

# DIN EN 16602-70-53:2015-05 (E)

## Space product assurance - Materials and hardware compatibility tests for sterilization processes; English version EN 16602-70-53:2015

---

<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

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

<b>Bibliography.....</b>	<b>53</b>
--------------------------	-----------

**Figures**

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

**Tables**

Table 4-1:Time/temperature equivalences for SAL 10 <sup>-6</sup> .....	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