SLOVENSKI STANDARD
SIST EN 16602-70-55:2015

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Zagotavljanje varnih proizvodov v vesoljski tehniki - Mikrobiološka preiskava letalske strojne opreme in čistih prostorov

Space product assurance - Microbiological examination of flight hardware and cleanrooms

Raumfahrtproduktsicherung - Mikorbiologische Prüfung von Flughardware und Reinräumen

Assurance produit des projets spatiaux - Examen microbiologique des matériels de vol et des salles blanches

Ta slovenski standard je istoveten z: **EN 16602-70-55:2015**

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07.100.99	Drugi standardi v zvezi z mikrobiologijo	Other standards related to microbiology
49.140	Vesoljski sistemi in operacije	Space systems and operations

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Space product assurance - Microbiological examination of flight hardware and cleanrooms

Assurance produit des projets spatiaux - Examen microbiologique des matériels de vol et des salles blanches

Raumfahrtproduktsicherung - Mikorbiologische Prüfung von Flughardware und Reinräumen

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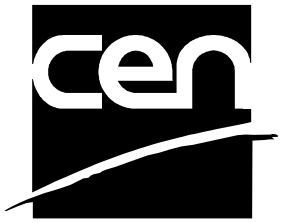

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Table of contents

Figures

Tables

European foreword

This document (EN 16602-70-55:2015) has been prepared by Technical Committee CEN/CLC/TC 5 “Space”, the secretariat of which is held by DIN.

This standard (EN 16602-70-55:2015) originates from ECSS-Q-ST-70-55C.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This document has been developed to cover specifically space systems and has therefore precedence over any EN covering the same scope but with a wider domain of applicability (e.g. aerospace).

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

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 for establishing the microbiological contamination on flight hardware and controlled environments are in place to meet the planetary protection constraints.

1
Scope

This standard defines test procedures for quantitative and/or qualitative microbiological examination of surfaces of flight hardware and in microbiologically controlled environments (e.g. cleanroom surfaces, cleanroom air, isolator systems).

The following test methods are described:

- Surface and air sampling and detection of biological contaminants with swabs, wipes, contact plates and air samplers, followed by cultivation for bioburden determination.
- Sampling of biological contaminants by DNA analysis from swabs and wipes.

The test methods described in this standard apply to controlling the microbiological contamination on all manned and unmanned spacecraft, launchers, payloads, experiments, ground support equipment, and cleanrooms with planetary protection constraints.

This standard does not address molecular contamination control.

This standard does not address the principles and basic methodology for controlling cleanrooms and associated controlled environments with constraints on particulate contamination.

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 16602-70-01	ECSS-Q-ST-70-01	Space product assurance - Cleanliness and contamination control

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 bioburden

quantity of viable microorganisms measured with a specified assay

3.2.2 biodiversity

identification of type of microorganism, measured with specified assays

3.2.3 anaerobic

gas with ≤ 40 ppm O_2

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
ASTM	American Society for Testing and Materials
DNA	Desoxyribonucleic acid
DNase	Deoxyribonuclease
IEST	Institute of Environmental Sciences and Technology
IPA	Isopropylalcohol
ISO	International Organization for Standardization
PBS	Phosphate buffered saline solution
PCR	Polymerase chain reaction
PDA	Potato Dextrose Agar

R2A	A low nutrient bacterial medium with agar
rDNA	Ribosomal DNA
RNase	Ribonuclease
S	Svedberg unit
TE	Tris-EDTA, 2-Amino-2-(hydroxymethyl)propane-1,3-diol ethylenediaminetetraacetic acid
TSA	Trypticase Soy Agar
TGA	Thioglycollate Agar

4 Principles

The activities related to microbial examination requirements, specifications, procedures and reports are described in Figure 4-1, and the related standardization requirements are captured in clause 5.

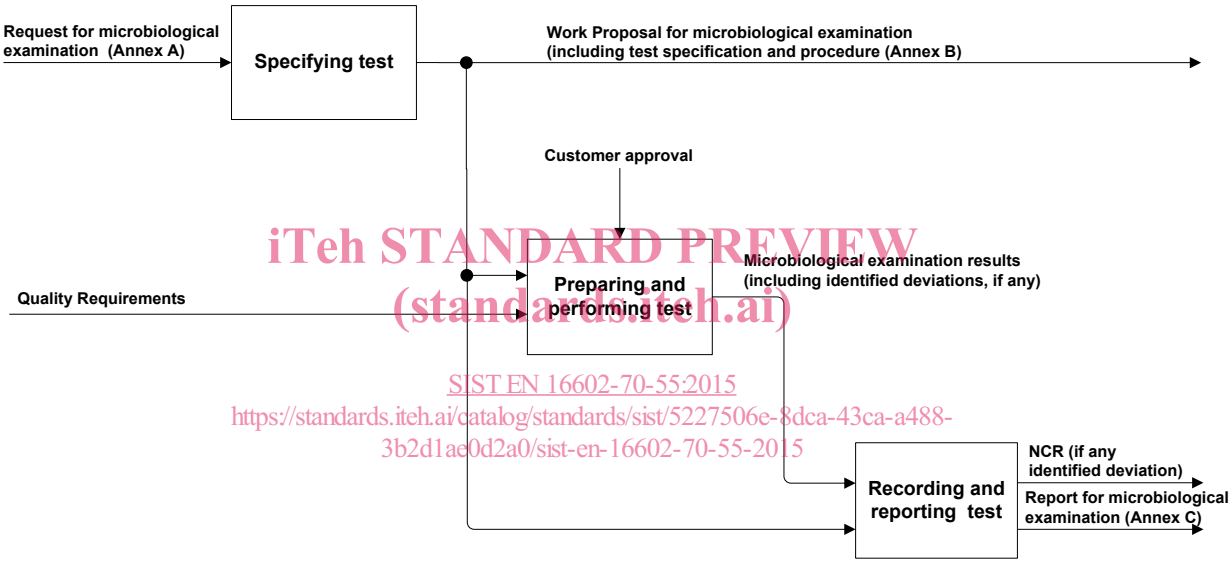

Figure 4-1: Microbiological examination process overview

Clause 5.1 provides the test specification.

Clause 5.2 and 5.4 provide the requirements for preparing, performing, recording and reporting microbiological examination.

The methods for bioburden determination are used to obtain an indication of the overall bioburden, but not for a general assessment of all microorganisms present in a sample.

5
Requirements

5.1 Specifying test

5.1.1 General provision

a. The customer shall provide a request for microbiological examination in conformance with Annex A DRD.

b. ECSS-Q-ST-20 shall be made applicable in the request for microbiological examination.

c. ECSS-Q-ST-10-09 shall be made applicable in the request for microbiological examination.

d. For safety and security, the test centre shall comply with the "Safety and security" requirements of ECSS-Q-ST-20-07.

NOTE Examples of safety issues are hazard and health. Example of security issues is access control.

e. Cleanliness and contamination control requirements according to ECSS-Q-ST-70-01 shall be applied for space hardware.

f. The supplier shall provide a microbiological examination proposal in conformance with Annex B DRD.

NOTE 1 Quality standards for microbiological laboratories should follow ISO 17025.

NOTE 2 Additional specific requirements (e.g. avoidance of certain chemical functionalities) can be imposed by the mission objectives.

5.1.2 Specifying the test means

5.1.2.1 Facilities

a. The work area shall comply to the rules and guidelines of good laboratory practice.

b. The ambient conditions for the process and work areas shall be (22 ± 3) °C with a relative humidity of (55 ± 10) % unless otherwise stated.

5.1.2.2 Equipment, reagents and consumables

a. The supplier shall identify and specify the list of the equipment, reagents and consumables necessary to set up and run the approved test procedures.

NOTE If the test procedures proposed in Annex D - Annex G are executed by the supplier, the corresponding equipment, reagents and consumables specification is described therein.

5.1.3 Specifying the test procedure

5.1.3.1 Test procedures

a. Surfaces with an area of maximal 25 cm^2 shall be sampled with swabs and surfaces with an area of maximal 1 m^2 shall be sampled with wipes.

NOTE Multiple swabs and wipes can be used to sample a larger surface area.

b. Bioburden shall be determined with assays for quantification of aerobic mesophilic bacteria.

NOTE 1 Example procedures are given in Annex D.1, D.2., E.1 and E.2.

NOTE 2 This sampling is only appropriate for materials and material combinations (e.g. electrochemical compatibility, see ECSS-Q-ST-70-71) that can tolerate sample collection using damp materials.

c. Biodiversity shall be determined with assays for determination of the type of micro-organism.

NOTE 1 Example procedures are given in Annexe D.2 to D.5 (swabs) and Annexes E.2 to E.5 (wipes).

NOTE 2 In addition, non-culture-based methods are used for the molecular analysis of non-cultivable microorganisms with example procedures in Annex D.6 (swab) and Annex E.6.1 (wipe).

NOTE 3 This sampling is only appropriate for materials and material combinations (e.g. electrochemical compatibility, see ECSS-Q-ST-70-71) that can tolerate sample collection using damp materials.

NOTE 4 For cleanroom control also contact plates and active air samplers can be applied with example procedures in Annex F (contact plates) and Annex G (active air sampling).

d. Air sampling shall be applied for continuous clean room monitoring.

5.2 Validation

a. The test procedures shall be validated in accordance to customer requirements or specifications.

NOTE This validation can include the determination of relative or absolute efficiencies of the sampling and analysis method to establish a correction factor for the absolute bioburden numbers.

5.3 Preparing and performing the microbiological examination

5.3.1 General

a. The microbiological examination proposal shall be provided for customer approval.

b. The test proposal shall include the procedures.

c. ECSS-Q-ST-20 shall apply for the establishment of the test procedures.

5.3.2 Preparing microbiological assays

5.3.2.1 Identification

a. Locations where microbiological assays are taken shall be clearly identified with appropriate details to maintain traceability.

NOTE For example, microbiological assay plan.

b. Assays shall be identified as a minimum by:

1. Date and time
2. Operator(s)
3. Reference to trace location of assay
4. Type of assay
5. Area of the assay or air volume taken
6. Storage conditions of assay sample.

5.3.2.2 Preparation, handling and storage of reagents and consumables

a. Rules and guidelines of good laboratory practice shall be followed.

5.3.3 Performing microbiological assays

a. The supplier shall perform the approved microbiological examination procedures in conformance with Annex B DRD.