



SLOVENSKI STANDARD
kSIST FprEN 16602-70-53:2014
01-julij-2014

Zagotavljanje varnih proizvodov v vesoljski tehniki - Preskušanje združljivosti materialov in strojne opreme za procese sterilizacije

Space product assurance - Materials and hardware compatibility tests for sterilization processes

Raumfahrtproduktsicherung - Kompatibilitätstests für Material und Hardware in Sterilisationsprozessen

Assurance produit des projets spatiaux - Essais de compatibilité des matériaux et matériels pour les processus de stérilisation

Ta slovenski standard je istoveten z: FprEN 16602-70-53

ICS:

11.080.99	Drugi standardi v zvezi s sterilizacijo in dezinfekcijo	Other standards related to sterilization and disinfection
49.140	Vesoljski sistemi in operacije	Space systems and operations

kSIST FprEN 16602-70-53:2014 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
FprEN 16602-70-53

April 2014

ICS

English version

Space product assurance - Materials and hardware compatibility tests for sterilization processes

Assurance produit des projets spatiaux - Essais de compatibilité des matériaux et matériels pour les processus de stérilisation

Raumfahrtproduktsicherung - Kompatibilitätstests für Material und Hardware in Sterilisationsprozessen

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/CLC/TC 5.

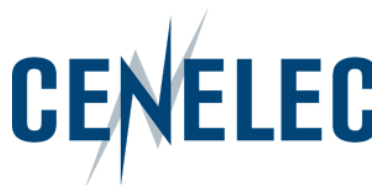
If this draft becomes a European Standard, CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN and CENELEC 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.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



**CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels**

Table of contents

Foreword	6
Introduction	7
1 Scope	8
2 Normative references	10
3 Terms, definitions and abbreviated terms	11
3.1 Terms from other standards.....	11
3.2 Terms specific to the present standard	11
3.3 Abbreviated terms.....	13
4 Principles	15
4.1 Introduction to sterilization processes	15
4.1.1 Overview	15
4.1.2 Dry heat	16
4.1.3 Beta or gamma radiation.....	16
4.1.4 Chemical sterilization	17
4.1.5 Steam sterilization.....	18
4.1.6 Main methods used and studied in the field of space application	18
4.2 Potential effects on hardware caused by sterilization.....	19
4.2.1 Direct effects	19
4.2.2 Indirect effects.....	19
4.2.3 Long duration effects.....	20
4.2.4 Technology risks	20
4.3 Qualification approach	20
5 Requirements	22
5.1 Specifying test	22
5.1.1 General provision	22
5.1.2 Specifying the test means	22
5.1.3 Specifying the test procedure	23
5.2 Preparing and performing test	24
5.2.1 General.....	24

5.2.2	Preparation of hardware.....	24
5.2.3	Pre and post tests	25
5.2.4	Sterilization test.....	26
5.3	Recording and reporting the test results	27
5.3.1	Test report	27
5.3.2	Test records.....	27
5.3.3	Acceptance criteria.....	27
Annex A (normative) Request for sterilization compatibility test - DRD		29
A.1	DRD identification.....	29
A.1.1	Requirement identification and source document.....	29
A.1.2	Purpose and objective.....	29
A.2	Expected response.....	29
A.2.1	Scope and content	29
A.2.2	Special remarks	29
Annex B (normative) Sterilization compatibility test specifications and procedures (Work Proposal) - DRD		30
B.1	DRD identification.....	30
B.1.1	Requirement identification and source document.....	30
B.1.2	Purpose and objective.....	30
B.2	Expected response.....	30
B.2.1	Scope and content	30
B.2.2	Special remarks	31
Annex C (normative) Sterilization compatibility test report - DRD		32
C.1	DRD identification.....	32
C.1.1	Requirement identification and source document.....	32
C.1.2	Purpose and objective.....	32
C.2	Expected response.....	32
C.2.1	Scope and content	32
C.2.2	Special remarks	33
Annex D (informative) Technology risks of sterilization.....		34
D.1	General.....	34
D.2	Polymer (organic) materials	34
D.2.1	Dry heat sterilization.....	34
	D.2.1.1. Overview.....	34
	D.2.1.2. Temperature limit	34
	D.2.1.3. Presence of air (oxidizing).....	35
	D.2.1.4. Phase change materials.....	35
D.2.2	Hydrogen peroxide sterilization	35

FprEN 16602-70-53:2014 (E)

D.2.3	γ-Radiation sterilization	36
D.3	Metallic materials	37
D.3.1	Dry heat sterilization	37
D.3.1.1	Precipitation hardened alloys	37
D.3.1.2	Low melting point	37
D.3.1.3	Memory shape alloys	37
D.3.2	Hydrogen peroxide sterilization	37
D.3.2.1	Oxidation	37
D.3.3	γ-Radiation sterilization	38
D.4	Ceramic materials	38
D.4.1	Dry heat sterilization	38
D.4.2	Hydrogen peroxide sterilization	38
D.4.3	γ-Radiation sterilization	38
D.5	Lubricants	38
D.5.1	Dry heat sterilization	38
D.5.2	Hydrogen peroxide sterilization	38
D.5.3	γ-Radiation sterilization	38
D.6	EEE components	39
D.6.1	Overview	39
D.6.2	Dry heat sterilization	39
D.6.3	Hydrogen peroxide sterilization	43
D.6.4	γ-radiation sterilization	47
D.7	Batteries	50
D.7.1	Overview	50
D.7.2	Dry heat sterilization	50
D.7.3	Hydrogen peroxide sterilization	50
D.7.4	γ-Radiation sterilization	50
D.8	Explosive devices	50
D.8.1	Overview	50
D.8.2	Dry heat sterilization	50
D.8.3	Hydrogen peroxide sterilization	51
D.8.4	γ-Radiation sterilization	51
D.9	Solar cell assemblies	51
D.9.1	Overview	51
D.9.2	Dry heat sterilization	51
D.9.3	Hydrogen peroxide sterilization	51
D.9.4	γ-Radiation sterilization	51
D.10	PCBs, populated	51
D.10.1	Overview	51

D.10.2	Dry heat sterilization.....	51
D.10.3	Hydrogen peroxide sterilization	52
D.10.4	γ -Radiation sterilization	52

Bibliography.....	53
--------------------------	-----------

Figures

Figure 4-1: Sterilization parameters.....	15
Figure 4-2: Test procedure flow diagram	21
Figure D-1 : Relative radiation stability of polymers (see ref 1).....	36

Tables

Table 4-1:Time/temperature equivalences for SAL 10^{-6}	16
Table 4-2: Main sterilization methods used for space missions	19
Table D-1 : Risk identification linked to dry heat sterilization.....	39
Table D-2 : Risk identification linked to hydrogen peroxide sterilization	43
Table D-3 : Risk identification linked to γ -radiation sterilization.....	47

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 16602-70-53:2015

<https://standards.iteh.ai/catalog/standards/sist/2ad84abc-c767-4ffb-8173-5ec4ceb63a1d/sist-en-16602-70-53-2015>

Foreword

This document (FprEN 16602-70-53:2014) has been prepared by Technical Committee CEN/CLC/TC 5 “Space”, the secretariat of which is held by DIN (Germany).

This document (FprEN 16602-70-53:2014) originates from ECSS-Q-ST-70-53C.

This document is currently submitted to the Unique Acceptance Procedure.

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 16602-70-53:2015](https://standards.iteh.ai/catalog/standards/sist/2ad84abc-c767-4ffb-8173-5ec4ceb63a1d/sist-en-16602-70-53-2015)

<https://standards.iteh.ai/catalog/standards/sist/2ad84abc-c767-4ffb-8173-5ec4ceb63a1d/sist-en-16602-70-53-2015>

Introduction

A properly formulated and executed test program for all hardware elements that have to undergo sterilization is essential to guarantee their nominal performance and to prevent any immediate or long-term detrimental effects.

The detrimental effects to be anticipated during sterilization depend on the applied process and include

- Direct effects: Materials degradation by heat, particulate and electromagnetic radiation, chemical interaction, cracking/fracture of materials or assemblies due to dimensional changes by expansion, out or off-gassing, etc.
- Indirect effects: Change in crystallinity of materials, accelerated ageing (e.g. burn-in of components), heating due to radiation, generation of secondary radiation, re-contamination after out or off-gassing, etc.
- Long-term effects: Generation of long-lived active centres (e.g. radicals) and subsequent post-degradation reactions, etc.

The objective of this Standard is to ensure a successful mission by the definition of a test protocol and acceptance criteria for the determination of hardware compatibility with sterilization processes.

<https://standards.it>

767-4ffb-8173-5ec4ceb63a1d/sist-en-16602-70-53-2015

1

Scope

This Standard describes a test protocol to determine the compatibility of materials, components, parts, and assemblies with sterilization processes. It is dedicated to test on non-flight hardware only. Any additional requirements that can be imposed by the potential use of test samples as flight hardware are not covered in this document (e.g. handling requirements). This Standard covers the following:

- Identification of critical test parameters to establish functional integrity of the hardware.
- Typical test protocols.
- Acceptance criteria.

Statements about compatibility of materials and components with sterilization processes in this document are made in general terms only. Other factors for determination of whether a material or component is suitable for a particular mission system application include:

- The potential number of sterilization cycles to which the material/component will be subjected in their live cycle.
- The additional stresses on materials/components introduced when they have become part of a larger unit/equipment/system undergoing sterilization.
- Compatibility of sterilization processes at e.g. materials level. This compatibility does not automatically guarantee that it will perform to its requirements in an assembly. The final application and possible interactions at higher assembly level are important considerations for qualification.
- Qualification of hardware achieved by specific sterilization parameters. They cannot be necessarily extrapolated to other sterilization parameters, not even within the same sterilization process.
- The drift in performance that can be induced by sterilization processes. This drift can cause equipments to fail to meet their specified performance requirements, even though each individual element/component remains within spec. An example of this is where 'Select-on-test' components are used to operate a component over a critically narrow range its full performance.

To assess ultimately the suitability/compatibility of a material or component for an application requires a full consideration of the impact of sterilization

processes to which it is subjected during its whole life. This includes sterilization processes it undergoes from the time it is a standalone component/material right through to when it experiences final sterilization as part of the complete system.

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 16602-70-53:2015](https://standards.iteh.ai/catalog/standards/sist/2ad84abc-c767-4ffb-8173-5ec4ceb63a1d/sist-en-16602-70-53-2015)

<https://standards.iteh.ai/catalog/standards/sist/2ad84abc-c767-4ffb-8173-5ec4ceb63a1d/sist-en-16602-70-53-2015>

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

Terms, definitions and abbreviated terms

3.1 Terms from other standards

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

3.2 Terms specific to the present standard

3.2.1 direct effect

change of an intrinsic materials property that is caused by the interaction with a process parameter during application of a sterilization process

NOTE A direct effect might not be observed immediately after sterilization, but can be manifested over longer duration, see also 'long duration effect'.

3.2.2 D-value, D₁₀ value

time or dose required to achieve inactivation of 90 % of a population of the test micro-organism under stated conditions

[ISO 11139]

3.2.3 exposure time

period for which the process parameters are maintained within their specified tolerances

[ISO 11139]

3.2.4 indirect effect

effect that is not manifested as change in an intrinsic materials property but is the consequence of secondary interactions

NOTE Typical examples include molecular contamination during chemical sterilization, formation of radiolysis gas during γ -sterilization, bond breakage due to CTE mismatch during thermal sterilization.

effect that is caused by the interaction with a non-process parameter after application of a sterilization process

FprEN 16602-70-53:2014 (E)

NOTE 1 A typical example is post degradation because of interaction of oxygen from air with 'active' centres generated during the sterilization process.

NOTE 2 An indirect effect might not be observed immediately after sterilization, but can be manifested over longer duration, see also 'long duration effect'.

3.2.5 long duration effect

direct or indirect effect that is not manifested immediately after sterilization or post materials investigation but only after longer duration

NOTE 1 Typical examples are slow cross-linking of active centres and embrittlement of materials after γ -sterilization or induced corrosion followed from chemical conversion after chemical sterilization.

NOTE 2 The time period after which long-duration effects become observable is materials and process specific, it can be as quick as days or as slow as years.

3.2.6 micro-organism

entity of microscopic size, encompassing bacteria, fungi, protozoa and viruses
[ISO 11139]

3.2.7 process parameter

specified value for a process variable

NOTE The specification for a sterilization process includes the process parameters and their tolerances.

[ISO 11139]

3.2.8 sterility

state of being free from viable micro-organisms

NOTE 1 In practice, no such absolute statement regarding the absence of micro-organisms can be proven.

NOTE 2 The definition of sterility in the context of this standard refers to the achievement of a required sterility assurance level.

[adapted from ISO 11139]

3.2.9 sterility assurance level

probability of a single viable micro-organism occurring on an item after sterilization

NOTE The term SAL takes a quantitative value, generally 10^{-6} or 10^{-3} . When applying this quantitative value to assurance of sterility, an SAL of 10^{-6} has a lower value but provides a greater assurance of sterility than an SAL of 10^{-3} .

[ISO 11139]

3.2.10 sterilization

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

NOTE In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a micro-organism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[ISO 11139]

3.2.11 sterilization process

series of actions or operations needed to achieve the specified requirements for sterility

NOTE This series of actions includes pre-treatment of product (if necessary), exposure under defined conditions to the sterilizing agent and any necessary post treatment. The sterilization process does not include any cleaning, disinfection or packaging operations that precede sterilization.

[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
CTE	coefficient of thermal expansion
DSM	Deutsche Sammlung von Mikroorganismen (German Collection of Microorganisms)
DML	declared materials list
DMPL	declared mechanical parts list
DPL	declared process list
EEE	electrical, electronic, electromechanical
ESCC	European Space Components Coordination