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STN	**Zabezpečovanie výrobkov kozmického programu. Skúšky kompatibility materiálov a konštrukčných častí pre sterilizačné postupy.**	**STN EN 16602-70-53** 31 0542

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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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 European Standard was approved by CEN on 18 October 2014.

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

Table of contents

Figures

Tables

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of an identical text or by endorsement, at the latest by July 2015, and conflicting national standards shall be withdrawn at the latest by July 2015.

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

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