
**Space systems — Contamination and
cleanliness control**

Systèmes spatiaux — Contrôle de la contamination et de la propreté

STANDARDSISO.COM : Click to view the full PDF of ISO 15388:2004



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

STANDARDSISO.COM : Click to view the full PDF of ISO 15388:2004

© ISO 2004

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions, abbreviations	2
3.1 Terms and definitions	2
3.2 Abbreviations	7
4 Management	7
4.1 Organization	7
4.2 Cleanliness requirement specification (CRS)	8
4.3 Contamination and cleanliness control plan (CCCP)	8
4.4 Interface control document (ICD)	9
4.5 Project reviews	9
5 Design activities	9
5.1 Identification of sensitive hardware	9
5.2 Nature of contaminants, their profile and their effects	9
5.2.1 General	9
5.2.2 Typical contaminants	9
5.2.3 Contamination profile	10
5.2.4 Effects of contamination on performance	10
5.3 Contamination prediction	10
5.4 Contamination budget	10
5.5 Cleanliness-oriented design	10
5.6 Selection of materials and processes	10
5.6.1 General	10
5.6.2 Outgassing	10
5.6.3 Sorbed water vapour	11
5.6.4 Offgassing	11
5.6.5 Quality control	11
6 Biocontamination	11
6.1 General	11
6.2 Contamination of hardware by microorganisms	11
6.3 Sterile hardware	12
6.4 Habitable space systems	12
6.4.1 Habitable spacecraft	12
6.4.2 Offgassing	12
6.5 Planetary protection	12
6.6 Sample protection	13
7 Contamination and cleanliness control for ground operations	13
7.1 Training of personnel	13
7.2 Cleanroom selection and cleanliness control	13
7.3 Cleanroom garments	14
7.3.1 General	14
7.3.2 Considerations for garment selection	14
7.3.3 Additional information	14
7.4 Ground support equipment (GSE)	14
7.5 Monitoring cleanliness of flight hardware and its near surroundings	14
7.6 Packaging, storage and transport	14

7.6.1	Packaging.....	14
7.6.2	Storage	15
7.6.3	Transport.....	15
7.7	Cleaning of flight hardware	15
7.7.1	General	15
7.7.2	Cleaning procedures.....	15
7.7.3	Bakeout	15
7.7.4	Contaminant source containment	15
7.7.5	Purging	16
Annex A (informative) Electronic databases.....		17
Bibliography.....		18

STANDARDSISO.COM : Click to view the full PDF of ISO 15388:2004

Foreword

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

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

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

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

ISO 15388 was prepared by Technical Committee ISO/TC 20, *Aircraft and space vehicles*, Subcommittee SC 14, *Space systems and operations*.

Introduction

This International Standard addresses the preferred programme elements recommended for contamination and cleanliness control of space systems. This document is written in general terms as a baseline for developing and implementing the control programme. It may be cited as a baseline within a statement of work and/or for assuring proposal precision and contractor performance. The users are responsible for integrating the elements of this document appropriate to their programme needs.

The purpose of contamination and cleanliness control is to prevent the degradation of the performance of space systems due to particulate and molecular contamination (including biocontamination), and to ensure the mission objectives are achieved.

STANDARDSISO.COM : Click to view the full PDF of ISO 15388:2004

Space systems — Contamination and cleanliness control

1 Scope

This International Standard establishes general requirements for contamination and cleanliness control to be applied, at all tiers of supply, to the development of space systems including ground processing facilities, ground support equipment, launch vehicles, spacecraft, payloads, and ground processing and on-orbit operations. It also provides guidelines for the establishment of a contamination and cleanliness control programme.

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 14624-3, *Space systems — Safety and compatibility of materials — Part 3: Determination of off-gassed products from materials and assembled articles*

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

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

ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods*

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

ISO 14644-5:2004, *Cleanrooms and associated controlled environments — Part 5: Operations*

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

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

ISO 14951-3, *Space systems — Fluid characteristics — Part 3: Nitrogen*

ISO 14951-9, *Space systems — Fluid characteristics — Part 9: Argon*

ISO 14952 (all parts), *Space systems — Surface cleanliness of fluid systems*

ISO 15859-3, *Space systems — Fluid characteristics, sampling and test methods — Part 3: Nitrogen*

ISO 15859-9, *Space systems — Fluid characteristics, sampling and test methods — Part 9: Argon*

ASTM E 595, *Standard Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment*

ECSS-Q-70-02, *Space product assurance — Thermal vacuum test for the screening of space materials*

UN Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies, Article IX, 10 Oct. 1967

3 Terms and definitions, abbreviations

3.1 Terms and definitions

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

3.1.1

bakeout

activity of increasing the temperature of hardware to accelerate its outgassing rates with the intent of reducing the content of molecular contaminants within the hardware

NOTE Bakeout is usually performed in a vacuum environment but may be done in a controlled atmosphere.

3.1.2

bioaerosol

dispersed biological agents (e.g. viable particles, allergens, toxins or biologically active compounds of microbial origin) in a gaseous environment

3.1.3

biocontamination

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

3.1.4

classification of airborne particle concentrations

level (or the process of specifying or determining the level) of airborne particulate cleanliness, expressed in terms of an ISO Class *N* which represents maximum allowable concentrations (in particles/m³) for the particle size considered

NOTE The concentrations are determined as specified in ISO 14644-1.

3.1.5

clean bench

table or bench top working surface where a filtered airflow is concentrated across the bench top

NOTE These bench tops have an established classification of maximum allowable airborne contaminants.

3.1.6

clean hood

work area with a workbench, overhead dust deflector and sideboards, and a self-contained filtering unit for airflow to the work area

NOTE These hoods have an established classification of maximum allowable airborne contaminants.

3.1.7

cleanliness level

established maximum allowable amount of contamination in a given area or volume, or on a component

NOTE The term may also apply to the predicted or measured extent of contamination.

3.1.8

cleanliness requirement specification

CRS

document that defines and identifies the spacecraft items and the environmental areas which are sensitive to contamination, the acceptable contamination levels at BOL and at EOL and the applicable contamination environment

3.1.9

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

3.1.10**cleanroom garments**

clothing designed, manufactured and worn specifically to prevent contamination of hardware by personnel working in the cleanroom

NOTE It include all items worn by personnel, such as coveralls, frocks, gloves, boots, finger cots and beard covers.

3.1.11**clean zone**

dedicated space 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 zone and in which other relevant parameters, e.g. temperature, humidity and pressure are controlled as necessary

NOTE This zone may be open or enclosed and may or may not be located within a cleanroom.

3.1.12**collected volatile condensable material****CVCM**

mass that outgasses from a material and subsequently condenses on a collector, expressed as a percentage of the initial specimen mass

3.1.13**contaminant**

any unwanted molecular or particulate matter that could affect or degrade the relevant performance or lifetime of the hardware to which it is attached

3.1.14**contaminate**

introduce a contaminant

3.1.15**contamination**

addition of contaminants to materials, fluids or surfaces

3.1.16**contamination and cleanliness control programme**

any organized effort to establish and achieve acceptable cleanliness and contamination levels during all phases of the space system project

3.1.17**contamination analysis document**

report of the analyses and results that are used to determine cleanliness requirements and contamination profiles and budgets

3.1.18**contamination and cleanliness control plan****CCCP**

document that describes how to implement a contamination and cleanliness control programme, as either an independent document or a part of the consolidated project plan

3.1.19**contamination budget**

allowable levels of cleanliness of hardware at each phase of ground and flight operations

3.1.20**contamination profile**

contamination-related conditions in each phase of ground and flight operations

NOTE 1 These includes airborne particulate cleanliness classes, pressure, humidity, temperature, number of personnel engaged in operations, cleaning activities, outlines of facilities and so on.

NOTE 2 The contamination profile is part of the CCCP.

3.1.21

cross-contamination

transfer of contaminants from one surface or component to another

NOTE Transfer may occur by migration along a surface, by physical contact, airborne as an aerosol, or as a gas or molecular matter.

3.1.22

debris

solid objects with their largest dimension greater than approximately 1 mm (1 000 µm) in size

3.1.23

electrostatic discharge

ESD

rapid, spontaneous transfer of electrostatic charge between bodies that have different electrostatic potentials

3.1.24

fibre

particle having a length-to-diameter aspect ratio of 10 or greater

3.1.25

generally clean

free from manufacturing residue, dirt, oil, grease, processing debris or other extraneous contamination

NOTE This level can be achieved by washing, wiping, blowing, vacuuming, brushing or rinsing.

3.1.26

ground support equipment

GSE

non-flight systems, equipment or devices necessary to support the operations of transporting, receiving, handling, assembly, inspection, test, checkout, servicing, launch and recovery of a space system at launch, landing or retrieval sites

3.1.27

interface control document

ICD

specification that describes the characteristics that must be controlled at the boundaries between systems, subsystems and other elements

3.1.28

microorganism

microscopical individual constituted to carry out life functions

NOTE 1 This includes organisms such as bacteria, protozoa, yeasts, moulds, fungi, algae and organisms that depend upon other life forms for reproduction such as viruses and parasites.

NOTE 2 Multicellular organisms and agglomerations of microorganisms may be visible to the unaided eye.

3.1.29

microscopical

visible only under a microscope

3.1.30

molecular contamination

contamination due to deposition of molecules on surfaces or their presence in gases or liquids

3.1.31

occupancy states of cleanrooms

3.1.31.1

as-built

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

3.1.31.2**at-rest**

condition where the installation is complete with equipment installed and operating in a manner agreed between the customer and supplier, but with no personnel present

3.1.31.3**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

3.1.32**offgassing**

evolution of gaseous products from a liquid or solid material into an atmosphere

NOTE This is a special definition for outgassing for the application described in ISO 14624-3.

3.1.33**outgassing**

evolution of gaseous species from a material, usually in a vacuum

NOTE Outgassing also occurs in higher-pressure environments.

3.1.34**particle**

unit of solid or liquid matter with observable size

NOTE See also 3.1.37.

3.1.35**particle concentration**

⟨on surface⟩ number of particles per unit area

3.1.36**particle concentration**

⟨by volume⟩ number of particles per unit volume of fluid

3.1.37**particle size**

- a) apparent maximum linear dimension of a particle in the plane of observation as observed with instruments such as optical, electron or atomic force microscopes
- b) equivalent diameter of a particle detected by automatic instrumentation

NOTE The equivalent diameter is the diameter of a reference sphere having known properties and producing the same response in the sensing instrument as the particle being measured. Other methods of defining size may be used but are dependent upon the measurement technique.

3.1.38**particulate contamination**

contamination due to deposition of particles on surfaces or suspension of particles in fluids

3.1.39**precision clean**

cleaning of hardware by approved engineering methods to meet quantitative cleanliness criteria

3.1.40**responsible organization**

organization that is responsible for the contamination and cleanliness control programme and is provided with the authority and resources needed for carrying out the programme

3.1.41

recovered mass loss

RML

TML of the specimen without the sorbed water:

$$\text{RML} = \text{TML} - \text{WVR}$$

NOTE The quantity RML is introduced because water is not a critical contaminant for some space systems (see 5.6.3).

3.1.42

sensitive hardware

hardware that may be degraded by contamination

3.1.43

significant surface

surface of an item or product that is required to meet established cleanliness level requirements

3.1.44

spacecraft charging

increase in electrostatic potential on spacecraft surfaces resulting from low-energy electron flux impinging on the surface

3.1.45

sterility

absence of viable microorganisms

NOTE Inactivated microbes may still represent an important form of biocontamination.

3.1.46

sterilization

act or process of killing all forms of microbial life on and in an object

NOTE Inactivated microbes may not be eliminated and may still represent an important form of biocontamination.

3.1.47

supplier

entity that has a contractual obligation to provide parts or services

EXAMPLES Subcontractor, vendor, distributor, manufacturer, etc.

3.1.48

surface cleanliness

level of contamination on a significant surface

3.1.49

total mass loss

TML

total mass of material outgassed from a test specimen that is maintained at a specified constant temperature and operating pressure for a specified time and measured within the test chamber

NOTE TML is expressed as a percentage of the initial specimen mass.

3.1.50

viable particle

isolated microorganisms or accumulated microorganisms (clumps) on a particle, capable of producing demonstrable growth

3.1.51**visibly clean**

absence of surface contamination when examined using a specified light source and angle of incidence, viewing distance and angle, and normal or magnified vision

3.1.52**water vapour regained****WVR**

mass of water vapour regained by a test specimen, after determination of TML and CVCM, on exposure to a specified relative humidity atmosphere (usually 50 % at 23 °C or 65 % at 20 °C) for 24 h

3.2 Abbreviations

AIT	Assembly, Integration and Test
BOL	Beginning Of (operational or mission) Life
CCCP	Contamination and Cleanliness Control Plan
CRS	Cleanliness Requirement Specification
CVCM	Collected Volatile Condensable Material
ECSS	European Cooperation for Space Standards
EOL	End Of (operational or mission) Life
ESA	European Space Agency
ESD	Electrostatic Discharge
FOV	Field Of View
GSE	Ground Support Equipment
GSFC	Goddard Space Flight Center (NASA)
ICD	Interface Control Document
IEST	Institute of Environmental Sciences and Technology (USA)
NASA	National Aeronautics and Space Administration (USA)
NPD	NASA Policy Directive
NPG	NASA Procedures and Guidelines
RML	Recovered Mass Loss
TML	Total Mass Loss
WVR	Water Vapour Regained

4 Management**4.1 Organization**

The supplier shall establish a contamination and cleanliness control programme, at the beginning of the project, for each level of configuration and item defined in the project. Performance requirements, defined by customer-supplier agreements, form the basis for cleanliness requirements.

4.2 Cleanliness requirement specification (CRS)

The supplier shall identify the hardware to be controlled, and specify the permissible cleanliness level in a quantitative manner. The hardware includes all items from component level to system level. The acceptable cleanliness levels of the hardware shall be specified at BOL and EOL, based on performance requirements and contamination analyses. The specification shall be established independently as a CRS or included in an overall project design specification. The cleanliness of hardware to be controlled at the boundary of systems, subsystems and other elements shall be stipulated in the ICD or its equivalent.

Cleanliness requirements that are more stringent than necessary to meet manufacturing and system performance requirements shall not be imposed at any level of assembly.

4.3 Contamination and cleanliness control plan (CCCP)

4.3.1 Specifying cleanliness necessitates the establishment of a budget for particulate and molecular contamination for all phases of the project and a clear methodology of how the required cleanliness levels can be achieved.

4.3.2 The supplier shall develop a contamination and cleanliness control plan that describes how to achieve and maintain the specified cleanliness level of the hardware during all the phases of the ground and flight operations. The plan may be an independent document or part of a consolidated project control plan.

4.3.3 The range of the plan and the level of detail shall be determined by the responsible organization with respect to the criticality of the hardware against contamination. This may require additional tasks to those described in this document or may lead to a reduction in the applicable requirements.

4.3.4 The CCCP shall:

- a) Contain a contamination budget for all phases of the ground and flight operations.
- b) Provide methodology for achieving and maintaining the required cleanliness levels.
- c) Define how to deal with situations that may result in cleanliness specifications not being achieved.

NOTE 1 Possible situations include failures of facilities and launch delays for a spacecraft.

NOTE 2 Corrective actions could include additional cleaning operations.

- d) Define single-point failure modes that can affect cleanliness, including equipment failures and human errors.
- e) Define the risk of cross-contamination between hardware elements.
- f) Provide measurement and monitoring methods, procedures and requirements.
- g) Define the sequence of cleanliness activities.
- h) Define the roles and responsibilities of the organizations which will implement the requirements.
- i) Provide descriptions of when and how the cleanliness activities are to be reviewed.
- j) Provide information on how to implement design activities.
- k) Provide information on how to train personnel and certify them.
- l) Provide references to procedures.

4.4 Interface control document (ICD)

4.4.1 The cleanliness of hardware to be controlled at the interfaces of different systems, subsystems and other elements shall be stipulated in the ICD or its equivalent.

4.4.2 The ICD may include the following types of information:

- a) limitations on particles, gases, vapours and debris crossing the interface;
- b) limitations on particles, gases, vapours and debris in the field of view of instruments and sensors;
- c) limitations on energy (ultraviolet and ionizing radiation, thermal radiation, radio frequency radiation, etc.) that will affect contaminant deposition and degrade performance.

4.5 Project reviews

The status of the contamination and cleanliness control programme shall be recorded and reported at the milestone project reviews where it shall be demonstrated that suitable activities are planned, are being implemented or have been successfully achieved.

5 Design activities

5.1 Identification of sensitive hardware

The supplier shall identify the sensitive hardware that may be degraded due to contamination during ground processing or flight and that shall be suitably protected. This hardware becomes the subject of detailed contamination and cleanliness control.

EXAMPLE Sensitive hardware includes optical detectors, optical assemblies and thermal control surfaces.

5.2 Nature of contaminants, their profile and their effects

5.2.1 General

The supplier shall identify the following:

- a) the nature of the contaminants which may degrade the performance of sensitive hardware in any way, such as particulate, molecular or biocontaminants, during all phases of ground and flight operations;
- b) the effects of contaminants on the sensitive hardware, using experience gained with similar spacecraft or similar operations in early phases of the project and, later, using data gained in realistic tests.

5.2.2 Typical contaminants

Typical contaminants are caused by factors such as outgassing (including re-emission of condensed contaminants, and return flux from collisions with the ambient atmosphere and spacecraft charging at high-Earth orbits); particles from materials, mechanisms or AIT facilities; grease from human handling, operation and AIT facilities; launch contaminants; leakage from pressurized units; microorganisms; ESD; exhaust products from thrusters; natural environments such as electron, proton and atomic oxygen fluxes; spacecraft charging; human waste dumps; and contamination from life support hardware.

5.2.3 Contamination profile

The supplier shall initiate the contamination profile that shows contamination-related issues, such as temperature, pressure, humidity and natural environments, in each phase of the life cycle and shall maintain it throughout development.

5.2.4 Effects of contamination on performance

The supplier shall develop a correlation between contamination levels and degradation in performance, and determine the allowable contamination limit for sensitive hardware. The cleanliness level requirements shall be estimated in the early phases, and become more detailed through performance analysis.

5.3 Contamination prediction

The supplier shall perform an analysis of contaminant transport and deposition for all phases of ground and flight operations. If the level of contamination exceeds the specifications, protective measures shall be implemented. The parameters necessary to perform the analysis could include view factors; the outgassing kinetics of relevant materials; the condensation kinetics and temperatures of significant surfaces; the scattering interactions with the neutral space environment; the electrodynamic interactions with ambient space plasma; surface interactions with space radiation, particularly with the incident ultraviolet radiation; etc.

5.4 Contamination budget

The supplier shall develop a contamination budget for both particulate and molecular species based on the contamination profile and design specification of hardware cleanliness. The contamination budget shall take into account the results of predictions, the probability of restoring cleanliness during ground and flight operations, as well as exposure times and the use of protective covers. Methods to be used for cleaning and maintaining cleanliness throughout all phases of the project shall be considered. Contamination levels for BOL and EOL shall be included in the budget.

5.5 Cleanliness-oriented design

The supplier shall develop methods to maintain the cleanliness of sensitive hardware, to reduce its sensitivity to contamination and to ease cleaning, and shall describe the outline of the cleanliness-oriented design in the CCCP. Typical preventive measures are: suitable location and orientation of sensitive hardware; minimizing the usage of outgassing materials; using venting holes, baffles and shields; using protective covers on the ground; controlling the temperature of outgassing hardware; designing cleaning processes; enclosing contamination sources; baking; processing human wastes; using molecular adsorbers; etc. The measures shall be chosen based on the cleanliness specification and the contamination budget.

The design of ground support equipment that is in the same room as, in close proximity to or in contact with flight hardware shall also be similarly considered.

5.6 Selection of materials and processes

5.6.1 General

Materials and processes shall be selected to minimize contamination as well as to meet other functional requirements. The primary screening items for materials are outgassing, offgassing, particle generation, fungus growth and fragility.

5.6.2 Outgassing

The initial screening of materials shall be in accordance with ASTM E 595, ECSS-Q-70-02 or a customer-recognized equivalent. The usual criteria are a TML of less than 1,0 % and a CVCM of less than 0,1 %. RML is used in ECSS-Q-70-02 instead of TML. The criterion for RML is also less than 1,0 %.

The requirements for the use of TML and RML depend on the performance requirements for the space system and specific uses of materials in the system (see 5.6.3).

Materials that pass the standard screening tests may nevertheless cause degradation of sensitive hardware and may require further characterization. The customer and supplier shall establish materials selection guidelines, with requirements that are more stringent, using other test methods, if justified by mission and performance requirements.

NOTE ASTM E 1559 (see Bibliography) and other, similar, test methods may be applicable to establishing guidelines for the selection of materials.

5.6.3 Sorbed water vapour

Some materials contain large quantities of sorbed water that contribute to the TML. If the outgassing of water vapour is not critical to the application, the outgassed water may be subtracted from the TML to provide an RML to meet the requirements. The adjusted mass loss value is given by the RML:

$$\text{RML} = \text{TML} - \text{WVR}$$

5.6.4 Offgassing

Materials shall be screened, in accordance with ISO 14624-3, for their offgassing characteristics, carrying out a toxicological assessment of the risks to personnel when the materials are used in habitable areas during flight.

5.6.5 Quality control

Suitable quality control processes to verify the performance of materials shall be maintained. Processes and compositions of commercial materials may not be controlled sufficiently to meet the requirements of space systems. The specification of quality control processes shall be determined on a case-by-case basis. ASTM E 595 or ECSS-Q-70-02 may be used as a quality control test for the outgassing characteristics of materials.

6 Biocontamination

6.1 General

The organisms that cause biocontamination are fungi, yeast, viruses and bacteria. They are contaminants by virtue of their biomass and also generate contaminants by virtue of their biological processes, thriving both on the ground and in flight. They are introduced on the ground during manufacturing, integrating and testing, transporting and operating processes. Human waste and metabolic byproducts accelerate the growth of microorganisms associated with water or nutrients. Hardware cleanliness can include requirements for viable organisms as well as dead organisms, chemical and particulate byproducts, and metabolic products from the organisms.

6.2 Contamination of hardware by microorganisms

6.2.1 Microorganisms produce substances that result from their metabolic and/or biological processes. These materials can cause contamination or corrosion.

6.2.2 A preventive measure is to eliminate or reduce moisture and nutrients. The prevention of the propagation of microorganisms, especially in rooms with recirculating-air systems, is difficult. Effective countermeasures are to install high-performance filters and implement effective cleaning processes. Designing hardware to be easily cleanable is also an important countermeasure.

6.3 Sterile hardware

6.3.1 Sterility requirements may be imposed on hardware for use in habitable systems, biological experiments and interplanetary missions. These requirements may be in addition to other contamination control requirements imposed on the system.

6.3.2 Sterile processing procedures include, but are not limited to, eliminating contact with contaminated objects, with bioaerosols in air and purge gases, and with personnel.

6.3.3 Ground-handling processes shall be designed to implement the sterility requirements on hardware. This includes maintaining the hardware in sterile environments, such as sterile packaging, sterile isolators and sterile rooms. See ISO 14698-1 for detailed descriptions. The CCCP shall include, or reference, the procedures required to meet hardware requirements.

6.3.4 Ground operations shall be monitored to verify that hardware cleanliness and environments meet the requirements. ISO 14698-2 provides additional details on the evaluation and interpretation of biocontamination data.

6.3.5 Personnel shall be provided with proper garments, as required, to prevent exposure to hazardous contaminants and to protect hardware from contamination.

6.4 Habitable space systems

6.4.1 Habitable spacecraft

Unique requirements are provided to protect onboard personnel from harmful contaminants, including biocontaminants and toxic materials. The requirements include the control of outgassing (offgassing) from materials and hardware and control of the flammability of materials. Objectionable odours are also controlled to maintain a comfortable environment within the habitable spacecraft. Special atmospheres, such as pure oxygen, shall also be considered in defining the requirements.

6.4.2 Offgassing

Materials used in habitable locations of spacecraft shall be screened for offgassing in accordance with ISO 14624-3.

6.5 Planetary protection

6.5.1 Planetary protection activities shall be included in the CCCP, responding to Article IX of the *UN Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies*, that contains the following requirement: "States Parties to the Treaty 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, where necessary, shall adopt appropriate measures for this purpose."

6.5.2 Protection of other planets requires limits on the quantities of viable organisms that may be transported to a planet that could have life forms currently, or have had them in the past. The level of protection required depends upon scientific judgement on the probability of life on the planet.

6.5.3 Protection of the Earth requires procedures to prevent possibly harmful organisms from other planets damaging the inhabitants and the environment of the Earth when vehicles and samples are transported back to the Earth.

6.6 Sample protection

Biological samples from scientific studies and routine monitoring shall be protected from contamination as necessary to meet system performance requirements. The protection methods shall be included in the CCCP.

7 Contamination and cleanliness control for ground operations

7.1 Training of personnel

Personnel shall be trained and certified as per the CCCP according to their assigned tasks. Additional information on personnel in cleanrooms can be found in Subclause 4.3 and Annex C of ISO 14644-5:2004.

7.2 Cleanroom selection and cleanliness control

7.2.1 The supplier shall select, based on the contamination budget as per Subclause 5.4, suitable environments for the manufacturing, assembling, transporting, integrating and testing of hardware. This includes launch site processing.

7.2.1.1 Cleanroom selection shall be based on hardware cleanliness requirements, required operating procedures and exposure times.

7.2.1.2 Allowable airborne particle concentrations shall be specified as a class of air for the operational occupancy state in accordance with ISO 14644-1.

7.2.1.3 Procedures for operational and at-rest conditions shall be specified to the extent necessary to meet hardware cleanliness requirements.

7.2.1.4 Special clean zones may be established to meet special hardware cleanliness requirements in a local area.

7.2.1.5 Operational monitoring of airborne and surface contaminants shall be specified to the extent required to meet project performance requirements and risk/cost benefits.

7.2.1.6 Materials, parts, hardware and test equipment that are authorized to be taken into cleanrooms shall be compatible with the cleanliness requirements of the area. An approved list of materials for use in cleanroom areas is recommended. The cognizant contamination control or systems engineer shall approve materials for use in cleanrooms.

7.2.2 Failures of facilities, such as electrical power and cooling water, and equipment breakdown shall be considered in the CCCP and relevant operating procedures defined to prevent damage to flight hardware. Single-point failure mechanisms, including human error, shall be analysed and avoided with special consideration placed on risk/cost benefits.

7.2.3 Facility operating procedures include overall cleaning and control of the cleanroom, monitoring of facility cleanliness and maintaining facilities. When flight hardware is present, cleaning of the cleanroom shall be limited to the extent necessary to meet hardware cleanliness requirements.

7.2.4 Additional information on the design, construction and start-up of cleanrooms can be found in ISO 14644-4.

7.2.5 Additional information on the operation of cleanrooms can be found in ISO 14644-5.

7.3 Cleanroom garments

7.3.1 General

One purpose of a cleanroom garment is to prevent contaminants generated by people from getting to the product. For some applications, the garment is also used to protect personnel from hazardous materials.

7.3.2 Considerations for garment selection

7.3.2.1 Garments shall be selected based on hardware cleanliness requirements, the type of airflow in the cleanroom and the location of the personnel relative to the hardware. The usual garment choices for aerospace use include a full coverall with a hood and shoe coverings or a frock and partial head cover with some type of shoe cover.

7.3.2.2 The garment shall have good ESD protection, high permeability to air and water vapour, low particle transmission capacity, low particle generation capacity, good cleanability and good wear properties, including resistance to laundering and dry cleaning.

7.3.2.3 For garment selection, one should note that the a frock does not retain the particles generated by the wearer of the garment because the bottom is open. Studies have shown that airborne-particle concentrations increase when frocks are worn as compared to coveralls. The open bottom allows large particles and debris to fall out. These will not become airborne but will deposit on the cleanroom floor or on product surfaces near the wearer. Frocks are not recommended when personnel are working above hardware or when product cleanliness levels are stringent. Frocks are suitable for the processing of hardware in clean benches where coveralls are not needed.

7.3.3 Additional information

Additional information on the selection and use of cleanroom garments can be found in Subclause 4.2 and Annex B of ISO 14644-5:2004.

7.4 Ground support equipment (GSE)

The selection and operation of ground support equipment in the same room as or near flight hardware shall consider the cleanliness requirements of the flight hardware and contamination sources such as outgassing and lubricants. Particle-generating materials or fragile surfaces shall be sealed or covered as well as possible. Equipment-cooling fans can generate a flow of molecular or particulate matter. The exclusion of such fans or the re-direction of their airflow away from flight hardware shall be considered.

7.5 Monitoring cleanliness of flight hardware and its near surroundings

Contamination shall be monitored to the predetermined levels and time intervals as per the procedures defined in the CCCP. Monitoring equipment shall be located at suitable places and under specified conditions. The cleanliness shall be monitored and recorded as per test plans and operating procedures, as required. Monitoring may include the following: concentrations of airborne particulate and molecular contaminants; deposition of particulate and molecular contaminants; temperature; relative humidity and room pressure. Some requirements for monitoring of airborne-particle concentrations in cleanrooms is contained in ISO 14644-2. Additional measurement methods can be found in ISO 14644-3.

7.6 Packaging, storage and transport

7.6.1 Packaging

Packaging shall be used to protect hardware during storage and transport. Packaging materials shall not increase the contamination of the hardware or contain volatile or transferable contaminants.