



NASA Procedural Requirements

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Subject: Planetary Protection Provisions for Robotic Extraterrestrial Missions

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CHAPTER 3. Planetary Protection Constraints

3.1 General

The following planetary protection constraints, as may be applicable to each mission, are required. Specific exceptions to these constraints may be requested by a flight project in accordance with the provisions of 2.4 - Request for Deviations.

3.1.1 Specification of Parameters

- a. In order for a flight project to demonstrate compliance with planetary protection requirements, appropriate mission specific parameters and specifications (such as the microbial burden requirement for a mission type to a given target planet) will be specified by the PPO at the initiation of the project. Each major parameter and specification will be defined and its value specified on a "Parameter Specification Sheet" which shall be valid when dated and signed by the PPO. Flight projects may use applicable values specified therein without further authorization. Deviations from specified values shall be handled per 2.4. All approved planetary protection parameter specifications are included in Appendix B.
- b. The values adopted by a project for undesignated parameters and specifications are subject to the approval of the PPO. These project-developed parameters and specifications will appear in the "Planetary Protection Plan" with later changes reflected in the "Pre-Launch Planetary Protection Report." Approval of these documents will constitute approval of the parameters and specifications contained therein. Alternatively, a project manager may request that the PPO issue appropriate Parameter Specification Sheets based on submitted new information and data.
- c. In addition to the primary purpose of designating parameters and specifications used in mission planning, Parameter Specification Sheets also may be used for other purposes, such as defining contamination-related process parameters (e.g., minimum temperature for microbial reduction processes, etc.).

3.1.2 Microbial Reduction

3.1.2.1 Microbial Reduction for Planetary Spacecraft (Including Capsules and Probes) - Post Assembly

- a. Microbial reduction for an entire planetary spacecraft (including planetary entry probes and planetary landing capsules) may be accomplished by any approved process. Currently, the only approved method for actively reducing spacecraft to near sterility levels is through the application of dry heat per the appropriate specifications in Appendix B.
- b. Alternate methods of microbial reduction may be proposed, such as by chemical or radiation techniques or various combinations of these techniques with heat. Approval of such methods will be based on a rigorous examination of supplied data which must demonstrate conclusively the biological effectiveness and reproducibility of the alternate method for the specific application under consideration.
- c. In no case shall basic parameters of microbial reduction processes (e.g., temperature, radiation type, etc.) be made binding in contractual instruments or governing project documents without documented approval of

these parameters by the PPO. Usually the specification of these basic parameters will be made in (1) the Microbial Reduction Plan, (2) Parameter Specification Sheets, or (3) contractor-prepared documents submitted for project approval. Approval of these documents by the PPO will constitute approval of the parameters.

3.1.2.2 Microbial Reduction Calculations

a. Validity of Parameter Values

Parameter values, other than those specified in applicable Parameter Specification Sheets, that are used in calculating microbial reduction process cycles shall be supported by data from reproducible laboratory tests or by suitable technical references.

b. Estimation of Surviving Microorganisms

A calculation of the microbial reduction produced by a given process shall demonstrate that the predicted number of microorganisms surviving the process does not exceed the acceptable value given in the "Pre-Launch Planetary Protection Report."

c. Microbial Reduction Temperature Constraints

For those microbial reduction process cycles that use transient temperature lethality effects, the "dry heat" temperature used to begin lethality calculations shall be as stated in a Parameter Specification Sheet. The minimum steady-state temperature of the dry heat cycle shall not be less than that specified in either the approved Microbial Reduction Plan or in a Parameter Specification Sheet.

3.1.2.3 Verification of Microbial Reduction

Verification that a spacecraft has achieved the required degree of microbial reduction shall not require microbiological assay of the interior of the spacecraft subsequent to the application of the microbial reduction process. Each spacecraft will be considered to have met its microbial reduction requirement provided that the following occur:

- a. Approved microbial reduction processes were used.
- b. The microbial burden of the spacecraft prior to the application of the microbial reduction process has been estimated (by a means acceptable to the PPO) to be within limits that will allow the planned microbial reduction process to be adequate.
- c. It has been verified and documented that the specified microbial reduction process parameters, such as time, atmospheric composition (including water vapor), and temperature, have been properly imposed on the spacecraft.

3.1.2.4 Microbial Reduction of Planetary Spacecraft Parts, Components, and Subsystems Prior to Spacecraft Assembly

It may be desirable to subject either all or certain elements of the spacecraft hardware to a microbial reduction process prior to their assembly. The microbial reduction of such hardware may be accomplished by methods other than those used for the entire spacecraft provided that the following occur:

- a. A statement is made in the Microbial Reduction Plan that unique microbial reduction techniques or processes different from those applied to such hardware during the microbial reduction of the entire spacecraft will be used.
- b. Each unique microbial reduction technique or process cycle is described in a process specification that includes the biological qualification and quality assurance requirements applicable to the process.
- c. Each unique microbial reduction technique or process cycle is approved by the PPO.
- d. The microbial reduction process specification to be used on an individual item of hardware must be cited in its detailed engineering specification, as an applicable document.
- e. The unique microbial reduction techniques or process cycles employed do not degrade the ability of the spacecraft to withstand the standard "dry heat" or other approved process cycles to be applied to the entire spacecraft.

3.1.2.5 Use of Microbial Barriers to Prevent Recontamination

- a. Preplanned operations involving the use of microbial barriers after microbial reduction processes have been conducted may be proposed as part of the Planetary Protection Plan or Subsidiary Plans. If the use of

microbial barriers is proposed, the appropriate plan shall describe the operation and qualification of both the hardware and techniques to be used. The following constraints apply to the design and operation of spacecraft microbial barriers:

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.

3.1.3 Microbiology Related Determinations

3.1.3.1 Death Rates of Populations of Microorganisms

Calculations involving the death rates of populations of microorganisms subjected to sterilizing conditions shall be based on a death rate model (kill curve) approved by the PPO.

3.1.3.2 Microbiological Assay

- a. The procedures used for the microbiological assay of spacecraft hardware and their associated environments shall be as defined in the current version of NPR 5340.1, "NASA Standard Procedures for the Microbiological Examination of Space Hardware," as modified and supplemented by the project's "Microbiological Assay Plan." The approval and use of alternative assay procedures consistent with mission and life detection objectives may be proposed to the PPO by the Project Manager.
- b. The following paragraphs describe required microbiological assays:
 1. In addition to those microbiological assays which a flight project organization or its contractors may wish to conduct, various verification assays (see Chapter 5) will be conducted for the PPO by an organization designated by the PPO. Verification assays may be observed by involved flight project and contractor organizations.
 2. Microbial samples taken from spacecraft hardware, the assembly facility environment, etc. shall be furnished to the PPO by the flight project (or contractors) in accordance with the quantity and locations identified in the Microbiological Assay Plan. Collection of microbiological samples may, at the option of the PPO, be subject to observation by the PPO or his/her designated representative. Microbiological samples will be processed by the organization designated by the PPO to obtain pertinent data (e.g., microorganism types and numbers).
 3. In the event that data are suspect due to possible laboratory contamination, an Assay Review Board, appointed by the PPO, shall be formed to review the suspect data and their causes. This Board shall be chaired by the PPO (or designee) with members representing both the organization conducting the assay and the involved flight project and such other members designated by the PPO to provide technical adjudication of the matter. The Board shall present its findings and conclusions to the PPO together with appropriate recommendations.

3.1.4 Launch and Post-Launch Operations (Categories III-V)

3.1.4.1 Launch Operations Constraints

To assure that planetary protection requirements are met throughout launch operations, and until the spacecraft leaves the atmosphere, the PPO (or designated representative) will be present at the launch site during launch operations. As a part of launch operations, the PPO shall verify that planetary protection requirements have been met and that the mission may be launched. To provide a basis for this judgment, the project shall make available to the PPO pertinent information and documentation generated since the Pre-Launch Planetary Protection Review and the Launch Readiness Review as well as real-time information relevant to planetary protection aspects of launch operations.

3.1.4.2 Post-Launch Changes

Changes from the original mission plan that become necessary as a result of post-launch anomalies shall be approved by the PPO before implementation if such changes potentially could affect compliance with planetary protection requirements (also see 2.4.b).

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