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

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

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 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^{-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