



Space product assurance

Bioburden control of cleanrooms

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This Standard is one of the series of ECSS Standards intended to be applied together for the management, engineering and product assurance in space projects and applications. ECSS is a cooperative effort of the European Space Agency, national space agencies and European industry associations for the purpose of developing and maintaining common standards.

Requirements in this Standard are defined in terms of what shall be accomplished, rather than in terms of how to organize and perform the necessary work. This allows existing organizational structures and methods to be applied where they are effective, and for the structures and methods to evolve as necessary without rewriting the standards.

The formulation of this Standard takes into account the existing ISO 9000 family of documents.

This Standard has been prepared by the ZZZZ (see document properties) Working Group, reviewed by the ECSS Executive Secretariat and approved by the ECSS Technical Authority.

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Change log

First issue

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Introduction

The UN Outer Space Treaty of 1967 sets up the general principles applicable to the exploration and use of outer space. Article IX of the Outer Space Treaty constitutes the primary statement of international law: “States parties shall pursue studies of outer space, including the Moon and other celestial bodies, and conduct exploration of them so as to avoid their harmful contamination and also adverse changes in the environment of the Earth resulting from the introduction of extraterrestrial matter and, when necessary, adopt appropriate measures for this purpose”. Harmful contamination in that sense is defined as biological contamination, including organic-constituents, to protect the environment in order to allow future exobiology research. The Committee On Space Research (COSPAR) has established some planetary protection guidelines, based on the Outer Space Treaty. These guidelines impose requirements on spaceflight missions according to target body/mission type combinations.

The objective of this Standard is to ensure that the proper procedures to control the microbiological contamination in controlled environments are in place to meet the planetary protection constraints.

1 Scope

This standard establishes the principles and basic methodology for microbiological control of cleanrooms and associated controlled environments with planetary protection constraints.

This standard does not address:

- the microbiological contamination on spaceflight hardware;
- molecular contamination control. Reference is made to other documents;
- fire and safety regulations; for these, see regulatory requirements and other national or local documentation.

This standard does not lay down the methods for determining the microbiological and particulate cleanliness levels. Reference is made to other documents.

2

Normative references

The following dated normative documents are called by the requirements of this ECSS Standard and therefore constitute requirements to it. Subsequent amendments to, or revisions of any of these publications do not apply.

NOTE However, parties to agreements based on this ECSS Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below.

ECSS-P-001B	ECSS – Glossary of terms
ECSS-P-00	Standardization Policy
ECSS-Q-00	Space product assurance - Policy and principles
ECSS-Q-20	Space product assurance - Quality assurance
ECSS-Q-20-09	Space product assurance - Nonconformance control system
ECSS-Q-40	Space product assurance - Safety
ECSS-Q-70-01	Space product assurance - Cleanliness and contamination control
ISO 14644 part 1	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness
ISO 14644 part 2	Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

3

Terms, definitions and abbreviated terms

3.1 Terms defined in other standards

For the purpose of this Standard, the terms and definitions from ECSS-P-001B apply.

3.2 Terms specific to the present standard**3.2.1 action level**

level set by the user in the context of controlled environments associated to specific requirements in the case that it is exceeded

3.2.2 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, increased attention to the process is expected

3.2.3 aseptic

state of being free from all living microorganisms (i.e. free of bioburden)

NOTE In practice, it is usually described as a probability function.

3.2.4 biobarrier(s)

barrier surrounding a spacecraft, capsule, system or component which prevents biological recontamination subsequent to microbial reduction procedures

3.2.5 bioburden

quantity of viable microorganisms that can survive a heat -shock of 80 °C for 15 minutes measured with a specified assay

3.2.6 bioburden controlled

defined zone or facility in which sources of bioburden contamination are controlled by specified means

3.2.7 bioburden reduction

process or processes used to reduce the viable microbial population on an hardware to an acceptable limit

3.2.8 biocontamination

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

3.2.9 biodiversity

identification of type of micro-organism, measured with specified assays

3.2.10 commissioning

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

3.2.11 controlled environment

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

3.2.12 disinfect

apply a process which destroys vegetative forms of harmful microorganisms, especially on inanimate objects or surfaces

NOTE Disinfection does not necessarily sterilise a surface or object.

3.2.13 formal system

system of biocontamination control with established and documented procedures

3.2.14 occupancy states

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

3.2.15 occupancy states

<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

3.2.16 occupancy states

<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

3.2.17 planetary protection

policy and the technical implementations to prevent forward and backward contamination

3.2.18 sporicide

substance capable of destroying bacterial spores

3.2.19 sterile

state of being free from all living microorganisms (i.e. free of bioburden)

NOTE In practice, it is usually described as a probability function.

3.2.20 sterilization

process of actively reducing the bioburden

3.3 Abbreviated terms

For the purpose of this Standard, the abbreviated terms from ECSS-P-001B and the following apply:

Abbreviation	Meaning
AIT	assembly, integration, and testing
AIV	assembly, integration, and verification
CFU	colony forming unit
COSPAR	Committee On Space Research
DHMR	dry heat microbial reduction
ESA	European Space Agency
ESD	electrostatic discharge
FMECA	failure mode effects and critical analysis
GSE	ground support equipment
HEPA	high efficiency particulate air
HVAC	heating, ventilation, air conditioning, and cooling
IPA	isopropyl alcohol (isopropanol)
ISO	international organisation for standardization
JPL	Jet Propulsion Laboratory
NASA	National Aeronautics and Space Administration
PP	planetary protection
PPO	planetary protection officer
P-PPE	prime-planetary protection manager

4 Principles

The activities related to requirements for bioburden control in cleanrooms, specifications, procedures and reports are described in Figure 4-1, and the related standardization requirements are captured in clause 5.

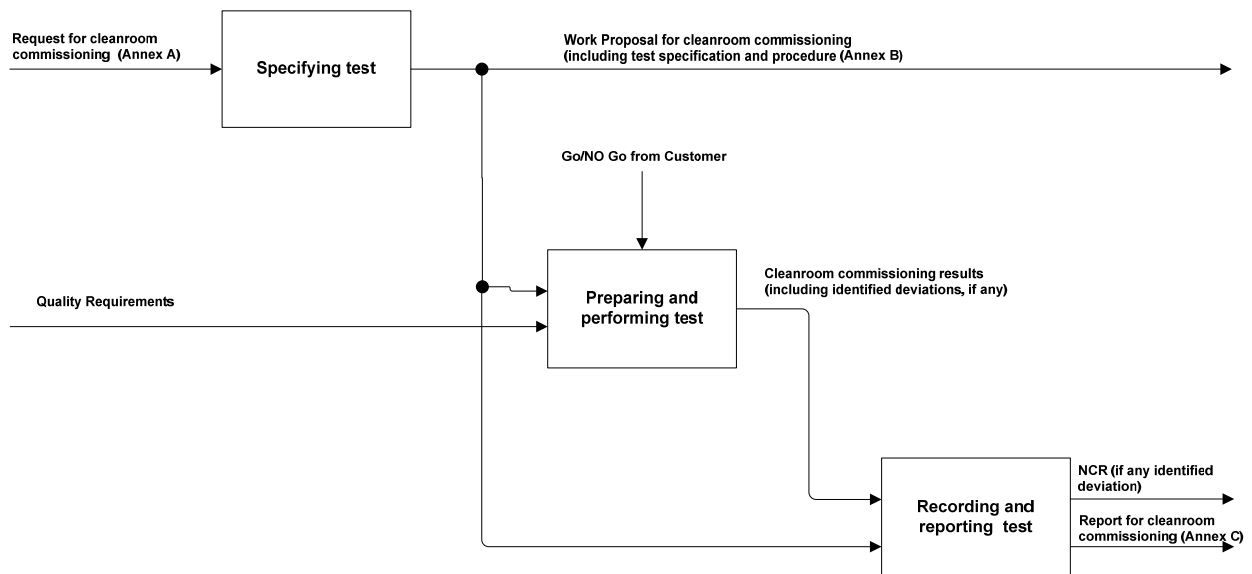


Figure 4-1: Microbiological examination process overview

Clause 5.1 provides the requirements for bioburden control, clause 5.2 the operational requirements, and clause 5.3 provides the requirements for preparing, performing, recording and reporting cleanroom commissioning.

5

Requirements

5.1 Bioburden control

5.1.1 Formal system

- a. A formal system of bioburden control shall be established, formally approved, implemented, documented as specified in Annex A, and maintained within bioburden controlled cleanrooms and associated environments.

NOTE The formal system assesses and controls factors that can affect the microbiological quality of the process.

5.1.2 Action and alert levels

5.1.2.1 General

- a. The user of the clean room shall set microbiological alert and action levels in accordance with the clean room cleanliness level and operations, and include them in the formal system specified in Annex A.

NOTE 1 The following action levels can be used as a guideline:

- Action levels as per “Assay Procedure 2” in ECSS-Q-70-55 for a bioburden controlled environment “during operations” are:
 - ≤ 10 CFU/m³ for air samples;
 - ≤ 2000 CFU/m² for surfaces;
 - ≤ 1 CFU/glove print (5 fingers).
- Action levels as per “Assay Procedure 2” in ECSS-Q-70-55 “during aseptic operations” are:
 - < 1 CFU/m³ for air samples
 - < 400 CFU/m² for surfaces;
 - < 1 CFU/glove print (5 fingers).

NOTE 2 Aseptic operations cannot be ensured without laminar air flow. This can cause undesirable electrostatic charging effects and needs to be managed properly.

- b. Alert levels shall be compatible with the action levels and the facility commissioning phase.
- c. The use of control charts methods may be applied to provide an objective and statistically mean to establish action levels and evidence any deviance in the bioburden control process and highlight excursion results.

NOTE See E.1 for commissioning phase and E.2 for guidelines on alert and action level.

- d. Action and alert level events require notification of appropriate representatives responsible for the bioburden control of the environment.

5.1.2.2 Investigation of alert and action level events

- a. In the case of an alert level event, the following shall be performed:
 - 1. an immediate investigation on the identity of the organism retrieved in abnormal level,
 - 2. record of laboratory tests and deviations, equipment performance, training of personnel, trend analysis , and any possible contributory anomalies or discrete events,

NOTE Example of trend analysis are bioburden levels and biodiversity analysis.

- 3. a deviation report.

NOTE 1 Alert level events can be associated to corrective action, or not.

NOTE 2 Additional information on the state of the environment (e.g. particulate level) should be evaluated.

- b. In the case of an action level event, an investigation shall be performed, which includes:
 - 1. root cause analysis,
 - 2. corrective action,
 - 3. impact on hardware,
 - 4. a deviation report.

NOTE See E.2 for guidelines on elements to be covered with the investigation.

- c. Three consecutive alert level events shall be treated as action level event.

5.1.2.3 Verification of the formal system

- a. The results of bioburden monitoring shall be examined periodically in order to verify that the formal system in use is functioning in accordance with the established procedures and the specified requirements have been fulfilled.

NOTE In some cases, the effective operation of the formal system cannot be appropriately verified without the establishment of supplementary tests and procedures, such as auditing, random sampling and analysis. This can also include the systematic verification of all working steps and equipment to ensure the system is functioning properly.

- b. If verification indicates deviations from the established limits or a change in the microbiological status of the bioburden controlled environment, corrective action shall be initiated.

5.2 Operational requirements

5.2.1 Cleanroom class

- a. Bioburden controlled environments shall be at least equivalent to cleanroom class ISO 7 “in operation” as per ISO 14644-1, with continuous monitoring as per ISO 14644-2.

NOTE 1 In some cases, aseptic operations cannot be ensured if a more stringent particulate control (e.g. ISO 5) is applied. Normally such conditions are provided by laminar air flow environments with at least an ISO 7 bioburden controlled environment in the background.

NOTE 2 For commissioning of bioburden controlled environment, see E.1.

5.2.2 Applicability of bioburden control

- a. Bioburden control shall apply to all items entering a bioburden controlled environment.

NOTE 1 This includes e.g. any (compressed) gases, liquids, equipment, and garment.

NOTE 2 Bioburden control is either via cleaning/sterilization and assays and/or isolation with biobarriers.

NOTE 3 Bioburden control for the regular air supply of the cleanroom is through HEPA filters.

5.2.3 Restrictions

5.2.3.1 Equipment

- a. All equipment used for bioburden control (including HVAC system) shall be subject to validation and planned maintenance;
- b. the return to use of All equipment used for bioburden control shall be subject to approval of appropriate representatives responsible for the bioburden control of the environment (e.g., local planetary protection manager) and/or formal revalidation of the environment.
- c. The layout of equipment shall provide for ergonomics that optimize comfort and movement of operators.
- d. Material flow shall be optimized to prevent unnecessary activities that could increase the potential for introducing contaminants.
- e. The design of equipment used in aseptic processing should limit the number and complexity of aseptic interventions by personnel.
- f. Equipment design shall be appropriate to facilitate ease of sterilization.
- g. The effect of equipment design on the clean room environment shall be addressed.

- h. Horizontal surfaces or ledges that accumulate particles shall be avoided.
- i. Equipment shall not obstruct airflow and, in critical areas, its design shall not disturb unidirectional airflow.

5.2.3.2 Cleaning solutions

- a. Cleaning solutions used shall be sterile prior to use.

NOTE See E.4 for guidelines on cleaning solutions.

- b. A clean room cleaning program shall be implemented in each controlled environment.

5.2.3.3 Personnel movement

- a. The number of personnel in an aseptic processing room shall be minimized.
- b. The flow of personnel shall be designed to limit the frequency with which entries and exists are made to and from an aseptic processing room.
- c. To prevent changes in air currents that introduce lower quality air, personnel movement adjacent to the critical area shall be restricted.

5.2.4 Bioburden monitoring of cleanroom environment

- a. The biodiversity in bioburden controlled environments shall be characterized at the commissioning phase
- b. The bioburden shall be monitored with active air sampling and active surface sampling devices.
- c. For routine testing of airborne bioburden either impaction/impingement sampler or filtration sampler shall be used.

NOTE As per procedure in ECSS-Q-70-55.

- d. For routine testing of airborne bioburden the total sample volume shall not be less than 1 m³.
- e. For routing testing of surface bioburden either swabs or contact plates shall be used.

NOTE As per procedure in ECSS-Q-70-55.

- f. For routine testing of surface bioburden the total sample area shall be on the order of 0,0025 m² (25 cm²).
- g. All bioburden and biodiversity assays shall be according to ECSS-Q-70-55.

5.2.5 Sampling plan

5.2.5.1 General

- a. A sampling plan shall be developed through the formal system (i.e., in the commissioning phase), and documented in conformance with Annex A.

5.2.5.2 Frequency of sampling

- a. The frequencies of sampling shall be developed using the selected formal system.
- b. This system shall encompass:

1. initial monitoring (i.e. during commissioning phase),
2. routine monitoring, and
3. contingencies for contamination events.

5.2.5.3 Sampling sites

- a. Sampling sites shall be determined through the selected formal system, and included in the sampling plan.

NOTE The sampling locations are established based on the risk assessment performed leading to the identification of risk zones and operational steps at risk

- b. The location of the designated sampling sites shall be selected in order to ensure all potential contamination sources are monitored

NOTE 1 That means, in addition to the “risk zone”, the designation and identification in the plan of areas such as access points, storage areas with significant levels of material or hardware and significant impedance to air flow, or areas of heavy personnel traffic.

NOTE 2 More than one sample can be taken at each site and different numbers of samples may be taken at different locations.

- c. Sampling shall be carried out at the bioburden control points defined in a written procedure which identifies the locations and frequency of sampling under nominal and non-nominal scenarios.

NOTE A schematic representation (map) of the facility showing the samples locations is considered to be essential.

5.2.5.4 Identification of samples

- a. The labelling of each sample shall carry the information or coding to provide traceability of the sample.
- b. The labelling of each sample shall include the following information as a minimum:
 1. Collection site (facility);
 2. Sampling location within facility;
 3. Occupancy state at time of sampling;
 4. No. of personnel present at time of sampling;
 5. Date and time of collection;
 6. Name of person collecting the sample;
 7. Size of sample in units of m³ (volume) or cm² (surface area);
 8. Details of all activities being performed at the time of sampling;
 9. Sampling method(s), as defined in ECSS-Q-70-55;
 10. Analysis method(s), as defined in ECSS-Q-70-55;
 11. Any deviations from the requirements of the sampling plan.

5.2.5.5 Processing of samples

- a. The procedures described in the ECSS-Q-70-55 shall be followed.

5.2.5.6 Expression, interpretation and reporting of results

- a. Quantitative results shall be expressed as colony-forming-units (CFU) per m³ (volume) or cm² (surface area).
- b. To assist in interpretation, results shall be reviewed over extended periods to determine trends.

5.2.6 Training

- a. A training programme shall be established in due time to allow appropriate training of all personnel.

NOTE See A3 for guidelines on the training programme.

- b. Only personnel with the appropriate level of training shall be permitted access to the bioburden controlled environment.

NOTE This includes personnel for cleaning and maintenance.

- c. Cleaning personnel shall be project dedicated people. 'Regular' cleaning personnel from the site cleaning contractor are not appropriate.

5.2.7 Personnel

- a. All personnel shall undergo regular medical screening to establish that they do not have a medical condition that can compromise the integrity of the bioburden controlled environment.

NOTE See A4.3 for examples of medical conditions of concern.

- b. Hygiene programmes should be established and should include procedures relating to the health, hygiene practices and clothing of personnel.
- c. Only certified personnel can access the bioburden controlled environments. This includes personnel for cleaning and maintenance.
- d. Non-essential personnel shall not be permitted in the bioburden controlled environment
- e. Preparatory activities (e.g. adhesive mixing) shall be conducted in dedicated external or peripheral areas, with due regard to requirements for spacecraft microbial contamination requirements.
- f. For accessing and working in a bioburden controlled environment, personnel shall wear at least a coverall, hood, face mask, boots, and two layers of sterile gloves.
- g. A vigilant and responsive personnel monitoring program shall be established.

NOTE See A4 for guidelines

5.2.8 Cleanroom garments

- a. Garments shall be compatible with ISO 7 cleanroom standards, or better.
- b. Garments shall be sterile.
- c. Sterile gloves shall be compatible with alcohol (IPA 70% or ethanol 70%) washes.

5.3 Cleanroom commissioning

- a. The customer shall request a cleanroom commissioning by using the DRD in Annex B.

- b. For safety (e.g. hazard, health) and security (e.g. access control), the test centre shall comply with ECSS-Q-20-07A , clause 9.

NOTE Example of safety requirements are hazard and health requirements. Example of security requirements are access control requirements.

- c. The supplier shall respond to the request specified in 5.3 a with a cleanroom commissioning proposal in conformance with Annex C – DRD, for customer approval.
- d. The supplier shall run the approved cleanroom commissioning campaign as described in Annex C –DRD.

NOTE An example of an approved cleanroom commissioning approach is given in Annex E.

- e. The supplier shall submit the test report in conformance with Annex D – DRD to the customer for approval

Annex A (normative)

Bioburden control formal system description - DRD

A.1 DRD identification

A.1.1 Requirement identification and source document

ECSS-Q-70-58A, requirements 5.1.1a and 5.2.5.1a.

A.1.2 Purpose and objective

The bioburden control formal system is established to assess and control factors that can affect the microbiological quality of the process.

A.2 Expected response

A.2.1 Scope and contents

- a. The bioburden control formal system description shall include:
 1. Limits established to ensure control, including alert and action level as established in accordance with 5.1.2.1a.
 2. Description of the monitoring scheme and schedule established.
 3. Description of the validation procedures established in accordance with 5.1.2.3 to verify that the formal system is working properly.
 4. Corrective actions established in accordance with 5.1.2.2b.2 to be taken when a monitoring result indicates that a particular factor of the process is not under control.
 5. Risk assessment for bioburden control.

NOTE For example: Process FMECA.

6. Description of the training procedures and access constraints established in accordance with 5.2.6.
7. Documentation to be established and maintained.
8. Process implementation documentation.

NOTE For example: Logbooks.

9. Periodic reviews/audits to be performed
10. Description of the sampling plan, including at least:
 - (a) The cleanliness level of the cleanroom to be applied and the appropriate degree of bioburden control for the activity being conducted.
 - (b) The sampling location(s) identified in accordance with 5.2.5.3, including the location of the primary “risk zone”; i.e.; the work area immediately adjacent to any contamination-critical hardware and the work activities/personnel associated with this location.
 - (c) The minimum number of samples to be taken in order to ensure representative results.

NOTE This number is dependant on the sample size/ volume. For small sample sizes, representativeness of the results cannot be guaranteed if this number is not significantly increased.

- (d) Frequency of initial monitoring sampling, established in accordance with 5.2.5.2b.1
- (e) Frequency of normal routine sampling, established in accordance with 5.2.5.2b.2..
- (f) Frequency of sampling for specific cases, established in accordance with 5.2.5.2b.3, including at least the following cases:
 - Suspected contamination events;
 - Action levels are exceeded;
 - Alert levels are exceeded (consecutively);
 - A change in the biodiversity;
 - After prolonged shut-down of activities;
 - After any significant maintenance work has been undertaken on the cleanroom.

NOTE For example: Maintenance on ventilation system, changes to furnishings or fittings, introduction of significant quantities of new hardware or equipment;

- After changes to the process that affect the cleanroom environment;
- After recording of unusual results;
- After non-routine changes to the cleaning or disinfection procedures;
- After unplanned incidents that could contribute to contamination;
- After any incidence of non-conformance to cleanroom operational specifications.

NOTE For example: Breaches of personnel dress/conduct code; out of specification airborne particulate levels, out of specification temperature or humidity levels, exceeding maximum no. of personnel, or introduction of non-sterile items or hardware.

- b. Sampling method(s), established in accordance with 5.2.5.5.

- c. Analysis method(s), established in accordance with 5.2.5.6.
- d. Factors pertinent to a particular situation that can affect results.
 - NOTE Ambient temperature, lead-time to processing of samples.
- e. The impact of operations, personnel and equipment, which contribute to contamination.

A.2.2 Special remarks

None.

Annex B (normative)

Request for cleanroom commissioning - DRD

B.1 DRD identification

B.1.1 Requirement identification and source document

ECSS-Q-70-58A, requirements 5.3a.

B.1.2 Purpose and objective

The purpose of this DRD is to specify the content of a request for cleanroom commissioning.

B.2 Expected response

B.2.1 Scope and content

- a. The Request for cleanroom commissioning shall include or refer to the following information:
 - 1. reference in making ECSS-Q-20 and ECSS-Q-20-09 applicable
 - 2. objective of the cleanroom commissioning,
 - 3. background and justification to the cleanroom commissioning,
 - 4. cleanroom to be commissioned,
 - 5. description of cleanroom commissioning activity, and
 - 6. deliverables.

B.2.2 Special remarks

None.

Annex C (normative)

Cleanroom commissioning specifications and procedures (Work Proposal) - DRD

C.1 DRD identification

C.1.1 Requirement identification and source document

ECSS-Q-70-58A, requirement 5.3c.

C.1.2 Purpose and objective

The work proposal is a document that defines the test activity for cleanroom commissioning. The work proposal for cleanroom commissioning is prepared by the test house, which is responsible for the test activity, and it is submitted to the customer for review and approval.

C.2 Expected response

C.2.1 Scope and content

- a. The WP shall include or refer to the following information:
 1. A proposed work description giving:
 - (a) the objectives of the cleanroom commissioning activity,
 - (b) cleanroom facilities to be commissioned
 - (c) test facilities, test procedures and reference to standards (this includes sources,)
 - (d) test conditions (i.e. environment, properties evaluated and measurement techniques),
 - (e) expected test output.

2. A proposed settlement describing the test procedures and any deviation from the conditions initially requested by the customer
3. A financial and administrative proposal including:
 - (a) responsible person for the activity,
 - (b) list of deliverable items
 - (c) work breakdown structure defining the required operations (i.e., preparation of specimens, , testing, evaluation of results, reporting) and responsibilities,
 - (d) time schedule,
 - (e) travel and subsistence plan (if applicable),
 - (f) itemized cost list, and
 - (g) milestone payment plan.

C.2.2 Special remarks

None.

Annex D (normative)

Cleanroom commissioning report - DRD

D.1 DRD identification

D.1.1 Requirement identification and source document

ECSS-Q-70-53A, requirement 5.3e.

D.1.2 Purpose and objective

The purpose of the cleanroom commissioning report is to provide quantitative evidence that the items were tested according to the sterilization compatibility test specifications and procedures.

D.2 Expected response

D.2.1 Scope and content

a. The cleanroom commissioning report shall include or refer to the following information:

1. description of the purpose, objective, content and the reason prompting its preparation,
2. description of the cleanroom to be commissioned or a reference to the document containing its identification characteristics

NOTE For example: Request for cleanroom commissioning.

3. description of the tools, methods, and procedures for cleanroom commissioning,

NOTE It often consist in describing the as- run test procedure as well as any deviation from the initial test procedure (including a discussion of possible effect on test).

4. the cleanroom commissioning results,

5. discussion about the test results,
6. conclusion and recommendations.

D.2.2 Special remarks

None.

Annex E (informative)

Cleanroom commissioning

E.1 Commissioning Activities

E.1.1 Elements

The commissioning phase of a bioburden controlled environment should contain the following elements:

- a. One detailed bioburden and biodiversity evaluation at rest.
- b. Five detailed bioburden and biodiversity evaluation at (simulated) operation.
- c. Establishing trends on bioburden and biodiversity.
- d. Establishing alert levels
- e. Establishing of monitoring scheme.

NOTE 1 The commissioning phase takes about half a year with the five detailed bioburden and biodiversity evaluation done in intervals during this period.

NOTE 2 The biodiversity evaluation should go to the species level.

NOTE 3 Spare MGSE/EGSE should be used for the commissioning phase. In case equipment is not available for the commissioning phase, a delta-commissioning should be performed.

NOTE 4 The commissioning phase should be used for the training of personnel.

NOTE 5 The commissioning phase should be used to establish routine bioburden monitoring schedules and locations for each different cleanroom activity type/activity level.

E.2 Action and alert level events

E.2.1 Investigation

An investigation after an action or alert level excursion should be initiated immediately and contain the following elements:

- Clearly identified reason for the investigation;
- Description of environment;
- Type of contaminant;
- Review sampling personnel (interviews);
- Review sampling techniques;
- Review analysis techniques;
- Review cleaning, disinfection and sterilization records;
- Review personnel monitoring, gloves and gown results;
- Review manufacturing records of items affected;
- Review overall environmental control and monitoring data of the environment, including associated environments (e.g., access areas);
- Review type of operations carried out;
- Review environment cleaning and sanitation records, including from associated environments (e.g., access areas);
- Review air pressure across the filters and inspect for any leaks in the filter;
- Check differential pressure;
- Evaluate mechanical equipment in the environment as source of contamination.

E.2.2 Sampling error

If sampling/analysis failure is identified as cause for the excursion, re-test results substitutes the original (faulty) test result. The original (faulty) test result should be retained for the records, with the appropriate explanation. If no sampling/analysis error is identified in the original test, the original test results cannot be invalidated and a detailed investigation should be performed.

E.2.3 Inconclusive findings

For inconclusive investigations where the cause of the excursion is not revealed, the out-of-specification results should be retained in the record together with the re-test analysis and should state the disposition of the item under investigation.

E.2.4 Microorganism Identity

Organism identity should be included as alert and action criteria. Atypical organisms even at numbers below the prescribed levels, should be included as triggers for action.

E.2.5 Frequency

Alert and action levels for new facilities (i.e., during commissioning) should be revisited every three to four months. For established facilities with continuous operation (i.e., after commissioning), an annual review is sufficient.

E.3 Training programme

E.3.1 Overview

Training cannot be appropriately implemented without the development of useable 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 can be conducted with the organization, or outside by an independent organisation. The training should be conducted before an individual is permitted to enter the controlled area.

E.3.2 Training levels

Different levels of training should apply depending on the individual task descriptions. The following levels should be used:

- a. Level 1: Highest level of training; personnel can work without direct supervision in bioburden controlled environment on flight hardware (e.g., supervisor, AIV engineer, quality assurance engineer, hardware owner, etc.);
- b. Level 2: Personnel can only work with direct supervision in bioburden controlled environment on flight hardware (e.g., PP support staff, general support staff, temporary visitors)
- c. Level 3: Personnel can only work with indirect supervision (e.g., video surveillance) in bioburden controlled environment in the vicinity of protected flight hardware (e.g., maintenance and cleaning personnel).

E.3.3 Sampling and analysis

The personnel in charge of the performance of the sampling and analysis methods should be trained in the following aspects of bio contamination control:

- a. basic principles of microbiology,
- b. fundamental of applied microbiology, hygiene and epidemiology
- c. good employee aseptic techniques and precautions
- d. principles of environmental control process
- e. microbiological sampling techniques
- f. basic principles of microbiological hazard analysis
- g. Understanding of microbiological alert and action levels.
- h. Principle of trend analysis
- i. Specialized training on all required laboratory method, and on any automated system to be used to assist microbial identification

E.3.4 Training verification

Training verification procedures should be established.

E.3.5 Training content

The training programme should contain the following elements:

- a. General policy and requirements,
- b. Microbiology,
- c. Hygiene,
- d. a specific section on how to operate in a bioburden controlled environment.

NOTE 1 The latter should be specific to the training level and dominated by practical exercises in a representative environment, including work flow and process control, gowning, and cleanroom discipline.

NOTE 2 See also B4.

NOTE 3 Refresher training course should be provided on a regular basis.

E.4 General guidelines for cleanroom design and operation

E.4.1 Design; general

Access to the bioburden controlled environment should be through successive layers of controlled environments (see Figure E- 1), e.g., from uncontrolled environment through a standard ISO 8 environment, to a standard ISO 7 environment before entering the bioburden controlled ISO 7, environment.

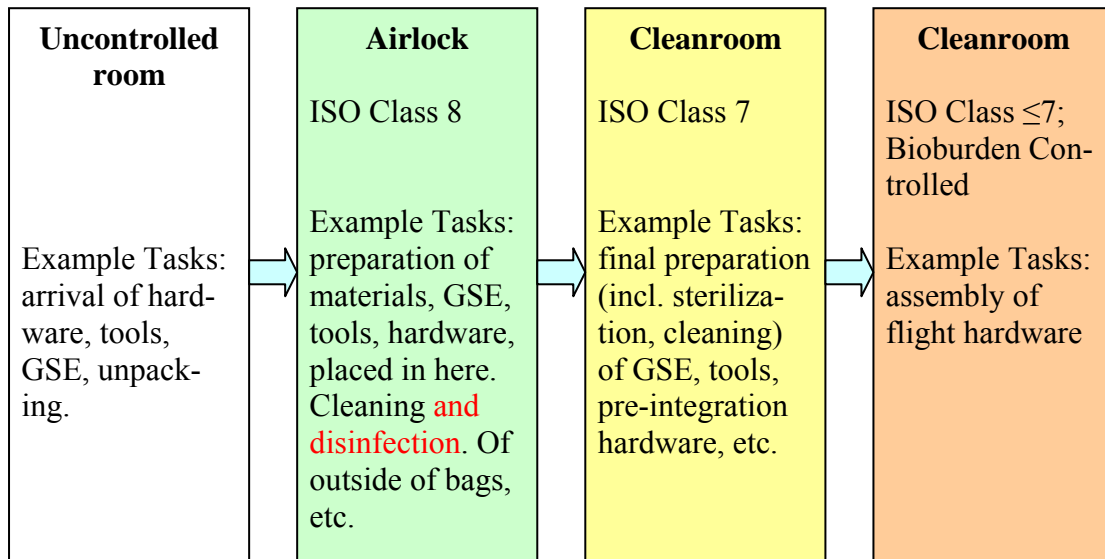


Figure E- 1: Cleanroom design schematic

E.4.2 Airflow

Airflow patterns should be evaluated for turbulence or eddy currents that can act as a channel or reservoir for air contaminants in the aseptic area. In situ air flow analysis in the should be performed in the critical area to demonstrate the maintenance of the unidirectional air flow and the sweeping action over and away from the sterile equipment under dynamic conditions.

NOTE Videotape or other recording mechanisms have been found to be useful aides in assessing airflow initially as well as facilitating evaluation of subsequent equipment configuration changes.

E.4.3 Access

E.4.3.1. Hardware and personnel

Separate entry pathways for hardware (including e.g. GSE, and flight hardware) and personnel should be provided.

E.4.3.2. Door operations

Automatic door operations should be utilized to reduce cross contamination and to facilitate the controlled air movement between adjacent cleanrooms with different cleanliness class.

E.4.4 Layout design

E.4.4.1. Surfaces

All exposed surfaces in the bioburden controlled environment should be smooth, impervious and unbroken. There should be no uncleanable surfaces and recesses. False ceilings should be sealed to prevent contamination from the space above them.

NOTE Sliding doors should not be used for this reason.

E.4.4.2. Pipes and ducts

Pipes and ducts and other utilities should be installed so that they do not create recesses, unsealed openings and surfaces which are difficult to clean/disinfect.

E.4.4.3. Changing rooms

Changing rooms should be designed as airlocks and used to provide a physical separation of the different stages of changing. The final stage of the changing room should be at the same grade as the areas into which it leads.

E.4.4.4. Hand washing and disinfection

E.4.4.4.1 In changing room

Hand washing facilities should be provided only in the first stages of the changing rooms. Disinfection solution dispensers to wash the hands (with and without sterile gloves) should be provided at the last stage of the cleanroom before entering the bioburden controlled environment.

E.4.4.4.2 In cleanroom

Disinfection solution dispensers to wash the hands (with sterile gloves) should be provided in several locations inside the bioburden controlled environment. Alcohol based dispensers for sterile gloves and face masks should be provided inside the bioburden controlled environment.

E.4.4.4.3 Preparation room

Cleaning and sterilization facilities should be available in the preparation area to the bioburden controlled environment. This should include:

- a. Sonic or precision cleaning;
- b. DHMR facility;
- c. Bagging capability in biobarriers, foils, and ESD for sterilization, and transport.

E.4.5 Storage space

Storage should be provided for sterilized tools and kits.

E.4.6 Monitoring

Back-up systems for cleanroom monitoring should be in place.

NOTE Independent of the status of the cleanroom control equipment (e.g., HVAC system), specific cleanroom levels can only be credited if monitored.

E.5 Operational guidelines

E.5.1 Surveillance

Continuous video surveillance should be used for all critical areas in bioburden controlled environments during operations. The documented activities should be used to trace back any contamination event detected by one of the regular microbiological assessments. All individuals in the cleanroom should be clearly identifiable by the video surveillance system (e.g., either specific symbol or colour coding of garment).

E.5.2 Communications

Radio communication between personnel inside the bioburden controlled environment and with personnel outside the bioburden controlled environment should be considered. This is especially recommended in laminar flow environment.

E.5.3 Packaging

Multiple bagging should be used whenever possible to facilitate storage on-site and transport through the different cleanroom areas. Unpacking (removal of biobarriers), inspection, cleaning, sterilization, and related activities on GSE and flight hardware should be conducted outside the bioburden controlled environment .

E.5.4 Flight hardware

The flight hardware should have sole occupancy of the bioburden controlled environment in all facilities. If this cannot be guaranteed, measures to prevent cross contamination should be established and the bioburden requirements shall apply to other users of the cleanroom

E.5.5 Maintenance

When equipment maintenance has been carried out within the bioburden controlled environment, the area should be cleaned, disinfected or sterilized where appropriate before processing can recommence if the required standards of biological (and particulate) cleanliness have not been maintained during the work.

NOTE Fumigation of bioburden controlled environments may be useful for reducing the viable microbiological contamination

E.5.6 Personnel access records

All personnel entering the bioburden controlled environment should be logged.

E.5.7 Task planning

For planning tasks, the planning shall address the fact that it can take experienced personnel 2-4 times longer to perform mechanical or electrical assembly under bioburden controlled conditions.

E.5.8 Garments

Ready-to-use (i.e., sterile) garment should be available in all required sizes.

E.5.9 Microbiological laboratory

A microbiology laboratory to analyse the assays should be in close proximity (not necessarily at the premise) to the bioburden controlled environment.

E.5.10 Cleanroom bioburden sampling

During the commissioning phase, one surface sample per square meter and per sampling campaign in a bioburden controlled environment should be used. During the routine monitoring phase one surface sample per two square meters and per sampling campaign in a bioburden controlled environment should be used.

NOTE The details of the environment and the operations to be carried out will affect the numbers of samples per surface area.

E.5.11 Medical monitoring of personnel

E.5.11.1. Medical screening

Medical screening for key personnel with access a bioburden controlled environment should start early enough to evaluate the impact on personnel selection. By experience, a certain percentage from the general public is unfit for work in a bioburden controlled environment (1/60-1/200). Medical conditions of concern are chronic bacterial or fungal conditions that cause excessive shedding of skin scale. Smokers release a higher amount of particulates in the period immediately after smoking. Limitations on smoking prior of entering a bioburden controlled environment should be considered.

E.5.11.2. Illness

Personnel who is ill should not be permitted access to the bioburden controlled environment if the medical condition results in either excessive particle generation, or in the inability to work in the appropriate garment. Provisions should be made for back-up crew during seasonal cycles of potential medical conditions (e.g., flu, allergies, etc.).

E.5.12 Bioburden monitoring

E.5.12.1. Garments

Monitoring should be accomplished by obtaining surface samples of each operators' gloves on a daily basis. This sampling should be accompanied by an appropriate sampling frequency for other strategically selected locations of the gown.

E.5.12.2. Intensive working

The responsible unit should establish a more comprehensive monitoring program for operators involved in operations which are especially labour intensive (i.e. those requiring repeated or complex aseptic manipulations)

E.5.12.3. Unacceptable operator bioburden levels

When operator bioburden levels show an increase trend in bioburden levels an investigation should be conducted promptly. Follow-up actions should include increased sampling, increased observation, retraining, and gowning re-qualification. Where levels do not subsequently return to normal, reassignment of individuals to operations outside the controlled area should be initiated

E.5.13 Gowning

E.5.13.1. Gowning Procedure

A detailed gowning procedure should be established and implemented. This should also be part of the training. The clothing and its quality should be appropriate for the process and the cleanliness level of the clean room.

E.5.13.2. Prior to arrival at work

Personnel should preferably bathe or shower the night before in order to allow natural skin oils to be re-established overnight. This practise assists in the reduction of skin particle shedding within the bioburden controlled cleanroom.

E.5.13.3. Prior to entry into the bioburden controlled facility

Personnel should remove all personal effects (e.g. watches, rings, bracelets, any other jewellery, and mobile phones) and any applied cosmetics. All outer garments should be removed and intermediate garments (e.g. “scrub suits” or other undergarments, beard masks, mob caps, and shoe covers) donned. Hands should be washed with disinfectant or detergent and dried with dispensable towels.

E.5.13.4. On Entry into final gowning area

Personnel should enter room making full use of appropriate contamination control measures, e.g. air showers, tacky mats, and locate washing and disinfection fluids and materials.

E.5.13.5. Gloves

Select appropriate size of sterile gloves. When handling gloves avoid contact with any external sterile surface. Do not pick up gloves by fingers of the gloves or outside of glove wrist. Always handle the inner surfaces of the gloves only, i.e.; inner surface of wrist of glove. If any inadvertent handling of the outer surface of the glove occurs during donning, these should be removed and discarded and a new pair selected. Disinfect hands and gloves using solutions provided.

E.5.13.6. Hood

Select sterile hood of appropriate size. Check sterile packaging to ensure it is still intact and that the items are within the prescribed expiry date. Discard any items that are past the expiry date or where the sterile packaging appears compromised. Open sterile packaging. Handle

hood by inner surfaces only. Don hood in one smooth motion, ensuring only inner surfaces of hood make contact with head and shoulders. If any inadvertent contact of head or body with the outer surface of the hood occurs, the hood should be removed and discarded and a new hood selected. Once hood is fitted, check in gowning mirror to ensure hood is correctly positioned over shoulders. Disinfect hands and gloves using solutions provided.

E.5.13.7. Face-Mask

Remove mask from sterile packaging, taking care to handle by the ties only. Position mask over hood and face, again using only the ties. Once in position, secure the mask with the ties and check the positioning in the gowning mirror. Ensure no skin is visible. Disinfect hands and gloves using solutions provided.

E.5.13.8. Coverall

Select coverall of appropriate size. Remove coverall from sterile packaging, handling only the inner surfaces. Allow to fall to full length, taking care to avoid contacting the floor and outer surfaces of the coverall with garments currently worn. Unzip if needed, taking care to limit the contact of gloved hand to the zip tag only. If possible, unzip from the inside of the garment.

Face coverall away from you, and gather up the arms and extra coverall, touching only the internal surfaces. Step into one leg of the coverall, avoiding contacting the coverall with the floor. Hand-rails to assist in balancing are suggested as an aid to this operation. Repeat operation with other leg, then carefully pull coverall up over shoulders, avoiding contact of any part of the body or undergarments with the outer surface. Carefully tuck hood into coverall. Zip up coverall and secure with snap-studs. Check Coverall and hood are fitted correctly in gowning mirror. Disinfect hands/gloves using solutions provided.

E.5.13.9. Boots

Select appropriate sterile over-boot size. Check sterile packaging to ensure it is still intact and that the items are within the prescribed expiry date. Discard any items that are past the expiry date or where the sterile packaging appears compromised. Open sterile packaging. As per the procedure for donning gloves, take care to avoid all contact with the sterile outer surfaces of the boot. Handle boots by inner surfaces only. Roll down the boot from the top, then pull boot over one foot and swing leg over boot-bar/bench into clean sector of gowning area. Leave the top of the boot rolled down. Repeat procedure with other boot. If any inadvertent handling of the outer surface of the boot occurs during donning, these should be removed and discarded and a new pair selected. As with donning of gloves, this procedure cannot appropriately be performed without some training and practise. Disinfect hands and gloves using solutions provided.

E.5.13.10. Final fitting of over-boots

Carefully roll tops of boots over legs of coverall to full extent, and secure with ties if applicable. Check entire dress is fitted in accordance with gowning procedure guidelines. Disinfect hands and gloves using solutions provided.

E.5.13.11. Goggles/Visors

Select a pair of sterilised or sanitized goggles and removed from packaging. Handle goggles by straps/ties only. Position over eyes, ensuring all remaining portions of face are covered. Check fitting in gowning mirror. Disinfect hands and gloves using solutions provided.

E.5.13.12. Second gloves

Select a pair of sterile gloves of the next size up to the ones used for gowning. Remove from sterile packaging, handling by inner surfaces only. Don gloves over first gloves using same

procedure as for first pair, but with the exception of ensuring that the wrists of the second pair extend over the sleeves of the coveralls, thus effecting a particulate seal over the sleeves. Disinfect hands and gloves using solutions provided.

E.5.14 Entering cleanroom

Perform final visual check of all aspects of dress code. Dress should comply with dress code requirements. Proceed into Cleanroom.

E.5.15 Cleanroom cleaning

E.5.15.1. Cleaning programme

The cleaning program for bioburden controlled environment should include regular cleaning of the environment with disinfectants and with sporicidal disinfectants..

E.5.15.2. Cleaning procedures

Cleaning procedures should include among others a detailed description of areas to be cleaned, cleaning tools, cleaning solutions and cleaning operations requirements, gowning and safety requirements and the detailed sequence of cleaning operations. Alternating different types of disinfectants on a periodic basis should be used to avoid build-up of resistant microbial population.

E.5.15.3. Cleaning records

A system for formal scheduling and recording of all routine cleaning operations performed in the biologically controlled cleanroom should be created. This should include a Cleaning Record Sheet which identifies the areas/locations cleaned and the frequency (periodicity) of each cleaning operation (i.e.; whether per shift, daily, weekly, or some other interval).

E.5.15.4. Reviews

Regular review and reassessment of cleaning efficiency should be performed based on the results of the monitoring program.

E.5.15.5. Cleaning frequency

Suggested cleaning frequencies and agents are:

- a. All surfaces (including floor) with a synthetic phenolic (contact time 10 minutes) after **each shift**. Alternate between pH 2 and 11 on a monthly basis.
- b. All surface in direct contact with the product (e.g., flight hardware) should be cleaned with alcohol (e.g., IPA 70% or ethanol 70%) (contact time 5 minutes) at least for **each shift**. 6% hydrogen peroxide (contact time 15 minutes) can be added to provide sporicidal effect.
- c. **Once per month** (or before critical operations) the bioburden controlled environment can be disinfected with a dry fogging system using a mixture of paracetic acid and hydrogen peroxide (sporicidal) (contact time 5 minutes).
- d. All surfaces (including floor) with a synthetic phenolic after **each shift**. Alternate between pH 2 and 11 on a monthly basis.

- e. All surface in direct contact with the product (e.g., flight hardware) should be cleaned with a 70% hydro alcoholic solution (e.g., IPA or ethanol) at least for **each shift**. 6% hydrogen peroxide can be added to provide sporicidal effect.
- f. **Once per month** (or before critical operations) the bioburden controlled environment can be disinfected with a dry fogging system using a mixture of paracetic acid and hydrogen peroxide (for sporidical effect) for decontamination of even inaccessible places..

E.5.15.6. Material compatibility with solutions

All For all cleaning, disinfection, and sterilization agents used should be compatible with the surfaces to which they are applied Material compatibilities with cleaning or disinfection solutions shall be evaluated before using those agents.

E.5.15.7. Validation of cleaning/disinfection

In-situ validation of the cleaning and disinfection procedures should be performed during the commissioning phase. If no labelling claims of disinfectant or sterilisation efficiency are known, in vitro validation of the disinfectant/sterilisation efficiency should be performed.

NOTE Recurrent and critical environmental isolates should be used in the in-vitro tests.

E.5.15.8. Cleaning solutions

Cleaning solutions should be 0,2 µm-filtered to provide for sterilization. Water for the preparation of cleaning solutions should be of WFI or Type I A quality.

E.5.15.9. Disinfectant solutions

Where disinfectants are used, more than one type should be employed

NOTE Only use disinfectants on clean surfaces. Dust, grease or other debris can render the disinfection process ineffective.

E.5.15.10. Cleaning sequence

The cleaning sequence should generally move from the cleanest area to the less clean area, ending with the down and de-gown rooms.

E.5.15.11. Cleaning restrictions

Cleaning should only be conducted during times of no work on flight hardware. Flight hardware should be covered during cleaning.

E.5.15.12. Vacuum cleaning

A central vacuum system with external exhaust should be used.

HEPA filtered units with internal exhaust. should not be used

E.6 Cleanroom working disciplines

E.6.1 Overview

All types and classes of cleanrooms should have appropriate working disciplines in order to achieve and maintain the desired cleanliness levels, and to ensure critical hardware is not contaminated. The following are considered applicable to bioburden controlled cleanrooms.

E.6.2 Access Control

E.6.2.1. Personnel

Only essential personnel should be allowed into the cleanroom. Numbers of personnel within the cleanroom should be kept to the minimum necessary at any one time.

NOTE Contamination levels and contamination potential increase as the number of personnel increase.

E.6.2.2. Untrained Personnel/Visitors

Untrained personnel or casual visitors should not be permitted. Only fully trained personnel or trainee personnel under appropriate trained supervision should be permitted access.

E.6.2.3. Access routing

Personnel should use the designated personnel access route only to the cleanroom, via the changing, antiseptic wash and gowning area. Access via equipment or hardware transfer ante-rooms (e.g. those routes used for large MGSE etc.) should not be used as an alternative means of access into the bioburden controlled area.

E.6.2.4. Doors

Doors should not be left or wedged open. Doors to another area should not be opened whilst the door to the preceding (less clean) area is still open.

NOTE Ideally, this should be rendered impossible by electronic interlocking

E.6.2.5. Materials:

Contaminating materials should not be taken into the cleanroom. If in doubt as to the suitability of ingress or use of any given material, the relevant Planetary Protection Responsible Engineer/Manager should be consulted. This extends to all cleanroom consumables (wipes, solvents, detergents, swabs etc.) which can be employed. A list of approved cleanroom consumables should be produced. Care should also be exercised in the uses of uncontrolled items by cleaning staff. All materials and equipments used for surface cleaning (mops, wipes, tacky rollers, detergents/surfactants, vacuum cleaners) should be dedicated and approved items.

The following lists some examples of common contaminating materials which may be introduced by personnel working in the area, but is not exhaustive:

f. . Paper (documents, packaging, tissues, books, newspapers etc.)

- g. Food, drinks, confectionary
- h. Personal jewellery
- i. CD Players, MP3 players, radios, mobile phones, electronic organisers
- j. Abrasives or powders
- k. Aerosols (e.g. perfumes, deodorants)
- l. Organic or natural materials e.g. wood, rubber, leather, cotton.
- m. Other personal effects such as tobacco products, purses, wallets, spectacle cases, car or door keys, currency, etc.
- n. Unauthorised writing implements (certain pens, pencils, marker pens)

E.6.2.6. Audits

Periodic audits of the cleanroom for presence of non-compliant materials should be performed.

E.6.3 Working Practises

E.6.3.1. Locomotion

Movements within the cleanroom should be slow and controlled. Erratic and rapid movements generate more particulate contamination and disturb the optimum airflow.

E.6.3.2. Housekeeping

Good housekeeping is important. Areas where items are closely positioned or cluttered act as contamination traps and will result in stagnant air pockets which are not removed by the normal unimpeded airflow.

E.6.3.3. Positioning of personnel

Personnel should be positioned down-stream of the air flow past the product. Leaning over the product increases the risk of particulate, organic and microbial contamination. Talking whilst facing or leaning over the hardware should not be permitted, even when wearing full face masks.

Personnel should not cough or sneeze whilst still facing critical hardware. If coughing or sneezing is unavoidable, the face should be turned away. Masks should be replaced after any such incident.

E.6.3.4. Planning

Before carrying out any operation in the cleanroom, the activity(s) should be thought through and pre-planned in order to minimise contamination potential

E.6.3.5. Hand-carried objects

When hand-carrying items in the clean room, these should not be held tight against the cleanroom garments, e.g. pulled into the stomach or chest, or under one arm. The outside of the garments are not 100% clean, and friction between the object being carried and the garment will generate particles and fibres. These and any associated bacteria can thus be transferred onto hardware or objects.

E.6.3.6. Handling of objects/surfaces

Wherever possible, objects should not be handled directly – e.g. sterilised tweezers or forceps can be used instead of gloved hands, which have a greater contamination potential than sterilised instruments. Personnel should avoid touching cleanroom surfaces unnecessarily. The recommended posture for the hands at rest is clasped in front of the body. Periodic disinfectant washing of the gloves as per that employed during the gowning procedure should be performed, particularly prior to critical handling operations, after contact with known contaminants, or after prolonged handling events.

E.6.3.7. Contact with non-flight hardware

Contact with non-flight items such as cabling; wiring or vacuum hoses should be avoided. Lay-flat polymer tubing with appropriate ESD control should be used to encapsulate cable bundles.

E.6.3.8. Cleanroom wipes/swabs

Wipes or swabs should be used only once, then discarded.

Bibliography

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