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Standards

Irish Standard  
I.S. EN 16602-70-53:2015

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

**I.S. EN 16602-70-53:2015**

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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

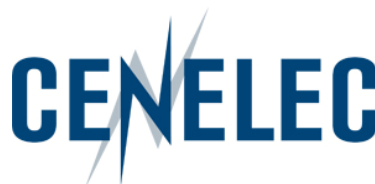
Raumfahrtproduktsicherung - Kompatibilitätstests für Material und Hardware in Sterilisationsprozessen

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## Table of contents

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<b>Foreword</b> .....	<b>6</b>
<b>Introduction</b> .....	<b>7</b>
<b>1 Scope</b> .....	<b>8</b>
<b>2 Normative references</b> .....	<b>10</b>
<b>3 Terms, definitions and abbreviated terms</b> .....	<b>11</b>
3.1 Terms from other standards.....	11
3.2 Terms specific to the present standard .....	11
3.3 Abbreviated terms.....	13
<b>4 Principles</b> .....	<b>15</b>
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
<b>5 Requirements</b> .....	<b>22</b>
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
<b>Annex A (normative) Request for sterilization compatibility test - DRD.....</b>		<b>29</b>
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
<b>Annex B (normative) Sterilization compatibility test specifications and procedures (Work Proposal) - DRD .....</b>		<b>30</b>
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
<b>Annex C (normative) Sterilization compatibility test report - DRD.....</b>		<b>32</b>
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
<b>Annex D (informative) Technology risks of sterilization.....</b>		<b>34</b>
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

## EN 16602-70-53:2015 (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	$\gamma$ -Radiation sterilization .....	52

<b>Bibliography.....</b>	<b>53</b>
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## 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 $\gamma$ -radiation sterilization .....	47

## Foreword

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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).

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## **Introduction**

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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

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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

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