ECSS-Q-ST-70-53C
15 November 2008

Space product assurance

Materials and hardware compatibility tests for sterilization processes

ECSS Secretariat
ESA-ESTEC
Requirements & Standards Division
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Foreword

This Standard is one of the series of ECSS Standards intended to be applied together for the management, engineering and product assurance in space projects and applications. ECSS is a cooperative effort of the European Space Agency, national space agencies and European industry associations for the purpose of developing and maintaining common standards. Requirements in this Standard are defined in terms of what shall be accomplished, rather than in terms of how to organize and perform the necessary work. This allows existing organizational structures and methods to be applied where they are effective, and for the structures and methods to evolve as necessary without rewriting the standards.

This Standard has been prepared by the ECSS-Q-70-53 Working Group, reviewed by the ECSS Executive Secretariat and approved by the ECSS Technical Authority.

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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.

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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.

ECSS-S-ST-00-01	ECSS system – Glossary of terms
ECSS-Q-ST-20	Space product assurance – Nonconformance control system
ECSS-Q-ST-20	Space product assurance – Quality assurance
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

ETFE	ethylene tetrafluoroethylene
ETO	ethylene oxide
GSE	ground support equipment
HDPE	high density polyethylene
IPA	isopropyl alcohol
ISO	International Organization for Standardization
LDPE	low density polyethylene
MIL-DTL	military detail specification
MIL-PRF	military performance specification
PCB	printed circuit board
PEEK	polyetheretherketone
PET	polyethylene terephthalate
PI	polyimide
POM	polyoxymethylene
PP	polypropylene
PPS	polyphenylene sulfide
PTFE	polytetrafluoroethylene
PUR	polyurethane
PVF	polyvinyl fluoride
OIT	oxygen induction time
OITP	oxygen induction temperature
SAL	sterility assurance level
UV	ultraviolet

4
Principles

4.1 Introduction to sterilization processes

4.1.1 Overview

Sterilization is a process killing all microorganisms. If there are survivors it is a bioburden reduction method. Sterilization processes are qualified in terms of probability to find one reference microorganism after their application, using the common and most resistant organism with respect to the sterilization method, named the SAL (Sterility Assurance Level). Independently of the method used - radiation, heat, gas - the reduction of microorganisms in time is in general a logarithmic curve, and follows ideally a straight line in a log diagram (see Figure 4-1). The sterilization parameter typically used for each process is D_{10}, the time necessary to divide the microbial population by a factor of ten (10% survivor, also commonly called 1 log reduction, or one decimal reduction). Knowing the initial population (for example 10^4 microorganisms) and the specification to reach (for example SAL 10^{-6}, meaning one microorganism for 10^6 items, or a 10^{-6} probability to find one microorganism on an item), the duration/dose will be 10 x D_{10}. A 6 log reduction is the typical SAL for medical applications.

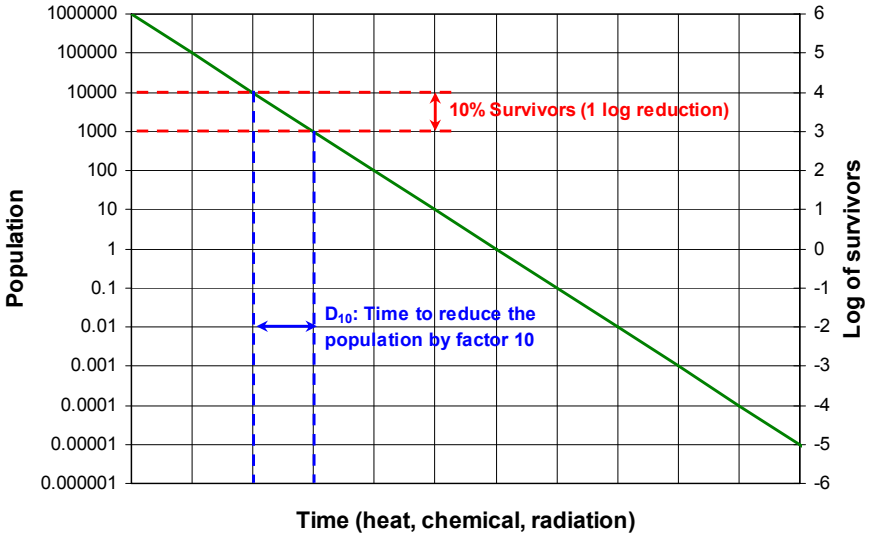

Figure 4-1: Sterilization parameters

In the following clauses a selection of potential sterilization processes for space hardware are described.

4.1.2 Dry heat

Dry heat is a bulk sterilization method. The effects of thermal sterilization on microorganisms depend on temperature, humidity and time. Typical parameters used for medical sterilization are given in Table 4-1. Qualified sterilization parameters to be used on flight hardware can deviate from these parameters. A typical microbiological indicator (most resistant of common microorganisms to dry heat) contains the spore *B. atrophaeus* DSM 675. The minimal temperature is 110 °C, below that the sterilization efficiency is considered insufficient. The maximum humidity level is 1.2 g/m^3 water, otherwise the process is not considered as dry heat.

Depending on the specification, other temperature and time combinations can be used, validated via microbiological indicators. Thermal studies and tests may be necessary for large volumes and for complex equipment in order to homogenize as far as possible the temperature of the equipment.

Table 4-1:Time/temperature equivalences for SAL 10^{-6}

T (°C)	D-value (h)
110	22
120	10
125	6
130	4
140	2
150	1

4.1.3 Beta or gamma radiation

Radiation is one of the most usual bulk sterilization processes used for medical devices. The typical dose for medical application is 25 kGy determined for the reference microorganism named *B. pumilus* DSM 492. Depending on the specification, other radiation doses can be used, validated via microbiological indicators.

Gamma rays are photons emitted from high activity radioactive cobalt 60 sources, a few 10^7 GBq usually, for a half life period of 5,27 years. The photon energies (1,17 and 1,33 MeV) are able to penetrate into several centimetres of steel. Beta radiations are electrons produced by particle generators and accelerators (30kV max). The electron energy, between 1 and 10 MeV max in order to avoid to break atom nuclei, allows a penetration depth of a few millimetre of steel. Compared to gamma radiations requiring minutes to hours of exposition, the dose rate of the beta process is very high and achieves a sterilization in only a few seconds to a few minutes.

Radiation sterilization is generally achieved inside a special blockhouse protecting, outside, the operators and the environment. In order to homogenize the radiation dose, the item is e.g. rotated around the source or revolved around one or two rotational axis. The dose and the dose rate are a function of the source activity and of the distance between the source and the sample.

4.1.4 Chemical sterilization

4.1.4.1 Overview

All kinds of chemical methods, using gas or liquid agents, are limited to sterilization of surfaces accessible for gas exchange. These processes are generally applied at temperatures below 60 °C.

4.1.4.2 Hydrogen peroxide (H_2O_2) sterilization

This method is known for its high degree of compatibility with high tech medical and surgical devices and instruments. The plasma phase destroys residual hydrogen peroxide before release of sterilized items. Methods using hydrogen peroxide gas without plasma are regarded as equally effective. Control of process parameters (humidity, pressure, gas concentration, time and temperature) is important.

Typical process parameters are the following:

- Temperature: Typically (40 – 60) °C
- Gas concentration typically between (4 - 10) g/m3 H_2O_2 in gas phase
- Pressure: Ambient or mixed (vacuum/ambient) cycles
- Duration typically 1 hour per cycle

Typical bioindicators for verification of the SAL for medical devices contain the *B. Stearothermophilus* DSM 5934. Gas sterilization methods are in general not suitable for parametric release.

4.1.4.3 Ethylene oxide (C_2H_4O)

This process results in extremely effective sterilization, using clearly established procedures. It is carried out in a closed medium (autoclaves) equipped with a gas stirring system. Typical parameters with an impact on the effectiveness of such sterilization are the following:

- Temperature: 40 °C to 70 °C generally in a slightly depressurized atmosphere
- Gas concentration of nominally between (5 - 8) g/m^3 of pure gas (15 g/m^3 max)
- Relative humidity of minimum 30 %
- Duration usually between 6 and 14 hours.

Typical bioindicators for verification of the SAL for medical devices contain typically the *B. atrophaeus* DSM 675 and *B. Stearothermophilus* DSM 5934.

In addition, after the sterilization process, sterile objects are taken into a warm-air desorption chamber (temperature 50 °C to 70 °C) for drawing out of virtually all residual gas that has diffused into or absorbed by the items or constituent materials (max. 2 ppm residual gas level specified for medical sterilization).

Due to the formation of non-volatile residues this sterilization poses a risk to contamination critical hardware.

4.1.4.4 Isopropyl alcohol

IPA (isopropanol) is the typical surface cleaning agent. It is not sporicidal, but a disinfectant (if applied in (60 – 70) % with water), but can be used in order to remove a large number of microorganisms from surfaces. IPA cleaning is usually used on space hardware, not only for biological cleanliness, and does not present particular incompatibilities. Without filtering alcohols are generally not sterile. In order to increase the bioburden reduction efficiency, sporicides can be used as for example alcohol containing a few percents of hydrogen peroxide or formaldehyde.

4.1.5 Steam sterilization

It is performed in autoclave in overpressure, at 100% of humidity, and therefore limited to sterilization of surfaces accessible for gas exchange. The efficiency depends on temperature, time and pressure (generally at 2 bar), typical procedures used for medical application require 20 minutes for 120 °C and 3 minutes for 134 °C. The sterilization effect is limited to surface.

Although not intended for flight hardware, steam sterilization can be a very useful process for e.g. GSE and tools.

4.1.6 Main methods used and studied in the field of space application

A summary of sterilization methods used for previous Mars missions is given in Table 4-2.

Table 4-2: Main sterilization methods used for space missions

Type	Methods	Sterilization type		Heritage	
		Surface	Bulk	Studied	Studied and used
CHEMICAL	Formaldehyde gas	X	--	Space components (US 1968)	--
	Ethylen oxide (EtO)	X	--	--	Ranger 1961/62
	Sporicidal solution (TBD)	X	--	Mars 96	Mariner Mars 1971
	Hydrogen peroxide	X	--	--	Mars96, Beagle2, DS2
THERMAL	Dry Heat	X	X	--	Viking, Mars96, Pathfinder, Beagle2, MER, Phoenix, MSL
STEAM	Steam (space hardware excluded)	X	--	--	Excluded on space h/w, only GSE, garments
RADIATIVE	Gamma / Beta radiations	X	X	--	Mars96, Beagle2

4.2 Potential effects on hardware caused by sterilization

4.2.1 Direct effects

Changes of intrinsic materials properties as a consequence of the interaction with a process parameter from a sterilization process can depend on a variety of parameters, e.g. environment, material, assembly state, time, post environment. A direct effect might not be observed immediately after sterilization, but can be manifested over longer duration (see clause 4.2.3)

4.2.2 Indirect effects

Indirect effects can be caused by different mechanisms and are here classified into two categories:

- Effects that are the consequence of secondary interactions. Typical examples include molecular contamination during chemical sterilization, formation of radiolysis gas during γ-sterilization, bond breakage due to CTE mismatch during thermal sterilization.
- Effects that are caused by the interaction with a non-process parameter after application of a sterilization process. A typical example is post degradation because of interaction of oxygen from air with 'active' centres generated during the sterilization process.

An indirect effect might not be observed immediately after sterilization, but can be manifested over longer duration, see also 'long duration effect'.

4.2.3 Long duration effects

Direct or indirect effects may not be manifested immediately after sterilization or post materials investigation but only after longer duration up to several years. 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.

4.2.4 Technology risks

A summary of technology risks is given in Annex D for guidance and preliminary assessment. The information provided within this Annex gives an overview of compatibility risks. It is a non-exhaustive list and the actual risk of degradation can deviate. Qualification cannot be deduced from this table and is evaluated on a case by case basis. Some means of risk mitigation are summarized below in case of incompatibility:

- Replacement, e.g. change of material or component.
- Redesign, e.g. use of fasteners instead of adhesives.
- Sterilization on lower assembly level (if possible) and aseptic assembly.
- Change of sterilization process.

  NOTE If the alternative to dry heat sterilization (bulk) results in the application of a surface sterilization process, the remaining presence of bulk bioburden can be an issue for the overall bioburden of the spacecraft

- Waiving sterilization.

  NOTE Non-sterilized items can be used taking into account a conservative assessment of the present bioburden based on the applicable planetary protection requirements.

4.3 Qualification approach

As a consequence of potential detrimental effects on sterilized items (see clause 4.2), qualification of hardware is starting from materials/components level up to higher assembly level as appropriate. The qualification test flow diagram is shown in Figure 4-2.

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.

Compatibility of sterilization processes on e.g. materials level does not automatically guarantee that it performs to its requirements in an assembly. The final application and possible interactions on higher assembly level are important considerations for qualification.

Qualification of hardware achieved by specific sterilization parameters cannot be necessarily extrapolated to other sterilization parameters, not even within the same sterilization process.

Clause 5.1 provides the specification for the qualification of items for sterilization processes.

Clause 5.2 and 5.3 provide the requirements for preparing, performing, recording and reporting the qualification test.

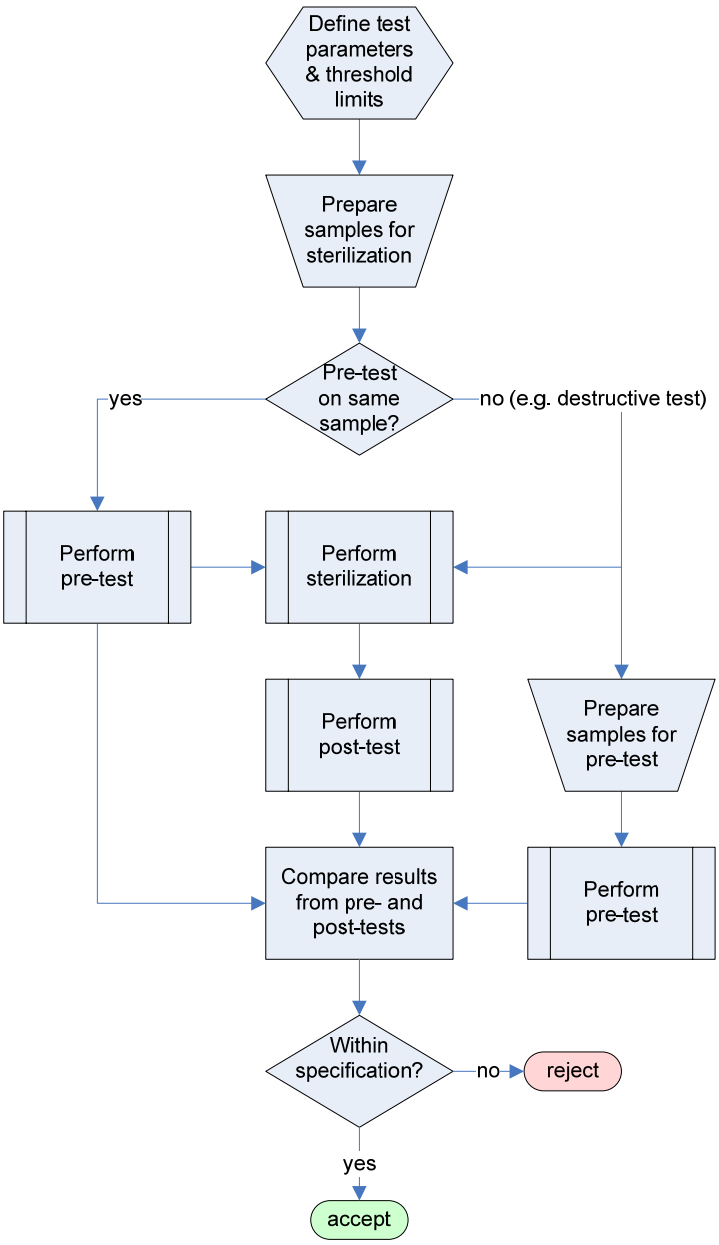

Figure 4-2: Test procedure flow diagram for sterilization

5
Requirements

5.1 Specifying test

5.1.1 General provision

a. The customer shall provide a request for a sterilization test in conformance with Annex A.

b. ECSS-Q-ST-20 shall be made applicable in the request for sterilization testing.

c. ECSS-Q-ST-10-09 shall be made applicable in the request for sterilization testing.

d. For safety and security, the test centre shall comply with ECSS-Q-ST-20-07, clause 9.

NOTE Examples of safety issues are hazard and health. Example of security issues is access control.

e. The supplier shall provide a sterilization compatibility test proposal in conformance with Annex B.

5.1.2 Specifying the test means

5.1.2.1 Facilities

a. The work area shall be at a cleanliness level that does not compromise the functionality of the test items or fulfil the imposed cleanliness requirements of the hardware.

b. The ambient conditions for the work areas shall be (22 ± 3) °C with a relative humidity of (55 ± 10) % unless otherwise stated.

c. The supplier shall use sterilization facilities as described in Annex B.

NOTE 1 Dry heat sterilization is described in ECSS-Q-ST-70-57, vapour phase (e.g. hydrogen peroxide) sterilization is described in ECSS-Q-ST-70-56.

NOTE 2 Sterilization compatibility tests need to be conducted with the same process parameters intended for the flight hardware. For example

compatibility with dry heat sterilization under ambient pressure does not compare to a vacuum process because of differences in thermal gradients.

5.1.2.2 Equipment

a. The supplier shall identify and specify the list of the equipment necessary to set up and run the approved test procedures.

5.1.3 Specifying the test procedure

5.1.3.1 Test procedure

a. The test procedures shall address the test conditions, control and monitoring of:

   1. Process parameters for sterilization.

      NOTE Required process parameters for dry heat sterilization are described in ECSS-Q-ST-70-57, and for vapour phase (e.g. hydrogen peroxide) sterilization are described in ECSS-Q-ST-70-56.

   2. SAL.

   3. Contamination.

b. The test procedure for controlling and monitoring the process parameters shall contain the following information:

   1. Process parameter measurement and recording methods.

   2. Process parameter acquisition during testing.

5.1.3.2 Controlling sterilization efficiency

a. In case of requirements to prove the sterilization efficiency (SAL), appropriate microbiological indicators shall be incorporated during sterilization and the following information provided for the test procedure:

   1. Microbiological indicator used during tests.

   2. SAL results.

      NOTE 1 Bioburden assessment procedures are described in ECSS-Q-ST-70-55.

      NOTE 2 Required microbiological indicators for dry heat sterilization are described in ECSS-Q-ST-70-57, and for vapour phase (e.g. hydrogen peroxide) sterilization are described in ECSS-Q-ST-70-56.

      NOTE 3 Besides the use of microbiological indicators, validation of process parameters can be used to

verify SAL, in case the sterilization process is parametric (post parametric verification).

5.1.3.3 Controlling the contamination

a. In case of cleanliness requirements of the hardware to be tested, contamination effects shall be controlled and the following information provided for the test procedure:

   1. Contamination assessment methods used during tests.
   2. Contamination results.

      NOTE Contamination can be induced by the sterilization process, e.g. in case of gas phase sterilization.

5.2 Preparing and performing test

5.2.1 General

a. The customer shall approve the sterilization compatibility test proposal including the procedures.

b. ECSS-Q-ST-20 shall apply for the establishment of the test procedures.

5.2.2 Preparation of hardware

5.2.2.1 Configuration

a. The material samples shall be prepared according to the relevant process specifications or manufacturer's data, representative for its end-function and the flight hardware (e.g. batch).

b. Assemblies shall be representative for its end-function and the flight hardware.

c. If it is not possible to test completed assemblies, the manufacturer shall submit samples made from the same materials and by the same processes, sequence and configuration as those used in the manufacture of the assemblies, representative for its end-function and the flight hardware.

5.2.2.2 Cleaning

a. The cleaning and other treatments of the sample shall be the same as that applied to the flight hardware, which the sample is intended to represent, prior to integration into the spacecraft.

b. Further cleaning or other treatments require customer approval.

5.2.2.3 Handling and storage

a. Samples shall be handled with clean nylon or lint free gloves.

b. Storage of samples shall be performed in a controlled area, with an ambient temperature of (22 ± 3) °C and relative humidity of (55 ± 10) % unless stated otherwise.

c. Physical damage during storage shall be avoided by packing the items in clean, dust and lint free material.

d. Limited-life materials shall be labelled with their shelf lives and dates of manufacture.

NOTE For handling and storage of sterilized items refer to ECSS-Q-ST-70-57 (dry heat) and ECSS-Q-ST-70-56 (vapour phase).

5.2.2.4 Conditioning of hardware

a. Special conditioning required by the customer for the end-use shall be implemented.

NOTE Without representative conditioning the results of the test are not valid. For example the humidity content of a small witness sample that conditions much quicker cannot represent the conditions at use of full-sized flight hardware that has been packed and sealed after sterilization.

5.2.2.5 Identification

a. Items submitted for testing shall be labelled to be uniquely identifiable.

b. Labels attached prior sterilization shall be legible after the process.

NOTE A label can be degrading during the sterilization process and possibly affect the performance of the sterilized item (e.g. contamination, adherence to packaging).

c. Labelling shall contain as a minimum:

1. Identification of item.
2. Sterilization process.
3. Date and contact information.
4. Precaution and warning when applicable.

5.2.3 Pre and post tests

a. The inspection and test methods as well as the relevant parameters to verify the functionality of equipment after sterilization shall be specified by the customer before the application of each sterilization process.

NOTE The extent of physical, chemical, mechanical or electrical properties to be verified before and after sterilization depend on the intended application of the hardware (e.g. materials, components, parts, and assemblies).

b. For mechanical testing or other forms of destructive analysis, representative samples for the hardware shall be supplied for comparison of results before and after sterilization.

c. The samples for pre and post tests shall be provided from the same manufacturing batch.

5.2.4 Sterilization test

a. The supplier shall run the approved sterilization test procedures as described in Annex B.

b. All sterilization processes shall be performed in non-operational mode.

c. The sequence of sterilization with other hardware tests shall be defined by the customer.

d. The process parameters for sterilization, shall be defined by the customer.

NOTE The processes for dry heat and vapour phase (e.g. hydrogen peroxide) sterilization are described in ECSS-Q-ST-70-57 and ECSS-Q-ST-70-56 respectively.

e. The specified sterilization time shall start after all surfaces of a hardware item are exposed to the minimum sterilization condition.

NOTE 1 Examples of sterilization conditions are: Temperature, radiation dose, or chemical reagent.

NOTE 2 Sterilization is a time dependent process.

f. Margin for number of sterilization cycles: The need of multiple sterilization shall be foreseen.

g. The number of sterilization cycles for specified hardware shall be defined by the customer.

NOTE The number can vary for different hardware items.

h. The time delay between two sterilization cycles as well as the storage conditions shall be defined by the customer.

NOTE Sterilization, independent of whether achieved by physical or chemical means, can cause the formation of 'hot' (reactive) centres in materials. These sites can be long-lived and can result in secondary degradation effects (see clause 4.2). The simulation of several sterilization cycles cannot be achieved by simple extension of the sterilization time, but

should take into account the complete process protocol as well as interaction with the external environment (e.g. different humidity levels) and possibly secondary effects.

5.3 Recording and reporting the test results

5.3.1 Test report

a. The supplier shall apply ECSS-Q-ST-20, clause 5.6.3.2 for the establishment of the test report.

b. The supplier shall provide the sterilization compatibility test report in conformance with Annex C for customer approval.

5.3.2 Test records

a. The test records of the sterilization test shall be retained for, at least, ten years or in accordance with customer requirements.

b. The test records of the sterilization test shall be composed of:

1. The request for sterilization compatibility testing.
2. The sterilization compatibility test proposal.
3. The sterilization compatibility test report.
4. A conclusion with respect to the compliance with the customer requirements (acceptance criteria) and associated nonconformances.

5.3.3 Acceptance criteria

a. Acceptance criteria shall be defined (beforehand) in common agreement between the test authority and the customer.

b. Traceability shall be maintained throughout the process from incoming inspection to final measurements and calculations, including details of the test equipment and personnel employed in performing the task.

c. Samples which have been tested and are not degraded within the defined limits by the execution of the approved sterilization test procedures shall be considered as having passed this test.

NOTE See clause 5.2.3.

d. The acceptance limits of degradation shall be allocated by the customer as part of the overall degradation budget including e.g. accumulation effects.

e. Synergistic or long-term degradation effects shall be considered if appropriate.

NOTE For example, parachute, airbags.

f. Stability of critical items during long term storage after sterilization shall be monitored by representative witness samples.

g. Drift of performance properties shall be taken into account if appropriate.

NOTE Drift can cause equipments to fail to meet their specified performance requirements, even though each individual element/component remains within specification. An example of this is where 'Select-on-test' components are used to operate a component over a critically narrow range its full performance.

Annex A (normative) Request for sterilization compatibility test - DRD

A.1 DRD identification

A.1.1 Requirement identification and source document

This DRD is called from ECSS-Q-ST-70-53, requirements 5.1.1a.

A.1.2 Purpose and objective

The purpose of the request for sterilization compatibility testing is to confirm that the materials to be evaluated are acceptable for use

- with respect to the specific sterilization test requirements of the customer, and
- prior to its validation and approval for selection as item of the "as designed" DML, DPL or DMPL depending on the nature of the item to be tested (e.g. materials, processes or parts) .

A.2 Expected response

A.2.1 Scope and content

a. The Request for sterilization compatibility testing shall include or refer to the following information:
   1. Objective of the test activity.
   2. Background and justification to the test activity.
   3. Items to be investigated.
   4. Description of test activity.
   5. Deliverables.

A.2.2 Special remarks

None.

Annex B (normative) Sterilization compatibility test specifications and procedures (Work Proposal) - DRD

B.1 DRD identification

B.1.1 Requirement identification and source document

This DRD is called from ECSS-Q-ST-70-53, requirements 5.1.1e.

B.1.2 Purpose and objective

The work proposal is a document that defines the test activity for sterilization compatibility of materials and hardware proposed by the test house. The work proposal for sterilization compatibility testing for materials and hardware is prepared by the test house, which is responsible for the test activity, and it is submitted to the customer for review and approval.

B.2 Expected response

B.2.1 Scope and content

a. The WP shall include or refer to the following information:

1. A proposed work description giving:

(a) The objectives of the test activity.

(b) Test facilities, test procedures and reference to standards.

NOTE This includes, for example, sources.

(c) Traceable identification of items, materials, hardware.

(d) Test conditions.

NOTE I.e. environment, properties evaluated and measurement techniques.

(e) Expected test output.

2. A proposed settlement describing the test procedures and any deviation from the conditions initially requested by the customer

b. A financial and administrative proposal including:

(a) Responsible person for the activity.

(b) List of deliverable items.

(c) Work breakdown structure defining the required operations and responsibilities.

NOTE I.e. preparation of specimens, testing, evaluation of results, reporting.

(d) Time schedule.

(e) Travel and subsistence plan (if applicable).

(f) Itemized cost list.

(g) Milestone payment plan.

B.2.2 Special remarks

None.

Annex C (normative)
Sterilization compatibility test report - DRD

C.1 DRD identification

C.1.1 Requirement identification and source document

This DRD is called from ECSS-Q-ST-70-53, requirements 5.3.1b.

C.1.2 Purpose and objective

The purpose of the sterilization compatibility test report is to provide quantitative evidence that the items were tested according to the sterilization compatibility test specifications and procedures.

C.2 Expected response

C.2.1 Scope and content

a. The sterilization compatibility test report shall include or refer to the following information:

1. Description of the purpose, objective, content and the reason prompting its preparation.
2. Description of the sterilization test facility.
3. Description of the items to be tested or a reference to the document containing its identification characteristics.

   NOTE For example: request for sterilization compatibility testing.
4. Calibration tools.
5. The test procedure or a reference to the document containing the description of the test procedure.

   NOTE 1 For example: sterilization compatibility test specifications and procedures DRD.

   NOTE 2 It often consist in describing the as- run test procedure as well as any deviation from the

initial test procedure (including a discussion of possible effect on test).

6. NCRs.
7. Sterilization process parameters.
8. The test results.
9. Discussion about the test s results.
10. Conclusion and recommendations.

b. Test records shall be made available in electronic form for incorporation in a database defined by the customer, and contain as a minimum the following:

1. Manufacturer.
2. Traceable identification numbers for sterilised items.

   NOTE For example: batch number, serial number.

3. Sample description (type of application, size, colour, number of samples).
4. Material name (trade name).
5. Chemical nature.
6. Thermal history / process parameters (for general materials property field).
7. Intended application.
8. Sterilization method, apparatus/facility, date.
9. Nominal/measured sterilization parameters (e.g. temperature, radiation dose, gas concentration).
10. Pre and post conditioning/storage parameters.
11. Pre- and post sterilization values of test parameters defined in 5.2 including date of tests.
12. Occurrence of NCRs.
13. Copy of the final inspection documentation (attached docs in new tab).
14. Copy of test reports (attached docs in new tab).

C.2.2 Special remarks

None.

Annex D (informative) Technology risks of sterilization

D.1 General

A review of technology risks for space hardware sterilization has been carried out to indicate known detrimental effects. The evaluation is limited to the following typical processes:

- Dry heat sterilization (typically 125 °C/48 h, 135 °C/12 h) considering multiple processes
- Hydrogen peroxide sterilization (typically 4-10 mg/L H_2O_2 in gas phase, max 60 °C/40 min)
- γ-Radiation sterilization (typically 25 kGy = 2,5 Mrad)

The described effects might not only lead to directly observed failures but can also cause indirect effects that are only manifested with the combined interaction of another environment such as solar irradiation or thermal cycling.

It is clear that such a review cannot be entirely exhaustive and does not provide sufficient information to omit appropriate qualification. Any piece of hardware (e.g. material, component, assembly) should be considered on its own within its individual boundary conditions.

D.2 Polymer (organic) materials

D.2.1 Dry heat sterilization

D.2.1.1. Overview

In case of dry heat sterilization it is important to recognize that it is not only the thermal environment that can affect hardware, but also that most commonly the process is performed with air, and thus provides a potentially oxidizing condition.

D.2.1.2. Temperature limit

A good indication of a material's susceptibility to higher temperature is the qualification limit, but the presence of air should be considered in addition (see clause D.2.1.3). Otherwise potential damage can be caused by crossing a glass transition temperature, by reaching a decomposition temperature (e.g.

polyurethanes ~150 °C), colourization (e.g. thermal control coatings), by mechanical stress due to CTE effects, etc.

In general the dry-heat sterilization process can be considered to induce accelerated ageing.

D.2.1.3. Presence of air (oxidizing)

The presence of oxygen during the dry heat sterilization process can lead to surface oxidation causing embrittlement and increase of hardness (e.g. seals), and colorization (e.g. thermal control coatings).

A thermal analysis screening test (e.g. differential scanning calorimetry) can be performed to assess the susceptibility of materials for oxidation by establishing the oxygen induction temperature (OITP) or oxygen induction time (OIT). The OITP is the temperature above which a rapid oxidation is observed, the OIT is the time after which the oxidation becomes significant for a given temperature.

D.2.1.4. Phase change materials

Sharp phase transitions induced by temperature can be used for actuation in various mechanisms. The thermal environment during sterilization can damage such devices.

D.2.2 Hydrogen peroxide sterilization

- Some resins are known to react with hydrogen peroxide, e.g. it can attack secondary and tertiary amino groups in epoxy resins. Epoxy resins that are cross-linked with a larger amount of amino-curing agents tend to be more susceptible for degradation.
- Materials that contain S-S linkages (e.g. sulphur vulcanised rubbers) can degrade due to oxidative attack of the sulphur bridges.
- Process incompatibility: Scavenging (i.e. absorption) of hydrogen peroxide into materials, e.g. cellulose, poly urethane and polyamide can occur.
- Process incompatibility: Catalytic decomposition of hydrogen peroxide by Cu, Ag, Mn.
- The presence of hydrogen peroxide during the sterilization process can lead to surface oxidation causing embrittlement and increase of hardness (e.g. seals), and colorization (e.g. thermal control coatings) and paint chipping.
- Diffusion of hydrogen peroxide into adhesive interfaces can affect the adhesive strength. In case adhesives are attached after sterilization, the process can change surface energy and thus adhesive strength.
- Diffusion into the matrix of resins and reaction with filler particles (e.g. silver) is possible. This reduces the performance of respective electrically or thermally conductive coatings or resins. (e.g. grounding).
- Velcro: Loss of 20% of peel strength have been observed -> 25% margin is recommended.

D.2.3 γ-Radiation sterilization

High energy radiation causes bond breakage leading to homolytic cleavage (free radical formation) or heterolytic cleavage (ion formation) of chemical bonds. Subsequently the 'hot' centres can undergo further transformations such as recombination (e.g. cross-linking), group transfer, or reaction with other molecules from the environment. The outgassing of radiolyses gas is possible. The physical effects can be competing, e.g. cross-linking can lead to embrittlement and increase in modulus, whereas termination reactions with low molecular weight species cause rather the reverse.

The reaction pathways depend very much on the nature and formulation of the materials, dose rate, temperature, time, etc., and are not predictable in a general sense. However, polymeric materials can be roughly classified in terms of their relative radiation stability as depicted in Figure D-1.

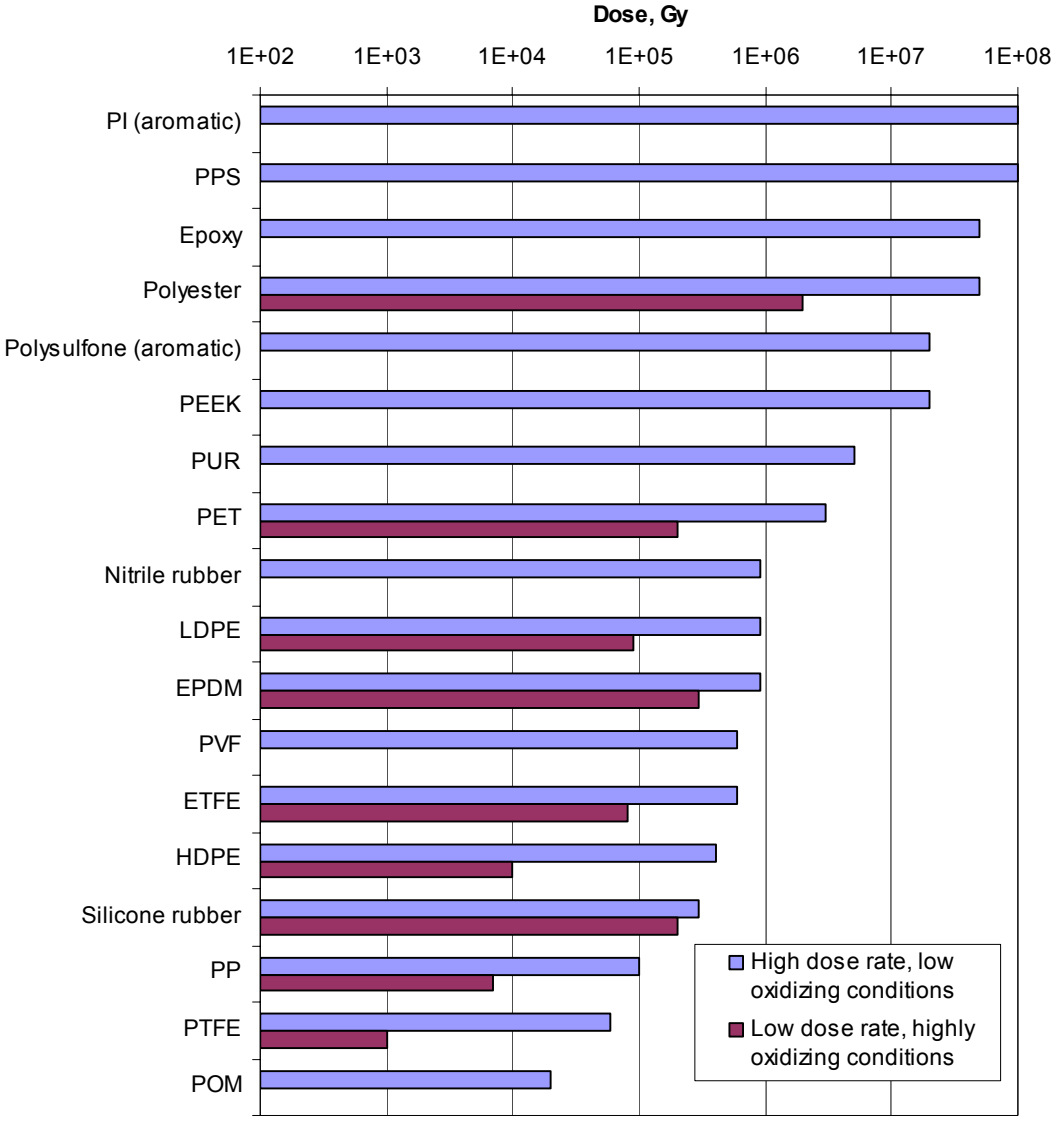

Figure D-1: Relative radiation stability of polymers (see ref 1)

Effects such as radiation induced crosslinking from ETFE and reduction in maximum elongation of PA 6 have been observed.

D.3 Metallic materials

D.3.1 Dry heat sterilization

D.3.1.1. Precipitation hardened alloys

Alloys such as the Al 2000 and Al 7000 series can be precipitation hardened for increase of strength. This heat treatment leads to the maximum of strength following a defined aging process. Dry heat sterilization can cause the alloy to go beyond its critical aging parameters, leading to a decrease in yield strength. As an example, the Al 7025 may only be heated at 150 °C for 1000s. Softening of other aluminium alloys can also occur depending on their heat treatment and work hardening.

D.3.1.2. Low melting point

- Indium has a melting point of 156 °C, but even lower temperatures can lead to creep and stress relaxation for seal applications, resulting in e.g. decrease in leak tightness.
- Indium solder are used e.g. on gold, the melting point is < 120 °C.

D.3.1.3. Memory shape alloys

Actuation/damage of mechanisms that contain memory shape alloys can occur due to the thermal environment during sterilization.

D.3.2 Hydrogen peroxide sterilization

D.3.2.1. Oxidation

- Silver is easily oxidised to Ag_2O by H_2O_2. Although it is usually protected as it would also undergo oxidation on ground (especially by sulphur derivatives), pinholes in optical coatings with underlying silver layers or coatings of wires underneath insulation can be effected by H_2O_2 diffusion or penetration.
- The H_2O_2 sterilization environment can increase the Al_2O_3 passivation layer on Al-coated optical surfaces. This is accompanied by a volume change and can be critical where geometry is crucial, e.g. for grating applications.
- The protection systems for less corrosion resistant alloys are designed to be compatible with air in clean room environments, there compatibility with a more aggressive H_2O_2 environment should be assessed.
- Sn/Pb solders: Lead can oxidise if exposed (normally behind conformal coating).

D.3.3 γ-Radiation sterilization

No risk expected, a critical threshold of 10MeV is not reached with sterilization conditions.

D.4 Ceramic materials

D.4.1 Dry heat sterilization

No detrimental effects expected with the exception of potential thermal stresses (see qualification temperature).

D.4.2 Hydrogen peroxide sterilization

Black anodization layers can fade during hydrogen peroxide sterilization. This has been observed if organic dyes are used. It should be noted that organic dyes are generally not accepted for space applications.

D.4.3 γ-Radiation sterilization

The ionizing radiation can cause formation of colour centres and consequently darkening in visible spectral range (e.g. optical windows, solar cell cover glasses). Cerium doped glasses are recommended to increase stability but result in a loss of a few % sterilization dose.

D.5 Lubricants

D.5.1 Dry heat sterilization

In case mild oxidation with air is a credible scenario see also clause D.2.1.3.

D.5.2 Hydrogen peroxide sterilization

The oxidizing environment can result in conversion of sulphide-based solid lubricants to the corresponding oxides ($WS_2 \rightarrow WO_2$, $MoS_2 \rightarrow MoO_2$), leading to increasing friction in mechanisms.

In addition the sulphides can react with hydrogen peroxide to sulphuric or sulphurous acid that can further damage materials.

D.5.3 γ-Radiation sterilization

Lubricants based on perfluoroethers are susceptible to ionizing radiation that can cause chain scission with subsequent group transfer and cross linking. These chemical conversion reactions have an influence on viscosity and therefore on the lubrication performance.

D.6 EEE components

D.6.1 Overview

See also ECSS-Q-ST-60 for EEE selection, control and procurement.

The performance of components can change to some extent after sterilisation (drift), which, although within manufacturer specification, can be critical for hardware design tolerance.

D.6.2 Dry heat sterilization

Table D-1: Risk identification linked to dry heat sterilization

(Part 1 of 4)

Technology	Associated standards	Risks 125 °C/48h	Risks 135 °C/12h
Capacitors, chip,	ESCC 3009 MIL-PRF-55681 MIL-PRF-123	No risk expected, possibly oxidation of end termination. max storage 150 °C	No risk expected, possibly oxidation of end termination. max storage 150 °C
Capacitors, molded, Ceramic	ESCC 3001, MIL-PRF-39014 MIL-PRF-20 MIL-PRF-123 MIL-PRF-49470	No risk expected, possibly oxidation of end termination. max storage 150 °C	No risk expected, possibly oxidation of end termination. max storage 150 °C
Capacitors, glass	MIL-PRF-23269	No risk expected	No risk expected
Capacitors, mica	ESCC 3007, MIL-PRF-39001	No risk expected, possibly oxidation of end termination. max storage 150 °C	No risk expected, possibly oxidation of end termination. max storage 150 °C
Capacitors, chip, solid, tantalum (e.g. TAJ, T495, CWR11)	ESCC 3011 ESCC 3012 MIL-PRF-55365	Maximum storage temperature is 125 °C	Damage or stressing will occur, failures likely
Capacitors, non-solid, tantalum, electrolytic (CLR79)	ESCC 3003 MIL-PRF-39006	Maximum storage temperature is 125 °C	Damage or stressing will occur, failures likely
Capacitors, solid, tantalum, electrolytic (CSR type)	ESCC 3002 MIL-PRF-39003	Maximum storage temperature is 125 °C	Damage or stressing will occur, failures likely
Capacitors, super metallized plastic film (CRH type)	ESCC 3006 MIL-PRF-83241	Maximum storage temperature is 125 °C	Damage or stressing will occur, failures likely

Table D-1: Risk identification linked to dry heat sterilization

(Part 2 of 4)

Technology	Associated standards	Risks	Risks
Capacitors, metallized film, (HTP86, KM94S, PM94S, PM90SR2, MKT, …)	ESCC 3006	Maximum storage temperature is 125 °C	Damage or stressing will occur, failures likely
Connectors, non filtered, D-sub rectangular	ESCC 3401	Depending on maximum storage temp specified	Damage can occur
Connectors, filtered, D-sub rectangular and circular	ESCC 3405	Depending on maximum storage temp specified	Damage can occur
Connectors, printed circuit board	ESCC 3401	Depending on maximum storage temp specified	Damage can occur
Connectors, RF coaxial	ESCC 3402	Temperature limitations, max ratings are typically 105 °C depending on variants	Temperature limitations, max ratings are typically 105 °C depending on variants
Connectors, microminiature, rectangular	ESCC 3401	Depending on maximum storage temp specified	Damage can occur
Crystals	ESCC 3501	Maximum rating 125 °C	Will present problems as outside of max rating
Diodes	ESCC 5000 MIL-PRF-19500	No problems expected as max rating is >150 °C	No problems expected as max rating is >150 °C
Diodes microwave	ESCC 5010 MIL-PRF-19500	No problems expected as max rating is >150 °C	No problems expected as max rating is >150 °C
Filters	ESCC 3008 MIL-PRF-28861	No problems expected	Exceeds max temperature ratings.
Fuses (CERMET) -	MIL-PRF-23419	No problems expected	No problems expected as AEM data sheet shows a derating curve to 150 °C
Heaters flexible	ESCC 4009	No problems expected	No problems expected
Inductors, coils, (moulded)	ESCC 3201 MIL-STD-981 MIL-PRF-39010	No problems expected, except for low Tg moulding compounds.	Exceeds max ratings and is determined by Tg of moulding compound
Inductors, coils (non moulded)	ESCC 3201 MIL-STD-981	No problems expected	No problems expected

Table D-1: Risk identification linked to dry heat sterilization

(Part 3 of 4)

Technology	Associated standards	Risks	Risks
Integrated circuits	ESCC 9000 MIL-PRF-38535	No problems expected	Storage to 150 °C for some devices- check Tmax ratings npte prolonged Al/Au intermetallics also Tg issues with PEMS
Integrated circuits microwave (MMIC)	ESCC 9010 MIL-PRF-38535	No problems expected	Exceeds max temperature ratings.
Microwave passive parts (circulators , isolators)	ESCC 3202 l	No problems expected for ESCC product. For commercial products verify temperature rating.	Exceeds max temperature ratings, complex assembly of polymer adhesives, encapsulates, etc.
Microwave passive parts (coupler, power dividers)	ESCC 3404 MIL-DTL-23971 (dividers)	No problems expected	Exceeds max temperature ratings, complex assembly of polymer adhesives, encapsulates, etc.
Microwave passive parts (attenuators, loads)	ESCC 3403 MIL-DTL-39030 (loads) MIL-DTL-3933 (attenuators)	Temperature rating depends on technologies, varies from 85 °C to 165 °C	Temperature rating depends on technologies, varies from 85 °C to 165 °C
Oscillators (hybrids)	ECSS Q-ST-60-05 level 1 MIL-PRF-55310	No problems expected	Higher temp can damage the crystal mounting
Relays, electromagnetic, latching and non-latching	ESCC 3601 ESCC 3602	No problems expected	Exceeds max temperature ratings.
Resistors, fixed, film (RNC and RLR type, except RNC90)	ESCC 4001 MIL-PRF-55182 MIL-PRF-39017	No problems expected	No problems expected
Resistors, high precision, fixed, metal foil (RNC90)	ESCC 4001 MIL-PRF-55182/9	No problems expected	No problems expected
Resistors, network, thick film MDM	MIL-PRF-83401	No problems expected	No problems expected
Resistors, current sensing (RLV type)	MIL-PRF-49465	No problems expected	No problems expected
Resistors, power, fixed, wire-wound (RWR type)	ESCC 4002 MIL-PRF-39007	No problems expected	No problems expected

Table D-1: Risk identification linked to dry heat sterilization

(Part 4 of 4)

Technology	Associated standards	Risks	Risks
Resistors, power, fixed, wire-wound, chassis mounted (RER type)	ESCC 4003 MIL-PRF-39009	No problems expected	No problems expected
Resistors, precision, fixed, wire-wound (RBR type)	MIL-PRF-39005	No problems expected, max temperature rating is 145 °C	No problems expected, max temperature raring is 145 °C
Resistors, fixed, thick and thin film chip RM series	MIL-PRF-55342	No problems expected	No problems expected, although precision can be lowered slightly still in spec
Switches, electromechanical	ESCC 3701 MIL-PRF-8805	No problems expected	Outside rating on some devices and thus damage can occur
Switches, thermostatic	ESCC 3702	No problems expected	No problems expected
Thermistors	ESCC 4006	Can be an issue depending on type and max rating	Can be an issue depending on type and max rating
Transformers	ESCC 3201	Can be an issue depending on type and max rating	Can be an issue depending on type and max rating
Transistors 3	ESCC 5000 MIL-PRF-19500	No problems expected	No problems expected
Transistors 3microwave	ESCC 5010 MIL-PRF-19500	No problems expected	No problems expected
Cables & wires, low Frequency4	ESCC 3901 N.B. MIL-W-22759 has less silver therefore red plague issues!	No problems expected	No problems expected
Cables, coaxial, radio frequency4	ESCC 3902 MIL-C-17	No problems expected	No problems expected
Surface Acoustic Waves (SAW)	ESCC 3502	No problems expected	Exceeds max temperature ratings
Charge coupled devices (CCD)	ESCC 9020	No problems expected	No problems expected
Opto discrete devices Photodiodes, LED, Phototransistors Opto-couplers	ESCC 5000 MIL-PRF-19500	No problems expected with the exception of max. temperature rating for indium 100 °C (e.g. seals), precision of positioning of optical parts	Can be issues on the max temperature ratings

D.6.3 Hydrogen peroxide sterilization

Table D-2: Risk identification linked to hydrogen peroxide sterilization

(Part 1 of 4)

Technology	Associated standards	Risks H_2O_2
		4-10 g/mL H_2O_2 in gas phase, max 60 °C/40 min
Capacitors, chip,	ESCC 3009 MIL-PRF-55681 MIL-PRF-123	Solderability or end termination affected, verification by test. Mil devices have 85/85 test carried out on lot.
Capacitors, moulded, Ceramic	ESCC 3001, MIL-PRF-39014 MIL-PRF-20 MIL-PRF-123 MIL-PRF-49470	Polymers can be affected by the hydrogen peroxide, verification with the manufacturers and oxidation of leads.
Capacitors, glass	MIL-PRF-23269	No risk expected
Capacitors, mica	ESCC 3007, MIL-PRF-39001	Solderability or end termination affected, verification by test. Mil devices have 85/85 test carried out on lot.
Capacitors, chip, solid, tantalum (e.g. TAJ, T495, CWR11)	ESCC 3011 ESCC 3012 MIL-PRF-55365	Organics and coatings could be compromised.
Capacitors, non-solid, tantalum, electrolytic (CLR79)	ESCC 3003 MIL-PRF-39006	Hermetic device, no problems expected
Capacitors, solid, tantalum, electrolytic (CSR type)	ESCC 3002 MIL-PRF-39003	Hermetic device, no problems expected
Capacitors, super metallized plastic film (CRH type)	ESCC 3006 MIL-PRF-83241	Hermetic device, , no problems expected
Capacitors, metallised film, (HTP86, KM94S, PM94S, PM90SR2, MKT, …)	ESCC 3006	Hermetic device, , no problems expected
Connectors, non filtered, D-sub rectangular	ESCC 3401	Unlikely to cause any problems although ionic media could lead to issues. In addition metal finished needs to be specified as Ag or bare contacts areas could lead to oxidation problems.
Connectors, filtered, D-sub rectangular and circular	ESCC 3405	Unlikely to cause any problems although ionic media could lead to issues. In addition metal finished needs to be specified as Ag or bare contacts areas could lead to oxidation problems.

Table D-2: Risk identification linked to hydrogen peroxide sterilization

(Part 2 of 4)

Technology	Associated standards	Risks H_2O_2
		4-10 g/mL H_2O_2 in gas phase, max 60 °C/40 min
Connectors, printed circuit board	ESCC 3401	Unlikely to cause any problems although ionic media could lead to issues. In addition metal finished needs to be specified as Ag or bare contacts areas could lead to oxidation problems.
Connectors, RF coaxial	ESCC 3402	Contamination issues for incorrect plated devices, correct metal finish to be ensured
Connectors, microminiature, rectangular	ESCC 3401	Unlikely to cause any problems although ionic media could lead to issues. In addition metal finished needs to be specified as Ag or bare contacts areas could lead to oxidation problems.
Crystals	ESCC 3501	No problems expected as hermetic, oxidation of leads possible
Diodes	ESCC 5000 MIL-PRF-19500	Can be issues for glass packaged for penetration of oxidant.
Diodes microwave	ESCC 5010 MIL-PRF-19500	Possibly issues for glass packages for penetration of oxidant.
Filters	ESCC 3008 MIL-PRF-28861	Oxidant can penetrate the structure and cause degradation. Body could oxidise, usually made of silver.
Fuses (CERMET) -	MIL-PRF-23419	Possibly issues with the polymer/ package
Heaters flexible	ESCC 4009	Can be permeable to hydrogen peroxide Turk J Chem suggests can be.
Inductors, coils, (moulded)	ESCC 3201 MIL-STD-981 MIL-PRF-39010	Possibly issues with the polymer/ package
Inductors, coils (non moulded)	ESCC 3201 MIL-STD-981	Possibly issues with the polymer/ package
Integrated circuits	ESCC 9000 MIL-PRF-38535	Possibly issues with PEMS, no problems expected for hermetic devices
Integrated circuits microwave (MMIC)	ESCC 9010 MIL-PRF-38535	Possibly issues with PEMS, no problems expected for hermetic devices
Microwave passive parts (circulators , isolators)	ESCC 3202 l	Not hermetic, damaged can occur
Microwave passive parts (coupler, power dividers)	ESCC 3404 MIL-DTL-23971 (dividers)	Not hermetic, damaged can occur

Table D-2: Risk identification linked to hydrogen peroxide sterilization

(Part 3 of 4)

Technology	Associated standards	Risks H_2O_2
		4-10 g/mL H_2O_2 in gas phase, max 60 °C/40 min
Microwave passive parts (attenuators, loads)	ESCC 3403 MIL-DTL-39030 (loads) MIL-DTL-3933 (attenuators)	Depends on technologies, damage can occur
Oscillators (hybrids)	ECSS Q-ST-60-05 level 1 MIL-PRF-55310	Hermetic device, no problems expected
Relays, electromagnetic, latching and non-latching	ESCC 3601 ESCC 3602	Damage can occur in case of penetration of hydrogen peroxide.
Resistors, fixed, film (RNC and RLR type, except RNC90)	ESCC 4001 MIL-PRF-55182 MIL-PRF-39017	Not hermetic, damage can occur
Resistors, high precision, fixed, metal foil (RNC90)	ESCC 4001 MIL-PRF-55182/9	Not hermetic, damage can occur
Resistors, network, thick film MDM	MIL-PRF-83401	Epoxy resin package, possible compatibility issues
Resistors, current sensing (RLV type)	MIL-PRF-49465	High temp mould compound and metal terminals
Resistors, power, fixed, wire-wound (RWR type)	ESCC 4002 MIL-PRF-39007	Moulded or coated compound caution
Resistors, power, fixed, wire-wound, chassis mounted (RER type)	ESCC 4003 MIL-PRF-39009	Welded construction in silicon adhesive in A body No problems envisage
Resistors, precision, fixed, wire-wound (RBR type)	MIL-PRF-39005	Moulded or coated compound caution
Resistors, fixed, thick and thin film chip RM series	MIL-PRF-55342	No problems expected film with Silicon coating
Switches, electromechanical	ESCC 3701 MIL-PRF-8805	Internal damage can occur
Switches, thermostatic	ESCC 3702	Internal damage can occur and cause problems with e.g. the disc and plunger.
Thermistors	ESCC 4006	Problems can occur, delicate construction.
Transformers	ESCC 3201	Materials can be damaged.

Table D-2: Risk identification linked to hydrogen peroxide sterilization

(Part 4 of 4)

Technology	Associated standards	Risks H_2O_2
		4-10 g/mL H_2O_2 in gas phase, max 60 °C/40 min
Transistors 3	ESCC 5000 MIL-PRF-19500	Hermetic device, no problems expected
Transistors 3microwave	ESCC 5010 MIL-PRF-19500	Hermetic device, no problems expected
Cables & wires, low Frequency4	ESCC 3901 N.B. MIL-W-22759 has less silver therefore red plague issues!	No problems expected, although penetration of the wire can present problems.
Cables, coaxial, radio frequency4	ESCC 3902 MIL-C-17	No problems expected although penetration of the wire can present problems.
Surface Acoustic Waves (SAW)	ESCC 3502	Hermetic sealed device, no problems expected
Charge coupled devices (CCD)	ESCC 9020	Seal can be insufficient and allow penetration of hydrogen peroxide
Opto discrete devices Photodiodes, LED, Phototransistors Opto-couplers	ESCC 5000 MIL-PRF-19500	Hermetic device, no problems expected, although caution if using lens devices.

D.6.4 γ-radiation sterilization

Table D-3: Risk identification linked to γ-radiation sterilization

(Part 1 of 3)

Technology	Associated standards	Risks radiation
		25 kGy = 2.5 Mrad
Capacitors, chip,	ESCC 3009 MIL-PRF-55681 MIL-PRF-123	No problems expected
Capacitors, molded, Ceramic	ESCC 3001, MIL-PRF-39014 MIL-PRF-20 MIL-PRF-123 MIL-PRF-49470	Radiation damage can occur to the polymer.
Capacitors, glass	MIL-PRF-23269	No problems expected (ref 2)
Capacitors, mica	ESCC 3007, MIL-PRF-39001	No problems expected, known to be radiation stable.
Capacitors, chip, solid, tantalum (e.g. TAJ, T495, CWR11)	ESCC 3011 ESCC 3012 MIL-PRF-55365	Radiation damage to the polymer can occur. Damage to coatings in layers possible too lead if internal damage to higher leakage. Verify.
Capacitors, non-solid, tantalum, electrolytic (CLR79)	ESCC 3003 MIL-PRF-39006	Radiation leakage possible. Effect can be minimal.
Capacitors, solid, tantalum, electrolytic (CSR type)	ESCC 3002 MIL-PRF-39003	Radiation leakage possible. Effect can be minimal.
Capacitors, super metallized plastic film (CRH type)	ESCC 3006 MIL-PRF-83241	Radiation leakage possible. Assessment on case by case basis as dielectric is due to change from suppliers
Capacitors, metallised film, (HTP86, KM94S, PM94S, PM90SR2, MKT, …)	ESCC 3006	Radiation leakage possible. Assessment on case by case basis as dielectric is due to change from suppliers
Connectors, non filtered, D-sub rectangular	ESCC 3401	Radiation damage to polymer materials can occur, problems unlikely.
Connectors, filtered, D-sub rectangular and circular	ESCC 3405	Radiation damage to polymer materials can occur, problems unlikely.
Connectors, printed circuit board	ESCC 3401	Radiation damage to polymer materials can occur, problems unlikely.
Connectors, RF coaxial	ESCC 3402	No problems expected
Connectors, microminiature, rectangular	ESCC 3401	Radiation damage to polymer materials can occur, problems unlikely.
Crystals	ESCC 3501	Radiation sensitive drifts can occur

Table D-3: Risk identification linked to γ-radiation sterilization

(Part 2 of 3)

Technology	Associated standards	Risks radiation
		25 kGy = 2.5 Mrad
Diodes	ESCC 5000 MIL-PRF-19500	Does rate could affect these devices ELDRS. Radiation performances needs to be assessed on case by case basis.
Diodes microwave	ESCC 5010 MIL-PRF-19500	Does rate could affect these devices ELDRS. Radiation performances needs to be assessed on case by case basis.
Filters	ESCC 3008 MIL-PRF-28861	No problems expected
Fuses (CERMET) -	MIL-PRF-23419	No problems expected
Heaters flexible	ESCC 4009	Can be radiative breakdown
Inductors, coils, (moulded)	ESCC 3201 MIL-STD-981 MIL-PRF-39010	No problems expected, depending on encapsulant
Inductors, coils (non moulded)	ESCC 3201 MIL-STD-981	No problems expected, depending on encapsulant
Integrated circuits	ESCC 9000 MIL-PRF-38535	TID issues are likely
Integrated circuits microwave (MMIC)	ESCC 9010 MIL-PRF-38535	Assessment required.
Microwave passive parts (circulators , isolators)	ESCC 3202 l	Can damage devices through materials damage.
Microwave passive parts (coupler, power dividers)	ESCC 3404 MIL-DTL-23971 (dividers)	Can damage devices through materials damage.
Microwave passive parts (attenuators, loads)	ESCC 3403 MIL-DTL-39030 (loads) MIL-DTL-3933 (attenuators)	Damage can occur depending on technologies
Oscillators (hybrids)	ECSS Q-ST-60-05 level 1 MIL-PRF-55310	Radiation degradation on the crystal and supporting logic possible
Relays, electromagnetic, latching and non-latching	ESCC 3601 ESCC 3602	No problems expected although review of materials is advised.
Resistors, fixed, film (RNC and RLR type, except RNC90)	ESCC 4001 MIL-PRF-55182 MIL-PRF-39017	Degradation of film materials can occur

Table D-3: Risk identification linked to γ-radiation sterilization

(Part 3 of 3)

Technology	Associated standards	Risks radiation
		25 kGy = 2.5 Mrad
Resistors, high precision, fixed, metal foil (RNC90)	ESCC 4001 MIL-PRF-55182/9	Degradation of film materials can occur
Resistors, network, thick film MDM	MIL-PRF-83401	Epoxy resin package, degradation can occur
Resistors, current sensing (RLV type)	MIL-PRF-49465	High temp mould compound and metal terminals, no problems expected
Resistors, power, fixed, wire-wound (RWR type)	ESCC 4002 MIL-PRF-39007	Moulded or coated compound, no problems expected
Resistors, power, fixed, wire-wound, chassis mounted (RER type)	ESCC 4003 MIL-PRF-39009	Welded construction in silicon adhesive in a body, no problems expected
Resistors, precision, fixed, wire-wound (RBR type)	MIL-PRF-39005	Moulded or coated compound, no problems expected. However, special encapsulates are used internally to reduce stress for precision - effects of radiation unclear.
Resistors, fixed, thick and thin film chip RM series	MIL-PRF-55342	No problems expected film with Silicon coating
Switches, electromechanical	ESCC 3701 MIL-PRF-8805	Internal damage can occur
Switches, thermostatic	ESCC 3702	Internal damage can occur
Thermistors	ESCC 4006	Materials damage can occur.
Transformers	ESCC 3201	Materials damage can occur.
Transistors 3	ESCC 5000 MIL-PRF-19500	Radiation will affect the devices
Transistors 3microwave	ESCC 5010 MIL-PRF-19500	Radiation will affect the devices
Cables & wires, low Frequency4	ESCC 3901 N.B. MIL-W-22759 has less silver therefore red plague issues!	Potential degradation of the insulator
Cables, coaxial, radio frequency4	ESCC 3902 MIL-C-17	Potential degradation of the insulator
Surface Acoustic Waves (SAW)	ESCC 3502	Problems if degradation of the Piezo occurs
Charge coupled devices (CCD)	ESCC 9020	Radiation will affect the devices
Opto discrete devices Photodiodes, LED, Phototransistors Opto-couplers	ESCC 5000 MIL-PRF-19500	Radiation will affect the devices

D.7 Batteries

D.7.1 Overview

The environmental limits of batteries are mainly defined by the susceptibility of separator and electrolyte to the exposed environment, affecting the mobility of charge carrier in short and/or long term.

In some cases electronics are integrated in batteries, e.g. in case of voltage restriction (see Annex D.6 for EEE components).

For qualification of batteries see ECSS-E-ST-20.

D.7.2 Dry heat sterilization

The key concern is the temperature; the maximum qualification temperature of a battery can be far below the temperature of a typical dry-heat sterilization cycle (e.g. Lithium ion batteries: typically (50 – 60) °C).

D.7.3 Hydrogen peroxide sterilization

Detrimental effects are limited to surface interaction and possibly damage of or penetration through seal.

D.7.4 γ-Radiation sterilization

Interactions are very specific to the used technology and electronics inside, for GEO missions test are typically performed up 2 kGy.

D.8 Explosive devices

D.8.1 Overview

The following considerations apply to pyrotechnic mixtures or compositions, primary explosives (e.g. lead azide, lead styphnate, tetrazene), pure high explosives (e.g. PETN, RDX, HMX, HNS), or high explosives with binders. Propellants are not considered.

For qualification of explosive devices, see ECSS-E-ST-33-11.

D.8.2 Dry heat sterilization

Problems can occur due to auto-ignition temperature, melting temperature or deterioration of reaction rate, explosive output (e.g. calorific, gas generation, detonation, shock-wave properties).

For compatibility with explosive devices, see ECSS-E-ST-33-11 clause 4.9 j, and k.

D.8.3 Hydrogen peroxide sterilization

Pyrotechnic device encapsulation needs to be compatible with hydrogen peroxide to ensure protection of the explosive.

For compatibility with explosive devices, see ECSS-E-ST-33-11 clause 4.9 a.

D.8.4 γ-Radiation sterilization

For Compatibility with explosive devices, see ECSS-E-ST-33-11 clause 4.14.4.2.

D.9 Solar cell assemblies

D.9.1 Overview

For qualification of solar cell assemblies see ECSS-E-ST-20-08.

D.9.2 Dry heat sterilization

In general no incompatibility is expected with current technologies. It should be noted that the temperature of the sterilization might be significantly higher than the operational environment and dominates the limit of qualification.

D.9.3 Hydrogen peroxide sterilization

In general no incompatibility is expected, possible interactions with the used adhesives should be considered (see clause D.2.2).

D.9.4 γ-Radiation sterilization

No incompatibility is expected for the photovoltaic cell for crystalline materials including Si and GaAs; possible detrimental effects in coverglass (clause D.4.3 or polymeric materials (clause D.2.3) should be considered.

D.10 PCBs, populated

D.10.1 Overview

For qualification of PCBs see ECSS-Q-ST-70-10.

D.10.2 Dry heat sterilization

Low Tg of matrix material from PCBs (e.g. epoxy) can cause stress in the Cu plating. Adhesives and conformal coatings underneath components can cause stress on solder joints due to CTE mismatch, especially with low Tg. Excessive growth of Sn/Cu intermetallic is possible on solder joints. The sterilization process should be considered during the verification of the assembly.

D.10.3 Hydrogen peroxide sterilization

Surface oxidation, e.g. of Pb from solders, is possible. Conformal coatings, compatible with the sterilization process, are preferred. For RF applications preference is given to selective plating (Sn/Pb and Au).

D.10.4 γ-Radiation sterilization

The main concern is related to the compatibility of components (see D.6.), compatibility with materials of the PCB should be considered.

Bibliography

ECSS-S-ST-00	ECSS system – Description, implementation and general requirements
ECSS-E-ST-20	Space engineering – Electrical and electronic
ECSS-E-ST-20-08	Space engineering – Photovoltaic assemblies and components
ECSS-E-ST-32-11	Space engineering – Explosive systems and devices
ECSS-Q-ST-60	Space product assurance – Electrical, electronic and electromechanical (EEE) components
ECSS-Q-ST-60-05	Space product assurance – Generic procurement of hybrids
ECSS-Q-ST-70-10	Space product assurance – Qualification of printed circuit boards
ECSS-Q-ST-70-55	Space product assurance – Microbial examination of flight hardware and cleanrooms
ECSS-Q-ST-70-56	Space product assurance – Vapour phase bioburden reduction for flight hardware
ECSS-Q-ST-70-57	Space product assurance – Dry heat bioburden reduction for flight hardware
NASA NPR 8020.12C	Planetary Protection Provisions for Robotic Extraterrestrial Missions