SLOVENSKI STANDARD
kSIST FprEN 16602-70-58:2014

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Zagotavljanje varnih proizvodov v vesoljski tehniki - Kontrola biološke obremenitve čistih prostorov

Space product assurance - Bioburden control of cleanrooms

Raumfahrtproduktsicherung - Kontrolle der Gesamtkeimzahl in Reinräumen

Assurance produit des projets spatiaux - Contrôle de la charge microbienne des salles blanches

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Space product assurance - Bioburden control of cleanrooms

Assurance produit des projets spatiaux - Contrôle de la charge microbienne des salles blanches

Raumfahrtproduktsicherung - Kontrolle der Gesamtkeimzahl in Reinräumen

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Foreword

This document (FprEN 16602-70-58:2014) has been prepared by Technical Committee CEN/CLC/TC 5 “Space”, the secretariat of which is held by DIN (Germany).

This document (FprEN 16602-70-58:2014) originates from ECSS-Q-ST-70-58C.

This document is currently submitted to the Unique Acceptance Procedure.

This document has been developed to cover specifically space systems and will the-refore have precedence over any EN covering the same scope but with a wider do-main of applicability (e.g. : aerospace).

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 control of 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.

This standard may be tailored for the specific characteristic and constrains of a space project in conformance with ECSS-S-ST-00.

2
Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this ECSS Standard. For dated references, subsequent amendments to, or revision of any of these publications do not apply, However, parties to agreements based on this ECSS Standard are encouraged to investigate the possibility of applying the more recent editions of the normative documents indicated below. For undated references, the latest edition of the publication referred to applies.

EN reference	Reference in text	Title
EN 16601-00-01	ECSS-S-ST-00-01	ECSS system – Glossary of terms
EN 16602-10-09	ECSS-Q-ST-10-09	Space product assurance – Nonconformance control system
EN 16602-20	ECSS-Q-ST-20	Space product assurance – Quality assurance
EN 16602-20-07	ECSS-Q-ST-20-07	Space product assurance – Quality assurance for test centres
EN 16602-70-55	ECSS-Q-ST-70-55	Space product assurance - Microbial Examination of Flight Hardware and Cleanrooms
	ISO 14644 part 1:1999	Cleanrooms and associated controlled environments - Part 1:Classification of air cleanliness
	ISO 14644 part 2:2000	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-S-ST-00-01 apply.

3.2 Terms specific to the present standard

3.2.1 action level

level set by the user in the context of controlled environment, and 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.

3.2.4 biobarrier(s)

barrier surrounding an item which prevents biological recontamination subsequent to microbial reduction procedures

3.2.5 bioburden

quantity of viable microorganisms measured with a specified assay

3.2.6 bioburden controlled

defined zone or facility in which bioburden is controlled by specified means

3.2.7 bioburden reduction

process or processes used to reduce the viable microbial population on an item 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 species 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 contamination is controlled by specified means

3.2.12 disinfection

a process which destroys vegetative forms of microorganisms

NOTE Disinfection does not necessarily sterilize 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.

3.2.20 sterilization

validated process used to render product free from viable micro-organisms

[ISO 11139]

3.3 Abbreviated terms

For the purpose of this Standard, the abbreviated terms from ECSS-S-ST-00-01 and the following apply:

Abbreviation	Meaning
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
EGSE	electrical ground support equipment
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 Organization for Standardization
MGSE	mechanical ground support equipment
NASA	National Aeronautics and Space Administration
PP	planetary protection
WFI	water for injection