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Entwurf

Raumfahrtproduktsicherung – Mikrobiologische Prüfung von Flughardware und Reinräumen; Englische Fassung FprEN 16602-70-55:2014

Space product assurance –
Microbial examination of flight hardware and cleanrooms;
English version FprEN 16602-70-55:2014

Assurance produit des projets spatiaux –
Examen microbiologique des matériels de vol et des salles blanches;
Version anglaise FprEN 16602-70-55:2014

Anwendungswarnvermerk

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Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfes besonders zu vereinbaren.

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Nationales Vorwort

Dieses Dokument (FprEN 16602-70-55:2014) wurde vom Technischen Komitee CEN/CLC/TC 5 „Raumfahrt“ erarbeitet, dessen Sekretariat vom DIN (Deutschland) gehalten wird.

Dieses Dokument ist derzeit zum einstufigen Annahmeverfahren vorgelegt.

Dieses Dokument wurde speziell zur Behandlung von Raumfahrtsystemen erarbeitet und hat daher Vorrang vor jeglicher Europäischer Norm, da es denselben Anwendungsbereich hat, jedoch über einen größeren Geltungsbereich (z. B. Luft- und Raumfahrt) verfügt.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 131-10-01 AA „Interoperabilität von Informations-, Kommunikations- und Navigationssystemen“ im DIN-Normenausschuss Luft- und Raumfahrt (NL).

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Nationaler Anhang NA
(informativ)

3 Begriffe und Abkürzungen

3.1 Begriffe aus anderen Normen

Für die Anwendung dieser Norm gelten die Begriffe nach ECSS-S-ST-00-01.

3.2 Für diese Norm spezifische Begriffe

3.2.1
Keimbelastung
Menge lebensfähiger Mikroorganismen, gemessen mithilfe eines festgelegten Assays

3.2.2
Biodiversität
Identifizierung der Art der Mikroorganismen, gemessen mithilfe festgelegter Assays

3.2.3
anaerob
Gas mit ≤ 40 ppm O_2

3.3 Abkürzungen

Für die Anwendung dieser Norm gelten die Abkürzungen in ECSS-S-ST-00-01 und die folgenden Abkürzungen:

Abkürzung	Bedeutung
ASTM	Amerikanische Gesellschaft für Materialprüfung (en: American Society for Testing and Materials)
DNA	Desoxyribonukleinsäure (en: Desoxyribonucleic acid)
DNase	Desoxyribonuklease (en: Deoxyribonuclease)
IEST	Institut für Umweltwissenschaften und Technologie (en: Institute of Environmental Sciences and Technology)
IPA	Isopropylalkohol (en: Isopropylalcohol)
ISO	Internationale Organisation für Normung (en: International Organization for Standardization)
PBS	phosphatgepufferte Salzlösung (en: Phosphate buffered saline solution)
PCR	Polymerase-Kettenreaktion (en: Polymerase chain reaction)
PDA	Kartoffel-Dextrose-Agar (en: Potato Dextrose Agar)

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Abkürzung	Bedeutung
R2A	ein nährstoff-reduziertes bakterielles Agar-Medium (en: a low nutrient bacterial medium with agar)
rDNA	Ribosomale DNA (en: Ribosomal DNA)
RNase	Ribonuklease (en: Ribonuclease)
S	Svedberg-Einheit (en: Svedberg unit)
TE	Tris-EDTA, Tris(hydroxymethyl)aminomethan-Ethylendiamintetraacetat (en: Tris-EDTA, 2-Amino-2-(hydroxymethyl)propane-1,3-diol ethylenediaminetetraacetic acid)
TSA	Trypticase-Soja-Agar (en: Trypticase Soy Agar)
TGA	Thioglycolat-Agar (en: Thioglycollate Agar)

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English version

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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If this draft becomes a European Standard, CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Foreword

This document (FprEN 16602-70-55:2014) has been prepared by Technical Committee CEN/CLC/TC 5 "Space", the secretariat of which is held by DIN (Germany).

This document (FprEN 16602-70-55:2014) originates from ECSS-Q-ST-70-55C.

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).

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

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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.

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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

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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

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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

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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.

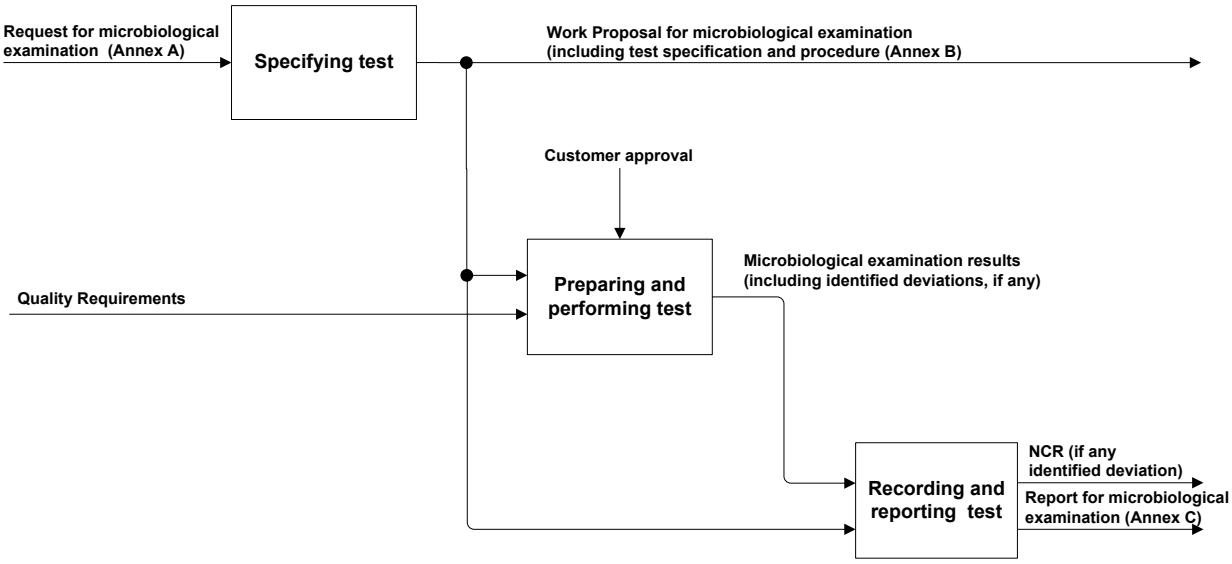

Figure 4-1: Microbiological examination process overview

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.

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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.

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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.

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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.

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NOTE 1 Examples of approved microbiological assay procedures are given in Annex D - Annex G.

NOTE 2 Sterile operations and sample processing are performed in laminar flow environment according to ISO 5 particulate cleanliness level defined in ISO 14644-1.

5.3.4 Personnel

a. Personnel conducting microbiological examination of flight hardware and cleanrooms shall be trained in microbiology.

NOTE Guidance on training can be found in ISO 14698 part 1, Annex G.

5.4 Recording and reporting the test results

5.4.1 Test records

a. The test records of the microbiological examination shall be retained for, at least, ten years or in accordance with customer requirements.

b. The quality records shall contain as a minimum the following:

1. Date and time of the assay campaign
2. Operator(s)
3. Type of assay and assay procedure
4. Traceable details about assay

NOTE For example, location, area, air volume.

5. Storage conditions of assay sample

NOTE For example, temperature after sampling at packaging, transport time, temperature at start of assay.

6. Details of the equipment used for the assay
7. Comments concerning any unusual occurrence during sampling, transport or assay
8. Reports of the microbiological examination results

NOTE Depending on customer requirements the calculation of the bioburden can include a correction factor (see 5.2).

c. The test records of the microbiological examination shall be composed of:

1. the request for microbiological examination in conformance with Annex A DRD,
2. the microbiological examination proposal in conformance with Annex B DRD,

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3. the microbiological examination report in conformance with Annex C DRD,

4. a conclusion with respect to the compliance with the project requirements (acceptance criteria) and associated non-conformances.

5.4.2 Test report

a. The supplier provide a test report in conformance with the DRD in Annex C and the requirements on "Test reports" of ECSS-Q-ST-20.

b. The supplier shall submit the test report to the customer for approval.

5.4.3 Acceptance criteria and nonconformance

a. Acceptance criteria shall be defined (beforehand) in common agreement between the test authority and the customer.

b. Any suspected or actual equipment failure shall be recorded as project non conformance report so that previous results may be examined to ascertain whether or not re-inspection and re-testing.

c. The test procedures shall contain an instantiation or adaptation for the test item of the non conformance processing flow chart as described in ECSS-Q-ST-10-09.

NOTE In the frame of research and development activities, this is not necessary.

d. The supplier shall notify the customer of the non conformance details.

e. Traceability shall be maintained throughout the process from incoming inspection to final measurements and calculations, including details of the test equipment and personnel employed in performing the task.

f. Evaluation of other properties may be invoked by the customer.

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Annex A (normative) Request for microbiological examination - DRD

A.1 DRD identification

A.1.1 Requirement identification and source document

This DRD is called from ECSS-Q-ST-70-55, requirement 5.1.1a.

A.1.2 Purpose and objective

The purpose of the request is the quantitative and/or qualitative microbiological examination of surfaces of flight hardware and in microbiological controlled environments (e.g. cleanroom surfaces, cleanroom air, isolator systems).

A.2 Expected response

A.2.1 Scope and content

a. The Request for microbiological examination shall include or refer to the following information:

1. Objective of the test activity.
2. Background and justification to the test activity.
3. Identification of flight hardware or cleanroom facilities to be investigated (including state of controlled environment at rest and operation).
4. Description of test activity.
5. Deliverables.
6. Applied quality standards for microbiological laboratory.

A.2.2 Special remarks

None.

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