SLOVENSKI STANDARD
SIST EN 16602-70-53:2015

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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

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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

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Foreword

This document (EN 16602-70-53:2015) has been prepared by Technical Committee CEN/CLC/TC 5 “Space”, the secretariat of which is held by DIN.

This standard (EN 16602-70-53:2015) originates from ECSS-Q-ST-70-53C.

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of an identical text or by endorsement, at the latest by July 2015, and conflicting national standards shall be withdrawn at the latest by July 2015.

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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

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.

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 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 16602-20-07	ECSS-Q-ST-20-07	Space product assurance – Quality assurance for test centres

3
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, D_{10} 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

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