentation

Documentation shall include

— description of the Formal System,

— risk assessment report,

— sampling plan,

— action, alert and target levels, as applicable,

— test and sampling procedures,

— test report,

— verification report, and

— training records.

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Annex A
(informative)

Guidance on determining airborne biocontamination

A.1 Introduction

This annex provides guidance on the determination of airborne biocontamination in situations where microbial control is considered desirable or necessary. This measurement involves collection of representative samples for the detection of those viable particles that need to be controlled and monitored.

This assessment of airborne biocontamination is carried out in accordance with the basic principles of this part of ISO 14698, which require the establishment of a Formal System to assess and control biocontamination where cleanroom technology is applied.

Techniques for the validation of a sampling device are given in Annex B.

A.2 Principle

Detection and monitoring of microbial contamination of the air in a risk zone is carried out by collecting viable particles with appropriate sampling devices, according to a sampling plan, when the risk zone is in the as-built and at-rest states, as appropriate, and routinely under normal operation in the risk zone.

A.3 Sampling devices

A.3.1 General

There are a great variety of methods available for the collection and enumeration of airborne viable particles[18]. The selection of a particular method and device will depend upon the purpose for which the sample is required. The collection efficiency of samplers will vary; an appropriate method or methods and equipment should be carefully selected.

Sampling devices fall into two categories:

a) passive sampling devices, such as settle plates;

b) active sampling devices, such as impact, impingement and filtration samplers.

The manufacturer of these devices should provide instructions for their use as well as information on their limitations. The collection efficiency of active sampling devices is discussed in Annex B.

A.3.2 Selection of a sampling device

The sampling rate, duration of sampling and type of sampling device can strongly influence the viability of the microorganisms that are collected. Impingement devices may not be suitable for sampling airborne viable particles because of their low sampling volume and low rate of sampling, and their tendency to disrupt clumps of viable particles.

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Because of the number and variety of microbial air sampling systems commercially available, the selection for a particular application should consider, as a minimum, the following factors:

a) type and size of viable particles to be sampled;

b) sensitivity of the viable particles to the sampling procedure;

c) expected concentration of viable particles;

d) ability to detect high or low levels of biocontamination;

e) appropriate culture media (see 5.5.2)[19];

f) time and duration of sampling;

g) ambient conditions in the environment being sampled;

h) disturbance of unidirectional airflow by the sampling apparatus;

i) sampler properties such as

   1) appropriate suction flow rate for low levels of viable airborne particles,

   2) appropriate impact/airflow velocity,

   3) collection accuracy and efficacy,

   4) ease of handling (weight, size) and operation (ease of use, auxiliary equipment, dependence on vacuum pumps, water, electricity, etc.),

   5) ease of cleaning and disinfection or sterilization, and

   6) possible intrinsic addition of viable particles to the biocontamination to be measured.

The exhaust air from the sampling apparatus should not contaminate the environment being sampled or be reaspirated by the sampling device.

A.3.3 Passive microbial sampling devices (sedimentation sampling devices)

Passive microbial air sampling devices such as settle plates do not measure the total number of viable particles in the air; they measure the rate at which viable particles settle on surfaces. Settle plates may therefore be used for the qualitative and quantitative evaluation of airborne contamination of products. This can be done by determining the settle plate count per time; then, by relating both the area and time of exposure of the product to that of the settle plate, the possible contamination of the product can be calculated[20], [21].

A.3.4 Active microbial sampling devices

A.3.4.1 General

The use of active air sampling devices in risk zones is essential for the assessment of the microbial quality of air. There are several types of active devices commercially available, each having its own limitations.

Based on the principles of sampling, the two main types of apparatus considered suitable for risk zones with normal (low level) biocontamination are impact samplers and filtration samplers.

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A.3.4.2 Impact and impingement samplers

Because there are a variety of impact and impingement samplers available for the detection of viable particles, the device selected for use should have the following characteristics:

a) impact velocity of the air hitting the culture medium that is a compromise between

   1) being high enough to allow the entrapment of viable particles down to approximately 1 µm, and

   2) being low enough to ensure viability of viable particles by avoiding mechanical damage or the break-up of clumps of bacteria or micromycetes;

b) sampling volume that is a compromise between being large enough to detect very low levels of biocontamination and being small enough to avoid physical or chemical degradation of the collection medium.

In areas of high biocontamination, the impaction method and sample volume should be selected in way appropriate to achieving separate colonies, to allow the results to be interpreted.

The device should meet the following minimum requirements:

— sufficient flow rate to collect 1 m^3 in a reasonable time, without significant drying of the sampling medium;

— appropriate air impact speed to the culture medium.

A.3.4.3 Filtration samplers

Filtration sampling devices are widely used for air sampling. By appropriate choice of pump, filter medium and filter size, almost any desired sample quantity can be collected in a given sampling period.

For the design and use of a filtration sampling device, the following factors should be considered:

a) ensure that the filtration conditions do not affect the viability of the microorganisms collected, e.g. by dehydration;

b) eliminate static electricity that will interfere with the rate of impact of viable particles onto the filter membrane;

c) apply the same constraints or suction flow rate and impact air velocity as in A.3.4.2;

d) ensure that the filter membrane holder can be connected to a vacuum source, fitted with a device for measuring the suction rate, without contamination of the filter material;

e) ensure that the filter membranes can be placed aseptically in the filter holder, can be removed aseptically after filtering the desired quantity of air and can be placed on solid culture medium or in liquid culture medium.

A.4 Expression of results

The number of viable particles should be expressed in viable units per cubic metre.

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Annex B
(informative)

Guidance on validating air samplers

B.1 Introduction

This annex describes a technique for determining the collection efficiency of samplers used for counting airborne microbes. Manufacturers or third-party testing organizations will usually perform this evaluation.

The collection efficiency of microbial air samplers can be considered in two ways: physical efficiency and biological efficiency. Physical efficiency is the ability of the sample to collect various sizes of particles. Physical efficiency is the same whether the particle is a microorganism, carries a microorganism or is an inanimate particle. Biological efficiency is the efficiency of the sample in collecting microbe-carrying particles. Biological efficiency will be lower than physical efficiency for a number of reasons, such as the survival of the microorganisms during collection and the ability of the collection medium to support their growth. The test method described in this annex is mainly concerned with physical efficiency.

B.2 Experimental method

B.2.1 Test chamber

A test chamber approximately 1 m wide by 1 m high by 2 m long is suitable, but any small, enclosed space would be acceptable. A test aerosol should be generated either within this area, or supplied to the area. The test area should be supplied with HEPA-filtered air and maintained at negative pressure by extracting air at a suitable rate. The extracted air should be HEPA filtered.

The airflow within the test chamber should be non-unidirectional with an air-change rate equivalent to that found in a typical cleanroom, i.e. between 20 and 60 per hour. To avoid local concentrations of unmixed air, care should be taken with the method of supplying and extracting air. A useful approach is to supply and extract sufficient air to ensure negative pressure conditions and to recirculate the remainder by means of a paddle or fan within the test area.

A particle counter and method of sampling air within the chamber should be provided to ensure the aerosol is well mixed and to check on its concentration.

Temperature and relative humidity should be maintained at (22 $\pm$ 2) °C and (50 $\pm$ 10) % RH, respectively. The apparatus within the test area shall be able to be manipulated from outside of the chamber, e.g. by use of gauntlets or half-suits.

B.2.2 Test strains of microorganisms

B.2.2.1 Strains for testing physical efficiency

The test strain should be *Bacillus subtilis* var. *niger* NCTC 10073 (= DSM 2277), which survives well in the collection conditions. The test strain should be prepared in a culture medium meeting the nutritional requirements of the test strain and used as a washed spore suspension.

NOTE Polystyrene spheres and other types of non-viable particles can be used to determine the physical efficiency of air samplers[22]. The results obtained are similar to those produced by microbiological particles. However, in some samplers it is impossible to detect all the non-viable particles, whereas if microbes are used, they will grow into colonies that can be easily seen and identified.

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B.2.2.2 Strains for testing biological efficiency

Many of the microbes in the air of occupied areas come from the skin of personnel; coagulase-negative Staphylococci predominate. However, it is also possible to find in some rooms a substantial number of microorganisms that come from the process. If biological testing is to be carried out, bacteria typical of those found in the room air should be tested. An organism such as *Staphylococcus epidermidis* (NCTC 11047; ATCC 14990) can be used. However, it should be noted that changes in the spray solution, the spray method and the collection conditions might cause the biological efficiency to vary and make this method less reliable than the physical efficiency.

B.2.3 Generation of microbe-carrying particles

Aerosols of a controlled particle size are produced by an apparatus such as the spinning-top or spinning disc aerosol generator[23]. The disc or top is spun at high speed and fed by a liquid suspension of microbes that are spun out as a fine homogeneous spray. By varying the speed, the size of the wet droplets can be varied. The droplets dry quickly and, depending upon the amount of insoluble material in the liquid, various sizes of small dry particles can be produced. The wet particle diameter can be determined by use of an equation that relates it to the density and surface tension of the liquid and the rotational speed and diameter of the spinning disc. Alternatively, it can be measured microscopically.

After formation, the wet particles will be reduced by evaporation to a size that depends upon their solid content. It is useful to increase their size and weight by incorporating potassium iodide into the spraying solutions. The diameter of the dry particle can be calculated using the following equations or determined microscopically by sampling the air in the test chamber by means of a filter membrane.

The radius (r) of any sphere is related to its volume (V) by the following equation:

$$r = \left(\frac{3}{4} V \div \pi \right)^{\frac{1}{3}} \tag{B.1}$$

In the case of a dry particle, its size will be determined by both the amount of solid material contained within the wet particle and the spore.

Therefore:

$$\text{Radius of dry particle} = \left\{ \frac{3}{4} \left(V_{\text{p}} + V_{\text{s}} \right) \div \pi \right\}^{\frac{1}{3}} \tag{B.2}$$

where

V_{s} is the volume of spore (approximately 0,5 μm^3);

V_{p} is the volume of particle after evaporation;

V_{p} can be calculated by

$$V_{\text{p}} = \frac{\text{volume of wet particle (m}^3\text{)} \times \text{concentration of solid in particle (g/m}^3\text{)}}{\text{density of the solid material in solution (g/m}^3\text{)}} \tag{B.3}$$

Having determined the radius of the dry particle the diameter is easily ascertained.

The aerodynamic behaviour of a particle will vary according to its density. Therefore, it is necessary to calculate the equivalent particle diameter of the dry particle, i.e. the size the dry particle would be if it were of unit density, as follows.

$$\text{Equivalent particle diameter} = d \left(\rho \right)^{\frac{1}{2}} \tag{B.4}$$

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where

d is the diameter of the dry particle;

ρ is the density of incorporated solid material.

B.2.4 Testing

The tests take place inside the chamber or in an area adjacent to it that has turbulent air conditions similar to a cleanroom. The sampler to be tested and a membrane-filter holder, containing a 0,45 µm filter, should be placed close to one another but far enough away from the aerosol generator to ensure that the particles are dry when sampled (approximately one metre). The particle counter should be used to check that the particle concentration is the same at the sampler and membrane-filter holder positions. The membrane sampler, operating at a flow rate of approximately 5 l/min, should not face upward but should face to the side or downward, preventing deposition by gravity of particles onto the membrane. Both samplers should be switched on together. The sampling time will depend on the concentration of microbe-carrying particles in the air but a few minutes should suffice. After the test, place the membrane on a plate containing casein-peptone soya meal-peptone agar or a validated, equivalent medium. After incubation of both sets of samples for two days at 37 °C, count the colonies.

Prior to use in the test, suspension of the washed spores, at a concentration not greater than 10^6/ml to 10^7/ml, in an 80 % solution of ethanol will ensure single spores are obtained in most of the particles. The necessary amount of aerosol generated will depend on the size of the chamber and the amount of air supplied and extracted. However, the aerosol concentration should not prolong sampling time and there should be no coincidence of bacterial colonies on the sampling medium.

Different concentrations of solids should be dispersed in the solutions to provide a range of particle sizes when sprayed. The concentrations of solids required can be calculated using the equations given in B.2.3. Five solutions should be prepared to provide particle sizes over a range of equivalent particle diameters of approximately 0,8 µm to 15 µm. For each particle size, at least 10 experiments should be carried out.

B.3 Interpretation of results

Use the yield from the test sampler and the membrane filter sampler from the same volume of air to calculate the efficiency using the following equation:

$$\text{Efficiency of sampler (\%)} = \frac{\text{test sampler count}}{\text{total count (from membrane sampler)}} \times 100 \qquad \text{(B.5)}$$

The results may be plotted as particle size against efficiency, with all points plotted as means with standard deviations of efficiencies.

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Annex C
(informative)

Guidance on determining biocontamination of surfaces

C.1 Introduction

This annex provides guidance on the determination of biocontamination of surfaces in situations, particularly risk zones, where biocontamination control is considered desirable or necessary. This measurement involves the collection of representative samples for the detection of viable particles that are present and that may need to be controlled or monitored. These methods might not give the total number of viable microorganisms present but, under controlled conditions, can give relevant and comparable results. These methods are applied routinely in the operational condition and, if appropriate, in as-built and at-rest conditions.

This assessment of airborne biocontamination is carried out in accordance with the basic principles of this part of ISO 14698, which require the establishment of a Formal System to assess and control biocontamination where cleanroom technology is applied.

C.2 Principles

A count of microorganisms on a surface at a point in time is obtained by a contact device or a swab. A contact device can apply a solid nutrient medium of known area to the surface, which is then incubated. The resultant colonies give a mirror-image “map” of the original viable units. A swab can be used to wipe a surface and the number of microorganisms removed by the swab can be counted.

A count of the rate at which microorganisms are falling on the surface is obtained by exposing, for a known period, a nutrient surface of known area, which is then incubated. The resultant colonies give a rate of deposition per area per period.

C.3 Sampling devices

C.3.1 Contact sampling devices

Contact plates or other devices can be used that allow a nutrient medium, held in a suitable flexible or rigid container, to make contact with the surface to be sampled. The accessible contact surface should be $\geqslant 20\ cm^2$.

The nutrient medium should be applied to the surface for a few seconds with a uniform and steady pressure to the whole area, without allowing any circular or linear movement. The device is then returned to its container and the sampled surface is cleaned to remove any nutrient residues.

C.3.2 Swabs

Collection of viable units may also be achieved by appropriate application of a swabbing technique. The use of sterile moistened swabs, sponges or wipes is particularly convenient for sampling large, non-absorbent, irregular or recessed surfaces not accessible to contact devices.

The swab should be pre-moistened with a sterile rinse medium. The swab should be stroked in close parallel sweeps over the defined sampling area, while being slowly rotated. Sampling of the same area should be repeated, stroking the same swab perpendicular to the initial sweep. The swab should then be placed in a

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specified amount of rinse liquid and agitated. The rinse liquid should be assayed for viable units. After sampling, the sample site surface should be cleaned to remove any residue of the rinse medium.

C.3.3 Settle plates

Settle plates are suitable for the qualitative and quantitative evaluation of possible surface contamination by airborne viable particles depositing from the air.

Where appropriate, the number of microorganism-carrying particles depositing from the air onto surfaces in a given time can be determined by settle plates containing a suitable culture medium; the plates are then incubated. This technique does not measure the total number of microorganisms present in the air; it measures the number that have settled onto a surface during the sampling period. The sensitivity of this method may be enhanced by using large-diameter Petri dishes (i.e. 14 cm diameter) and extending exposure time, while taking care to avoid dehydration of the culture medium[24].

C.4 Expression of results

The number of viable particles on surfaces should be expressed in viable units per 1 dm^2, or in the case of settle plates, per 1 dm^2 per hour (1 $dm^2 = 100\ cm^2$).

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Annex D
(informative)

Guidance on determining biocontamination of textiles

D.1 Introduction

D.1.1 This annex provides guidance on the determination of biocontamination of textiles in situations where microbial contamination control is considered desirable or necessary.

This assessment of the biocontamination of textiles is carried out in accordance with the basic principles of this part of ISO 14698, which require the establishment of a Formal System to assess and control biocontamination where cleanroom technology is applied.

This assessment involves the collection of representative samples for detection and monitoring of viable particles that are present on, or are shed by, textiles.

Textiles used in risk zones should be of an adequate cleanliness level as appropriate for the work activity, the purpose for which they are used or both. Textiles should be monitored for biocontamination in order to minimize the risk of adversely influencing the activities, products, devices, etc. in risk zones.

D.1.2 In relation to the selection of textiles for, and the assessment of, related biocontamination in risk zones the following factors should be considered:

a) type and form of textile(s), e.g. protective clothing, wipes, etc.;

b) choice of fabric;

c) particle generation and dispersion characteristics of the fabric;

d) inadequate barrier effect due to inadequate fabric filtration properties;

e) cleaning, decontamination or sterilization of the textiles;

f) particle removal efficiency from the textile;

g) garment design;

h) textile permeability, surface condition and abrasion resistance.

D.1.3 If the biocontamination of a textile is found to be excessive, appropriate methods will be required to find possible causes. Typical causes include

a) poor particle retention due to fabric properties such as fibre type, weave or design,

b) incorrect usage, e.g. clothing not changed frequently enough,

c) insufficient decontamination, or ineffective cleaning or both,

d) inappropriate textile washing cycles for the microbiological constraints of the risk zone, and

e) recontamination after laundering.

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This annex is not intended to give guidance on the determination of the permeability of fabrics to viable particles. Nor does it cover specific aspects of textiles that may be required for certain fields of application such as sterilized and departiculated textiles, nor textile quality as judged by visual inspection or by touch.

D.2 Principle

Detection and monitoring of microbial contamination of a textile in a risk zone is carried out by collecting viable particles with appropriate sampling devices, according to a sampling plan.

D.3 Contact sampling devices

For determination of viable particles on textiles, suitable contact devices may be used (see Annex C), including those appropriate for testing small textile items. If possible, the fabric should be held against a hard, flat, smooth surface before the contact plate is applied.

When using sampling devices based on dehydrated media on a support, rehydration may be carried out by using the quantity of liquid indicated by the manufacturer; alternatively, this can be done by using solutions that inactivate or neutralize detergents or disinfectants or that neutralize both detergents and disinfectants.

NOTE Where textiles are required to be sterile before use, as part of the sterilization validation the microbial contamination of the textiles can be determined by using mechanical agitation (e.g. using a stomacher) to remove the microorganisms from samples of the textile placed into an extraction solution. This extraction solution is then membrane filtered.

D.4 Expression of results

The number of viable particles should be expressed in viable units per 1 dm^2 of the textile sampled (1 dm^2 = 100 cm^2).

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Annex E
(informative)

Guidance on validating laundering processes

E.1 Introduction

This annex provides guidance on, and describes a technique for, the validation of laundering processes in situations where control of biocontamination is considered desirable and necessary.

E.2 Test method

E.2.1 Principle

The validation involves using pieces made of a textile of the same type as those that undergo the laundering process. These pieces are contaminated by known microorganisms in a measured quantity. The pieces are then put through the laundering process that is to be validated. The ability of the process to reduce by a factor of 10^5 the number of bacteria and 10^4 the number of yeasts and fungal spores is checked.

The following controls are performed:

a) Control A: enumeration of viable units in initial microorganism suspension. Control A is designed to demonstrate that initial numbers of microorganisms are high enough to allow measurement of the desired reduction of the microorganism population.

b) Control B: enumeration of viable units on control pieces that have undergone exactly the same procedure as the test piece with the exception of the laundering process. Control B is designed to demonstrate that the viability of microorganisms does not change over the validation period.

c) Control C: enumeration of viable units on control pieces that have undergone exactly the same procedure as the test piece, including the laundering process, but have been contaminated with the microorganism suspension only after the laundering process. Control C is designed to demonstrate that the technique for counting the number of surviving microorganisms is appropriate to the process conditions (time, mechanical effect, temperature, presence of residues of washing product(s) on the textiles, etc.).

For the test proper, a suspension of known microorganisms is prepared in a protein solution. A known volume of the suspension is applied to the test pieces. The test pieces are subjected to the laundering process as part of a simulated normal textile load. Enumeration of microorganisms on test pieces is done after the laundering process. The reduction of the microorganism population is measured and compared to the values mentioned above.

It is essential that garments used in the simulated normal load be made sterile before reuse or are destroyed.

E.2.2 Microorganisms

E.2.2.1 Bacteria

At a minimum, the following bacterial strains should be used:

a) *Enterococcus hirae* ATCC 10541;

b) *Escherichia coli* ATCC 10536.

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E.2.2.2 Fungi

If fungicidal activity is claimed, at a minimum the following fungal strains should be used:

a) *Saccharomyces cerevisiae* ATCC 9084;

b) *Aspergillus niger* ATCC 16404.

E.2.2.3 Bacterial spores

If sporocidal activity is claimed, at a minimum the spores of the following strain should be used: *Bacillus subtilis* var. *niger* ATCC 6633.

E.2.3 Microbial suspensions

E.2.3.1 Suspension medium

Sterile peptone saline water should be used as the suspension medium for the suspension of bacteria. For fungi, add 0,05 % (v/v) of polysorbate 80 or other validated chemical. Sterile distilled water should be used for bacterial spores.

E.2.3.2 Recovery medium

The suspension medium, distilled water or any solution that can be filtered in test conditions can be used. If a disinfectant neutralizing agent must be used, this can be added to the recovery medium.

E.2.3.3 Protein solutions

The following aqueous solutions are prepared.

— Solution A: 3 % (w/V) bovine albumin (Cohn's fraction V), adjusted to pH = 6,8 ± 0,2 if necessary, sterilized by membrane filtration.

— Solution B: 15 % (w/V) yeast extract adjusted to pH = 7 ± 0,2, sterilized by a validated procedure.

— Solution C: solutions A and B are mixed in the ratio 100:20, so that the concentration of each protein is 2,5 % (w/V).

E.2.4 Control and test pieces

The pieces, made from a de-sized textile, must be representative of the textiles that undergo the laundering process to be validated. They should be used only once. The pieces should have an overall size of 10 cm × 5 cm, including a contaminated area of 5 cm × 5 cm and free end(s) used to attach them to a textile in the load.

Pieces are wrapped in a material permeable to steam and sterilized by a validated procedure.

E.2.5 Preparation of the inoculum

A suspension of $\geqslant 10^8$ bacterial cells, or $\geqslant 10^7$ fungal cells or bacterial spores per millilitre is prepared.

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E.2.6 Procedure

E.2.6.1 Controls

These are as follows.

— Control A: enumerate VU in duplicate in an agar medium after appropriate dilution of the inoculum suspension. The mean of the two counts in the dilution containing 30 VU/ml to 300 VU/ml is called N. Check that the number in the original suspension was $\geqslant 10^8$/ml for bacterial cells or $\geqslant 10^7$/ml for fungal cells or bacterial spores.

— Control B: using appropriate dilutions, inoculate two control pieces with 0,5 ml of a suspension containing 30 VU/ml to 300 VU/ml and two other control pieces with 0,5 ml of a suspension containing 300 VU/ml to 3 000 VU/ml. These four control pieces are handled and tested together with the test pieces throughout the test, with the exception of the laundering process. When returned to the laboratory, they are incorporated in a nutritive agar medium and incubated. VU are counted. The mean count corresponding to the most heavily contaminated control pieces is called N'_1 and the other is called N'_2.

— Control C: 0,5 ml of protein solution C (see E.2.3.3) is applied to one control piece. The latter undergoes the whole laundering process. The control piece is then immersed in 100 ml of a recovery medium, agitated for 15 s to 30 s and deposited in a Petri dish. Then 1 ml of a suspension containing 30 VU/ml to 300 VU/ml is applied to the control piece. The latter is covered with 10 ml of agar medium, incubated and then counted. The count is called n_1. The 100 ml of recovery medium used previously is filtered through a filtration membrane capable of retaining microorganisms. After rinsing three times, the membrane is covered with 50 ml of new recovery medium. The 1 ml of the suspension containing 30 VU/ml to 300 VU/ml is added to the 50 ml of recovery medium and then filtered. The membrane and the filtration apparatus are rinsed with another 50 ml of recovery medium and then filtered, after which the membrane is transferred onto an agar medium and incubated. The count is called n_2. Calculate $n = (n_1 + n_2)/2$.

If $N \cong N'_2 \cong n$, the experimental conditions are validated for the test proper.

If $N'_2 \leqslant 0{,}5\ N$ and/or $N'_1 \leqslant 0{,}05\ N$ and/or $n \leqslant 0{,}5\ N$, the experimental conditions are not validated for the test proper. Redo the controls, for example, adding appropriate compounds to neutralize chemical residues in control pieces submitted to the laundering process.

E.2.6.2 Test proper

Mix and leave in contact for 5 min at ambient temperature 3 ml of the microorganism suspension (E.2.5) and 2 ml of the protein solution C of (E.2.3.3). Apply 0,5 ml of the resulting suspension to the test piece. For each microorganism tested, contaminate three test pieces.

After the laundering process, the control pieces are brought back to the laboratory as quickly as possible. Each piece is transferred into 100 ml of recovery medium and agitated for 15 s to 30 s. Then the following steps are performed.

a) Transfer 0,1 ml in 9,9 ml recovery medium and agitate. Transfer these 10 ml onto a filtration membrane three times with 50 ml new recovery medium. Place the membrane on an agar nutritive medium and incubate.

b) Transfer 1 ml onto a filtration membrane and then rinse three times with 50 ml new recovery medium. Place the membrane on an agar nutritive medium, and incubate.

c) Transfer the remaining 98,9 ml onto a filtration membrane and rinse three times with 50 ml new recovery medium. Place the membrane on an agar nutritive medium and incubate.

d) Transfer each test piece aseptically to a Petri dish, cover with agar medium and incubate.

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n'_1 is the number of VU determined on the membranes — the mean of counts resulting from E.2.6.2 a), b) and c).

n'_2 is the mean number of VU determined on the test pieces in E.2.6.2 d).

$R = n'_1 + n'_2$ is therefore the number of residual microorganisms following the laundering process.

E.2.7 Interpretation of results

Calculate the ratio of the number N of microorganisms applied to the control pieces to R. Check if the laundering process ensures reduction by a factor of at least 10^5 of the number of bacteria and reduction by at least 10^4 of the number of yeasts and fungal spores.

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Annex F
(informative)

Guidance on determining biocontamination of liquids

F.1 Introduction

This annex provides guidance on the determination of biocontamination in liquids (aqueous or non-aqueous) in situations where control of biocontamination is considered desirable and necessary. This measurement involves the collection of representative samples for the detection of viable particles that are present and that could need to be controlled or monitored.

This assessment of the biocontamination of a liquid is carried out in accordance with the basic principles of this part of ISO 14698, which require the establishment of a Formal System to assess and control biocontamination where cleanroom technology is applied. In addition, the following factors should be considered:

a) microbial ecology and related parameters in risk zones;

b) expected concentration of the viable particles in the specific liquid(s);

c) condition of the liquid(s);

d) accuracy and efficiency of collection.

F.2 Principle

Collection of samples for the detection and monitoring of microbial contamination of liquids in risk zones is carried out with appropriate sampling devices and according to a sampling plan, when the risk zone is at-rest and routinely under normal operation. Qualitative and quantitative detection of viable particles may be achieved by direct or indirect measurement techniques.

F.3 Procedure

F.3.1 General

There are a variety of methods available for the determination of biocontamination of liquids. The selection of a particular method will depend on the nature of the liquid and the volume of sample required. For example, pour plates, spread plates, membrane filtration and other methods can be used[25].

Pressure of liquids shall be suitably reduced for sampling. Attention should be paid to the liquid condition and the expected concentration of viable units in the liquid.

F.3.2 Sample preparation

Depending on the liquid and biocontamination level, the sample can be assayed directly or after appropriate treatment.

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F.3.3 Sample investigation

Methods for the detection of biocontamination should be selected that are appropriate to the nature of the liquid(s) to be sampled.

F.4 Expression of results

The number of viable particles should be expressed in viable units per 1 ml (1 cm^3).

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Annex G
(informative)

Guidance on training

G.1 Introduction

This annex provides guidance on training personnel in the context of the control of biocontamination of cleanrooms and associated controlled environments.

An essential contribution to all elements of quality management systems and the key to quality management is a continuous, organized and appropriate training programme for all persons who work with the system chosen according to this part of ISO 14698. All persons involved, including sub-contractor personnel, should be trained in an appropriate manner to enable consistent, reliable and reproducible results and delivery of services. Particular consideration should be given to the training of persons involved in microbiological monitoring and laboratory analysis.

Training requires the development of usable procedures and training materials, coupled with documentation and record keeping of the performance elements applied, as well as a system for verification of training. Training may be conducted within the organization, or outside by an independent organization.

This annex is not intended to supply criteria for assessment of competence, level of performance, performance appraisals or a complete personnel training programme, but to point out the most important activities and elements to include in a training and verification cycle in the field of biocontamination control.

G.2 Elements for standardized training programmes

G.2.1 General

Training documents should be prepared wherever the procedure warrants it, and in that case should be a detailed presentation of the single steps of procedures. Each step should be divided into its constituent parts to describe fully the content and scope of the training required for these steps.

G.2.2 Training documents

A training document should consider the following aspects:

a) listing of documents and references to be used during training;

b) description and definition of training objectives and methods to be used;

c) descriptions of the details of each procedural step, as appropriate, for a full understanding of the requirements for performing that specific step;

d) results of measurements, if appropriate;

e) scheduled training courses, whether held in-house or elsewhere;

f) description of the evaluation of the effectiveness of training.

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A unified training manual should be developed for the selected system, rather than production of individual guides for each procedure or assay. A uniform document format should be adopted and should focus on the procedure concerned, avoiding excessive comprehensive background information.

G.2.3 Training manual

The department or organization should collate all the training documents related to a particular area or facility into a single manual to serve as the training manual. This manual should translate and standardize the details of a procedure into separate, clearly understandable steps to be used to achieve acceptable performance.

A training manual should typically be used for the following purposes:

a) training new employees;

b) implementation of new methods, instruments and sampling devices;

c) good microbiological and hygiene practices and laboratory safety;

d) risk analysis;

e) changes in the sampling and monitoring plan;

f) re-training when less than satisfactory performance is reported;

g) periodic verification.

G.2.4 Microbiological and biocontamination control procedures

Formal training for all persons assigned to controlled environments and individuals responsible for the administration and general operation of the environmental control programme, including sampling personnel and laboratory technicians, should include

a) basic principles of microbiology,

b) fundamentals of applied microbiology, hygiene and epidemiology,

c) good employee aseptic techniques and precautions,

d) principles of environmental control processes,

e) microbiological sampling techniques,

f) basic principles of microbiological hazard analysis,

g) understanding microbiological target, alert and action levels,

h) principles of trend analysis,

i) specialized training on all required laboratory methods, and additionally on any automated system to be used to assist microbial identification, and

j) instruction on writing clear reports.

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G.3 Training verification

G.3.1 General

Verification should be made that training has taken place and is documented. Verification that personnel have been trained in the specified system should be procedure-based. Therefore, verification of training should focus on the specifics of procedure performance. To make it easier to verify an employee's performance on the procedures associated with the employee's job, a systematic approach to implementation of training verification is recommended.

G.3.2 Assessment tools

After the training verification procedure is developed, it is necessary to design an assessment tool to verify the effectiveness of training. The employee's performance should be assessed against an established performance standard as defined by the laboratory/department management/supervision or training institution. A variety of “measuring tools” may be used to verify performance, for example:

a) assessment against the objectives of the training programme;

b) written tests;

c) assessment of response to

   1) case studies from the fields of concern,

   2) problems, and

   3) situations related to procedure;

d) response to oral questioning related to procedure;

e) testing of known and unknown samples.

Pass/fail criteria should be known to all participants before assessment is carried out.

G.3.3 Documentation

G.3.3.1 General

Documentation of the results of training may be supported on a variety of systems. Consistency in record keeping and formatting of employees' records is important to the documentation of the training verification.

Documentation should comply with regulatory and accreditation requirements and standards, with organizational (employer) or departmental policies or both, and with laboratory department or section services and guidelines.

G.3.3.2 Retention of records

Records should be held in a clear, written form indicating

a) the identity of trainee,

b) who was responsible for training,

c) where records are kept and who has access,

d) when records can be discarded, and

e) when and how records are reviewed.

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