NASA Procedural Requirements

NPR 8020.12D
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COMPLIANCE IS MANDATORY

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Request Notification of Change (NASA Only)

Subject: Planetary Protection Provisions for Robotic Extraterrestrial Missions

Responsible Office: Science Mission Directorate

Appendix D. Planetary Protection Specification Sheets

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PARAMETER TITLE: Clean Room Requirement

VALUE			APPLICATION	
UPPER			MISSION	
ACCEPTABLE	Class 100,000		PP CATEGORY	II, III and IV
LOWER			PLANET	All

PARAMETER DEFINITION: Procedures for spacecraft and payload assembly.

APPLICABLE SOURCE: Spacecraft and payloads.

CONSTRAINTS: All PP Category II, III and IV missions shall assemble and maintain spacecraft and payloads in Class 100,000 or ISO class 8 cleanrooms in the operational mode (Ref. 1, 2). The class is to be monitored and verified, with the sampling frequency and number of locations per a clean zone as specified in Ref. 1 or 2 for any flight hardware location within the cleanroom. Attendant controls and procedures must be similar to those employed by the Viking Project or Ref. 2. This requirement is independent of any other requirement, e.g., any bioburden limitation.

REFERENCES:
1. "Clean Room and Clean Work Station Requirements, Controlled Environments", Federal Standard No. 209C, 1987

(or latest revision).

2. "Cleanrooms and associated controlled environments" "Part 1: Classification of air cleanliness," ISO 14644-1, 1999. "Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1," ISO 14644-2, 2000. "Part 5: Cleanroom Operations," ISO 14644-5, 2004.

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PARAMETER TITLE: Average Encapsulated Microbial Density [X]

VALUE			APPLICATION	
UPPER	130/cm^3		MISSION	All
ACCEPTABLE	130/cm^3		PP CATEGORY	III, IV
LOWER	130/cm^3		PLANET	All

PARAMETER DEFINITION: The average density of spores buried inside nonmetallic spacecraft material. This value reflects reductions experienced in the manufacture of the basic material, but it does not account for any burden reduction during higher level assembly and test.

APPLICABLE SOURCE: Nonmetallic portions of the spacecraft.

CONSTRAINTS: If this parameter is used, it must be applied to the total volume of nonmetallic material and further subdivisions using source-specific density values d v(0) shall not be made.

This value was derived assuming the subsequent use of heat sterilization. If processes are proposed that do not include heat for a PP Category IV mission, the value must be reassessed to assure its applicability for the proposed usage. It may be used without restriction for PP Category III mission burden estimates.

REFERENCES: Planetary Quarantine Advisory Panel (PQAP) Review, September 28, 1971, Denver, CO

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PARAMETER TITLE: Source Specific Encapsulated Microbial Density [X]

VALUE			APPLICATION	
UPPER			MISSION	All
ACCEPTABLE	See Below		PP CATEGORY	III, IV
LOWER			PLANET	All

PARAMETER DEFINITION: The average number of spores buried inside the ith subassembly or component of a spacecraft. The number can be expressed in terms of volume or area according to the application as specified below.

APPLICABLE SOURCE: Nonmetallic materials on the spacecraft.

CONSTRAINTS: Source-specific density values can be used only if applied to the entire volume of spacecraft non-metallic material without resorting to the average density value, dv(0), for any portion thereof. Values for this parameter must be derived for all applicable sources. Values are selected from the following categories and ranges depending upon the composition of, and manufacturing process for, each designated source:

Encapsulated Organisms in:	[X]
Electronic piece parts	3-150/cm^3

Other nonmetallic materials	1-30/cm^3
Enclosed surface densities:	
Cleanroom-highly controlled	0.05-0.5cm^2
Cleanroom-normal control	0.5-10/cm^2
Uncontrolled manufacturing	10-100/cm^2

In the use of this parameter, a rationale shall be presented for the selection of values less than the maximum of the applicable range specified. This value was derived assuming the subsequent use of heat sterilization. If processes are proposed that do not include heat for a PP Category IV mission, the value must be reassessed to assure its applicability for the proposed usage. It may be used without restriction for PP Category III mission burden estimates.

REFERENCES: PQAP Review, September 28, 1971, Denver, Colorado.

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PARAMETER TITLE: Surface Microbial Density (d_S (0))

VALUE			APPLICATION	
UPPER			MISSION	All
ACCEPTABLE	See Below		PP CATEGORY	III, IV
LOWER			PLANET	All

PARAMETER DEFINITION: The average number of spores on any free surface (nonencapsulated) of a spacecraft system, subsystem, assembly, or subassembly.

APPLICABLE SOURCE: All fallout burden on the spacecraft (exposed and mated).

CONSTRAINTS: Values of this parameter are selected from the following categories, depending on the manufacturing process and cleaning and contamination control procedures for the designated hardware:

Cleanroom 10^4 or better - highly controlled	50/m^2
Cleanroom 10^4 - normal control	$5x10^2/m^2$
Cleanroom 10^5 - highly controlled	$1x10^3/m^2$
Cleanroom 10^5 - normal control	$1x10^4/m^2$
Uncontrolled manufacturing	$1x10^5/m^2$

For estimating surface densities for vegetative microorganisms (for purposes other than to establish terminal sterilization cycles), multiply the above values by a factor of 10.

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PARAMETER TITLE: Temperature Dependence of D-Value , Z

VALUE			APPLICATION	
UPPER	21C		MISSION	All
ACCEPTABLE	21C		PP CATEGORY	IV
LOWER	21C		PLANET	All

PARAMETER DEFINITION: The change in temperature which produces a factor of 10 change in a given D-value.

APPLICABLE SOURCE: All microbial burden subjected to dry heat sterilization cycles.

CONSTRAINTS: Applicable within the temperature range of 104C to 125C. Applicable to dry heat sterilization cycles, meeting requirements of NPR 8020.12D.

REFERENCES:
1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: D-Value for Microbial Spore Burden on Exposed Surfaces (D_{S125})

VALUE			APPLICATION	
UPPER	0.5 hr.		MISSION	All
ACCEPTABLE	0.5 hr.		PP CATEGORY	IV
LOWER	0.5 hr.		PLANET	All

PARAMETER DEFINITION: Time required to destroy 90 percent of the nonhardy microbial spore population on surfaces subjected to sterilizing dry heat at a temperature of 125C at an absolute humidity corresponding to a relative humidity of less than 25 percent referenced to the standard conditions of 0C and 760 torr pressure.

APPLICABLE SOURCE: All nonhardy microbial spore populations located on spacecraft "free" surfaces (i.e., such that gas exchange can take place).

CONSTRAINTS: Specified D-value can be applied where sterilization cycle conditions stated in NPR 8020.12D have been met. Thermal response of materials must be considered in design of sterilization cycles. Project must specify method for the measurement of these parameters and make allowances for stabilization times.

REFERENCES:
1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: D-Value for Microbial Spore Burden on Mated Surfaces (D_{M125})

VALUE			APPLICATION	
UPPER	1.0 hr.		MISSION	All
ACCEPTABLE	1.0 hr.		PP CATEGORY	IV
LOWER	1.0 hr.		PLANET	All

PARAMETER DEFINITION: Time required to destroy 90 percent of the nonhardy microbial spore population on mated surfaces of spacecraft subjected to sterilizing dry heat at a temperature of 125C at an absolute humidity corresponding to a relative humidity of less than 25 percent referenced to the standard conditions of 0C and 760 torr pressure.

APPLICABLE SOURCE: All nonhardy spore populations on mated surfaces of spacecraft.

CONSTRAINTS: Specified D-value can be applied where sterilization cycle conditions stated in NPR 8020.12D have been met. Thermal response of materials must be considered in design of sterilization cycles. Project must specify method for the measurement of these parameters and make allowances for stabilization times.

REFERENCES:
1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: D-Value for Encapsulated Microbial Spore Burden (D_{B125})

VALUE			APPLICATION	
UPPER	5.0 hr.		MISSION	All
ACCEPTABLE	5.0 hr.		PP CATEGORY	IV
LOWER	5.0 hr.		PLANET	All

PARAMETER DEFINITION: Time required to destroy 90 percent of the nonhardy microbial spore population encapsulated in nonmetallic spacecraft material subjected to sterilizing dry heat at a temperature of 125C.

APPLICABLE SOURCE: All nonhardy spore populations buried within nonmetallic spacecraft materials.

CONSTRAINTS: Specified D-value can be applied where sterilization cycle conditions stated in NPR 8020.12D have been met. Thermal response of materials must be considered in design of sterilization cycles. Project must specify method for the measurement of these parameters and make allowances for stabilization times.

REFERENCES:
1. Recommendations of PQAP Subcommittee 1A Resulting from Deliberations on July 25-26, 1968.

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PARAMETER TITLE: Fraction of Hardy Organisms and their Survival of Nominal Sterilization Cycles (N_H/N_0)

VALUE			APPLICATION	
UPPER	1×10^{-3}		MISSION	Any Requiring Sterilization
ACCEPTABLE	See Below		PP CATEGORY	IV
LOWER	1×10^{-4}		PLANET	All

PARAMETER DEFINITION: Hardy (heat resistant) organisms as a fraction of the total spore population on spacecraft surfaces. Survival of the hardy organisms is expressed as the ratio of the hardy organisms surviving a nominal sterilization cycle to the initial presterilization total spore population.

APPLICABLE SOURCE: All microbial spore populations located on spacecraft surfaces.

CONSTRAINTS: Hardy organisms comprise a fraction of 1×10^{-3} of the total spore population on spacecraft surfaces. For nominal sterilization cycles, i.e., 35-50 hours at temperatures of 111 - 125°C, the surviving fraction of hardy organisms is 1×10^{-4}. Therefore, in designing or assessing spacecraft sterilization cycles, the logarithmic death-rate model based on the D and Z values provided elsewhere in this specification book should not be used to predict lethality greater than 1×10^{-3} for microbial spore populations on spacecraft surfaces. The model is valid, however, for calculating lethality up to the level of the hardy surviving fraction, which, at 1×10^{-4}, establishes the maximum allowable lethality for the nominal sterilization cycles described above.

REFERENCES:
1. Thermal Resistance of Naturally Occurring Airborne Bacterial Spores. J. R. Puleo, et al., Planetary Quarantine Laboratory, Jet Propulsion Laboratory, Cape Canaveral, FL, 1978.

2. Statistics of the NH/N0 Ratio. Paper presented at the "Hardy" Organisms conference, Ames Research Center, November 1974, by P.D. Stabekis, Exotech Research & Analysis, Inc., Gaithersburg, MD.

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PARAMETER TITLE: Time-Temperature for Absolute Sterility (K (†T))

VALUE			APPLICATION	
UPPER	≥ 0.5 sec @ ≥ 500C		MISSION	All
ACCEPTABLE	Same		PP CATEGORY	All
LOWER	Same		PLANET	All

PARAMETER DEFINITION: The short time-high temperature conditions at which all organisms will be completely destroyed.

APPLICABLE SOURCE: Any source of terrestrial organisms associated with spacecraft hardware. Sources can be encapsulated, mated surface, open surface or airborne. The temperature must exist at the location of the microbial burden for the required time duration.

CONSTRAINTS: Spacecraft organisms and their associated environment must reach a temperature of at least 500C and must remain at this temperature for at least one half second. This specification was derived from high temperature sterilization tests of microbial contamination.

REFERENCES:
1. Hoffman, R. K., et al. Thermal Inactivation of Aerosolized Bacillus subtilis var. niger Spores. Appl. Microbiol. 22(4): Oct. 1971.

2. Recommendations of PQAP, meeting held Feb. 1, 1973, New Orleans, LA.

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PARAMETER TITLE: Probability of Surface Organisms Surviving Ultraviolet Radiation (P (uv))

VALUE			APPLICATION	
UPPER	1		MISSION	All
ACCEPTABLE	See Below		PP CATEGORY	IV
LOWER	$< 10^{-4}$		PLANET	All

PARAMETER DEFINITION: Probability that a randomly selected organism exposed to extraterrestrial ultraviolet radiation will survive the dose applicable to the mission specific conditions.

APPLICABLE SOURCE: All organisms exposed to extraterrestrial ultraviolet radiation.

CONSTRAINTS: Selection of a particular value is to be made in two steps as follows:

1. Assuming complete exposure of the microorganisms, i.e., no shielding, P(uv) is determined by the function described below. The value of P(uv) as a function of time is a straight line on a log-log scale. For Martian missions, the line is defined by the following two points:

(a) P(uv) = 1 for a time of exposure of 1 minute, or less, and

(b) P(uv) = 1×10^{-4} for a time of exposure of 1 hour.

P(uv) for times of exposure other than the above can be obtained by interpolation or extrapolation of these two points. For distances other than for Mars (1.5A.U.), the time of exposure needed shall be scaled by an inverse square relationship.

2. The value obtained in accordance with the above must be increased to allow for the effects of shielding by structures or by small particles such as dust and debris.

REFERENCES: PQAP Review on January 18-19, 1972, at Cape Canaveral, FL.

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PARAMETER TITLE: Constraints for Biobarriers

(1) Microbial barriers that are continuously maintained at a static pressure of at least 1244 Pascals (9.3 Torr; 5 inches of H2O) above the ambient pressure shall be considered microbiologically sealed. For sample handling systems, lower-pressure differentials may be employed for biological safety cabinets per the regulations of the U.S. Centers for Disease Control and Prevention (Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets. 2nd Ed.2000. http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm).

(2) Microbial barriers that operate essentially at ambient pressure through the use of microbial filters shall be considered microbiologically sealed if the following occur:

(i) The designs of all filter mountings, barrier joints, seals etc., have been tested in accordance with applicable design and test specifications and found capable of retaining 99.97 percent of all particles or organisms greater than 0.3 um in size.

(ii) The filters are High Efficiency Particulate Air Filters ("HEPA Filters") capable of removing 99.97 percent of all particles greater than 0.3 um in size.

(iii) All elements of the filter system are procured, installed, tested, inspected, and maintained using appropriate quality assurance provisions.

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