SLOVENSKI STANDARD
SIST EN 16602-70-56:2015

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Zagotavljanje varnih proizvodov v vesoljski tehniki - Zmanjšanje biološke obremenitve v parni fazi za letalsko strojno opremo

Space product assurance - Vapour Phase Bioburden Reduction for Flight Hardware

Raumfahrtproduktsicherung - Reduktion der Gesamtkeimzahl bei Dampfphase für Flughardware

Assurance produit des projets spatiaux - Réduction en phase gazeuse de la charge microbienne des matériels de vol

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ICS:

49.140	Vesoljski sistemi in operacije	Space systems and operations

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EUROPEAN STANDARD

NORME EUROPÉENNE

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English version

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This European Standard was approved by CEN on 16 November 2014.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN 16602-70-56:2015) has been prepared by Technical Committee CEN/CLC/TC 5 “Space”, the secretariat of which is held by DIN.

This standard (EN 16602-70-56:2015) originates from ECSS-Q-ST-70-56C.

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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.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 proper procedures for reducing the microbiological contamination on flight hardware are in place to meet the planetary protection constraints.

1
Scope

This standard specifies procedures for the reduction of microbiological contamination of flight hardware using hydrogen peroxide vapour.

The procedures specified in this standard cover:

- Reduction of microbiological contamination on exposed surfaces.
- Reduction of microbiological contamination in controlled ambient and vacuum environments.

This standard also specifies requirements for the conditioning of the flight hardware, bioburden reduction cycle development, and equipment to be used for applying a bioburden reduction procedure.

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

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 16601-40	ECSS-M-ST-40	Space project management - Configuration and information management
EN 16602-10-09	ECSS-Q-ST-10-09	Space product assurance - Nonconformance control system
EN 16602-70-53	ECSS-Q-ST-70-53	Space product assurance - Materials and hardware compatibility tests for sterilization processes
EN 16602-70-55	ECSS-Q-ST-70-55	Space product assurance - Microbial examination of flight hardware and cleanrooms
EN 16602-70-58	ECSS-Q-ST-70-58	Space product assurance - Bioburden control of cleanrooms
	IEST-STD-CC1246D	Institute of environmental science and technology - product cleanliness levels and contamination control program

3 Terms and abbreviated terms

3.1 Terms from other standards

For the purpose of this Standard, the terms and definitions from ECSS-S-ST-00-01 apply.

For the purpose of this Standard, the terms and definitions from ECSS-M-ST-40, ECSS-Q-ST-70-01, ECSS-Q-ST-70-55 and ECSS-Q-ST-70-58 apply, and in particular the following:

Bioburden

Bioburden reduction

Cleanliness level

Product item

3.2 Terms specific to the present standard

3.2.1 biological indicators

viable microorganisms providing a defined resistance to a specific process

NOTE The process is a hydrogen peroxide bioburden reduction.

3.2.2 controlled ambient conditions

1000 hPa pressure, temperature from 25 °C to 45 °C and relative humidity from 3 % to 50 %, as measured at 35 °C

3.2.3 controlled vacuum conditions

temperature from 25 °C to 45 °C and pressure from 1,3 hPa to 13,3 hPa

3.2.4 cycle

sequence of individual steps

NOTE For the purpose of this standard, the individual steps are preconditioning, bioburden reduction Ct-value and venting. Each step has associated control and monitoring parameters like time and hydrogen peroxide vapour concentration.

3.2.5 exposed surfaces

internal and external surfaces free for gas exchange

NOTE Examples: Free for gas exchange are e.g., exterior surfaces, interior surfaces of boxes with venting holes, surfaces of honeycomb cells, surfaces of the outer and inner plies of multi-layer insulation, open cell foam.

3.2.6 overkill

equivalent to a 12 order of magnitude bioburden reduction

3.2.7 parametric release

declaration that a product is at a certain bioburden level, based on records demonstrating that the process parameters were delivered within specified tolerances

NOTE Parametric release can be used for achieving bioburden reduction with heat (temperature and time record sufficient, no need for biological test) but is not acceptable for bioburden reduction using chemicals (biological test for process monitoring is mandatory).

3.2.8 positive control

testing the viability of biological indicators and the quality of the culture medium

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
BIs	biological indicators
cfu	colony forming unit
COSPAR	Committee on Space Research
Ct	time integrated (hydrogen peroxide) concentration
ESD	electrostatic discharge
L	litre (volume in controlled environment)
mg	milligram (hydrogen peroxide)
NCR	nonconformance report
sec	seconds

3.4 Nomenclature

The following nomenclature apply throughout this document:

a. The word “shall” is used in this standard to express requirements. All the requirements are expressed with the word “shall”.

b. The word “should” is used in this standard to express recommendations. All the recommendations are expressed with the word “should”.

NOTE It is expected that, during tailoring, all the recommendations in this document are either converted into requirements or tailored out.

c. The words “may” and “need not” are used in this standard to express positive and negative permissions respectively. All the positive permissions are expressed with the word “may”. All the negative permissions are expressed with the words “need not”.

d. The word “can” is used in this standard to express capabilities or possibilities, and therefore, if not accompanied by one of the previous words, it implies descriptive text.

NOTE In ECSS “may” and “can” have a complete different meaning: “may” is normative (permission) and “can” is descriptive.

e. The present and past tense are used in this standard to express statement of fact, and therefore they imply descriptive text.