



# SLOVENSKI STANDARD SIST EN 16602-70-58:2015

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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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### **ICS:**

13.040.35	Brezprašni prostori in povezana nadzorovana okolja	Cleanrooms and associated controlled environments
49.140	Vesoljski sistemi in operacije	Space systems and operations

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EUROPEAN STANDARD

EN 16602-70-58

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 49.140

English version

## 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

This European Standard was approved by CEN on 25 October 2014.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

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.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of 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 United Kingdom.

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## European foreword

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This document (EN 16602-70-58:2015) has been prepared by Technical Committee CEN/CLC/TC 5 "Space", the secretariat of which is held by DIN.

This standard (EN 16602-70-58:2015) originates from ECSS-Q-ST-70-58C.

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

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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.

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# 1 Scope

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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. (standards.iteh.ai)

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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## 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

## Terms, definitions and abbreviated terms

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### 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

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**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:

<b>Abbreviation</b>	<b>Meaning</b>
<b>AIV</b>	assembly, integration, and verification
<b>CFU</b>	colony forming unit
<b>COSPAR</b>	Committee On Space Research
<b>DHMR</b>	dry heat microbial reduction
<b>ESA</b>	European Space Agency
<b>ESD</b>	electrostatic discharge
<b>EGSE</b>	electrical ground support equipment
<b>FMECA</b>	failure mode effects and critical analysis
<b>GSE</b>	ground support equipment
<b>HEPA</b>	high efficiency particulate air
<b>HVAC</b>	heating, ventilation, air conditioning, and cooling
<b>IPA</b>	isopropyl alcohol (isopropanol)
<b>ISO</b>	International Organization for Standardization
<b>MGSE</b>	mechanical ground support equipment
<b>NASA</b>	National Aeronautics and Space Administration
<b>PP</b>	planetary protection
<b>WFI</b>	water for injection