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Exotech Systems, Inc.

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August 3, 1971

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National Aeronautics and Space Administration
Headquarters
Planetary Quarantine Office
Washington, D. C. 20546

Attention: Lawrence B. Hall Code SL

Subject: Fifth Quarterly Progress Report, contract NASw-2062, Planning, Evaluation and Analytical Studies to Implement Planetary Quarantine Requirements.

Gentlemen:

This report constitutes the fifth quarterly progress report summarizing work through June 30, 1971 on the 8 active tasks of the contract.

Emphasis during this reporting period was on activities in support of the following:

- Planetary Quarantine Seminar in Seattle, Washington June 18 and 19, 1971.
- Presentations to the AIBS Planetary Quarantine Advisory Panel June 20 and 21, 1971 in Seattle, Washington on (a) probability of microbial release, (b) estimation of buried burden, and (c) approach to the control of safety margins in the implementation of planetary quarantine requirements.
- Meeting of the COSPAR Panel on Planetary Quarantine in Seattle, Washington, week of June 21, 1971.

Task 8. Evaluation of Planetary Quarantine Requirements

The Planetary Quarantine Office continuously reviews and reassesses requirements and constraints imposed upon space flight projects. Under this task evaluations are conducted to support the justification and establishment of these requirements. Work was performed in the following areas:

(a) A method was developed to permit the allocation of PQ requirements to an entire flight mission, leaving suballocation flexibility (e.g., to lander and orbiter portions) to the flight project.

(b) A preliminary analysis was performed of the probability of impact of Mariner Mars 1971 to determine if a 50 year orbital lifetime can be expected with 95% confidence. This analysis relates to concern on the part of some members of the Space Science Board with the adequacy of current orbital lifetime requirements.

(c) Mr. E. Bacon of Exotech Systems, Inc. co-authored a paper with Dr. Fox and Mr. L.B. Hall of NASA on "Development of Planetary Quarantine in the United States" for presentation at the COSPAR meeting in Seattle, Washington, June 1971.

(4) Supporting services were provided to the NASA Planetary Quarantine Office in preparation for the meeting of the COSPAR Planetary Quarantine Panel in Seattle, Washington.

Task 9. Quarantine Document System for Planetary Flight Missions

The Quarantine Document System is an indexed file of material pertinent to the review of flight project quarantine plans and operations. This task covers the operation, maintenance and updating of the system.

The collection has grown to 241 individual documents relating to all active planetary flight projects. All of these documents have been catalogued and indexed.

Considerable use of this file was made in preparation for the June meetings in Seattle, Washington and a substantial increase in the collection is anticipated as a result of these meetings.

Task 10. Microbial Contamination Logs for Venus and Mars

Logs listing pertinent contamination data for completed planetary missions are required by the Planetary Quarantine Office. This task covers the preparation and updating of logs for Venus and Mars.

During the reporting period microbial contamination logs for Venus and Mars were updated and issued. Recent U.S. and U.S.S.R. missions were added and revisions were made to contamination estimates based upon new values for quarantine parameters including the probability of growth.

Further revisions will be effected following planetary encounter for recently launched missions, and as a result of a review of the Contamination Logs by COSPAR committees during the Seattle meetings.

Task 11. Evaluation of Flight Project Quarantine Plans

Efforts under this task support the Planetary Quarantine Office evaluation of flight project quarantine plans for compliance with NASA PQ requirements and compatibility with accepted practices.

No formal plans were submitted during this reporting period for review by the Planetary Quarantine Office. However, an informal review was made of Viking plans for treating the problem of bioshield recontamination.

Mr. Samuel Schalkowsky of Exotech Systems, Inc. attended Viking Project review meetings at Langley on March 24 and June 1, 1971 in relation to bioshield recontamination and other Viking PQ matters.

Task 12. Supporting Technology Transfer

Emphasis during this reporting period was on the preparation of state-of-the-art reports on Ethylene Oxide Sterilization and Filtration, as summarized below:

(a) Ethylene Oxide Sterilization

A preliminary literature search to develop a basis for the state-of-the-art report on ethylene oxide sterilization has been completed. Topics of specific concern in this search included the limitations associated with the use of ethylene oxide on spacecraft, environmental factors that determine its relative efficiency and microorganism characteristics affecting its efficiency. With few exceptions, notably the temperature effect and the sterilization rate, sufficient information has been obtained and the first draft is near completion.

It was also determined through the literature search that consideration had to be given to the microorganism age, or stage of development, and the population of microorganisms on the object to be sterilized. Sections treating these topics have thus been added to the text and the literature search will continue as the need for specific information arises.

(b) Filtration of Microorganisms

A preliminary review of the literature was performed and the annotated outline was completed. The documents obtained through the literature search include information concerning the kinds of air and liquid filters currently in use, evaluation of their efficiencies, testing techniques and comparison of air filtration to other air cleaning methods.

Lack of documented information was noted in the area of direct filter application in the spacecraft sterilization process. It is in this direction that our present efforts are focused. Personal contacts are used as the main source for this information while efforts continue to obtain pertinent documents. A draft of the state-of-the-art report will be completed by the end of August.

Task 13. Specification of the Probability of Microbial Release

Appendix A, entitled, "Analysis of Microbial Release Probabilities," summarizes the data presented at the PQ seminar and to PQAP in Seattle on this topic. As noted therein, a specific recommendation is provided for the value of microbial release from solids, based on preliminary erosion data from Boeing/JPL. More complete data is now available on the Boeing tests and will be reviewed in the next reporting period. In addition, conclusions will be reached on the recommended values for microbial release from open and mated surfaces.

Task 14. Estimation of the Encapsulated Microbial Burden

As noted in the previous quarterly report, this task is being performed in collaboration with personnel from PHS–Phoenix. A preliminary report on the status of this work was made to the AIBS Planetary Quarantine Advisory Panel during its April 22, 1971 meeting in Atlanta.

Appendix B contains the material presented on this topic at the PQ Seminar June 18, 1971 and to PQAP the following week in Seattle, Washington. The following highlights current status and plans for the next reporting period:

(1) There is general acceptance of the approach to the estimation of buried burden through microbial densities. These densities represent the burden per unit volume inside materials as received by manufacturers of spacecraft equipment and the additional surface burden, per unit area, encapsulated in the course of spacecraft equipment manufacture (e.g., conformal coating). Flight projects would be responsible for estimating the volumes and areas involved, as well as accounting for the sterilizing effects of spacecraft manufacture and test.

(2) We are continuing to evaluate requirements for laboratory testing of buried burden in support of PHS–Phoenix activities. This work is strongly dependent upon receiving data concerning Mariner Mars '69 materials from JPL.

(3) We are collaborating with PHS–Phoenix in obtaining data for estimating the probability of microorganisms surviving grinding processes. This parameter is essential to the realistic interpretation and extrapolation of bio-assay work on buried contamination.

(4) We are continuing to provide support to PHS–Phoenix in the utilization of our analytical model (see Task 15 below)

for the experimental assay of buried contamination in selected parts and materials.

The analysis of all available experimental data will be completed in the next reporting period as a basis for recommending specific values for the volume and bio-densities.

Task 15. Supporting Analysis of Planetary Quarantine and Sterilization Parameters

This task includes analyses, as necessary, to support the specification of flight project requirements, the review of flight project procedures, and the recommended changes in PQ constraints. In addition to the analytical work noted in the previous task write ups, the following work was performed:

(a) Assay of Encapsulated Microbial Burden

This work supports the design of experimental procedures and evaluation of laboratory data at PHS–Phoenix; it is also used to interpret data reported in earlier investigations of buried burden.

Following the change in the systems model in which the buried load was redefined as a random variable, a statistical procedure to estimate the density of buried load in spacecraft materials was developed and is now being fully documented in a self-contained report.

(b) Estimation of Lander Recontamination

The analytical model developed earlier in support of evaluations of bio-shield recontamination approaches has been completed and is currently being documented.

(c) Control of Safety Margins in PQ Implementation

This subject has become central to the establishment of parameter values in the implementation of PQ requirements, including the probability of release, encapsulated burden and many others. An initial approach to the avoidance of excessive safety margins has been developed and presented at the PQ Seminar and to PQAP in Seattle. Appendix C summarizes this material. Future work in this area will take into account the recommendations made by PQAP.

Very truly yours,

EXOTECH SYSTEMS, INC.

Edward J. Bacon /S. [illegible]

Edward J. Bacon
Project Manager

APPENDIX A

ANALYSIS OF MICROBIAL RELEASE PROBABILITIES

by
Edward J. Bacon
Exotech Systems, Inc.
Washington, D.C.

Presented
AIBS Semi-Annual Spacecraft Sterilization Technology
Seminar

Seattle, Washington
June 1971

RELEASE OF BURIED BIOBURDEN

- FACTOR IN ESTABLISHING HEAT STERILIZATION REQUIREMENTS
- PRESENTLY USED VALUE OF UNITY MAY BE UNDUELY CONSERVATIVE
- THERE IS LABORATORY TEST DATA AND A METHODOLOGY FOR DETERMINATION OF MORE REALISTIC VALUE

BASIC RELEASE MECHANISMS

(1) Release as an immediate consequence of fracture in hard impact — P_B (rI)

(2) Release resulting from erosion of landed material — P_B (re)

(3) Release resulting from erosion of material fragments — P_B (rIe)

$$P_B(r) = P_B(rI) + P_B(re) + P_B(rIe)$$

$$P_B(re) > P_B(rIe)$$

USE: $P_B(r) = P_B(re) + P_B(rI)$

RELEASE BY EROSION

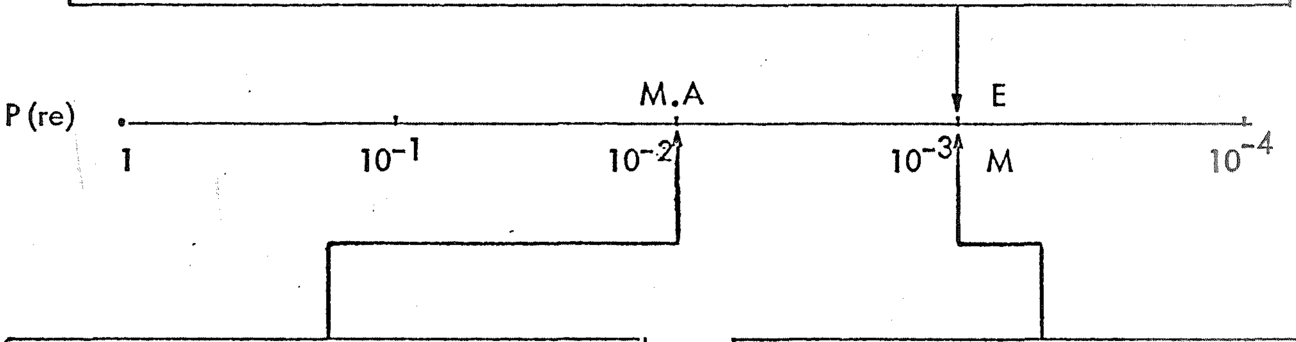
$$P_B(re) = P(e)\,P(se)$$

$P_B(re)$	Probability of Release of a Buried Microorganism Due to Erosion
$P(e)$	Probability of Total Erosion of the Lander
$P(se)$	Probability that an Individual Organism Will Survive the Erosion Process

ESTIMATION OF P (re)

BASELINE DATA — JPL/BOEING TESTS

- Methyl Methacrylate & Ecobond discs seeded with B. subtilus spores
- Erosion rates: Equivalent to 0.6—30 m/year
- Observed probability of survival: $P\ (se) \approx 10^{-3}$



MAX. ADVERSE – 0.99 CONF.

Erosion rates on Mars not as high as in baseline experiments, but sufficiently large to produce complete erosion

$\therefore\ P\ (e) = 1$

At the lower erosion rates.

$P\ (se) \approx 10^{-2}$

MEDIAN – 0.5 CONF.

High erosion rates likely

- Continuous strong winds
- High frequency yellow clouds
- High concentration of eroding particles-dust devils

$\therefore\ P\ (e) \approx 1$

Probability of surviving high erosion rates

$P\ (se) \approx 10^{-3}$

LEAST CONSERVATIVE VALUE OF P(re)

$P\ (re)_{MEDIAN} = 10^{-3}$

$P\ (re)_{MAX.\ ADVERSE} = 10^{-2}$

LEAST CONSERVATIVE: $P\ (re) = 2.3 \times 10^{-3}$

RELEASE BY IMPACT — RELATIVE SIGNIFICANCE

$$P_B(r) = 2.3 \times 10^{-3} + P(rI)$$

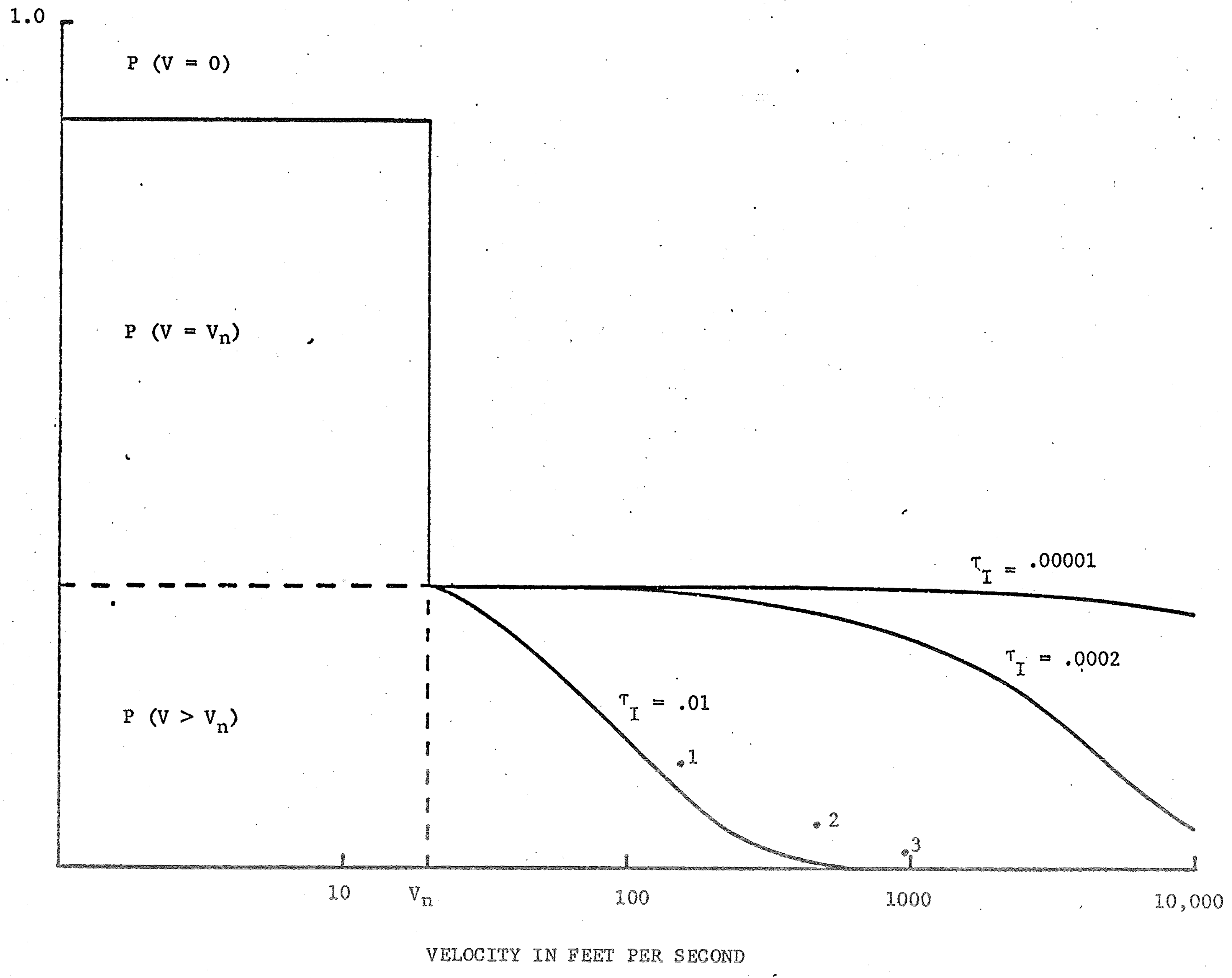
IF $P(rI) < 2.3 \times 10^{-3}$

THEN $P_B(r) = P_B(re) \approx 2.3 \times 10^{-3}$

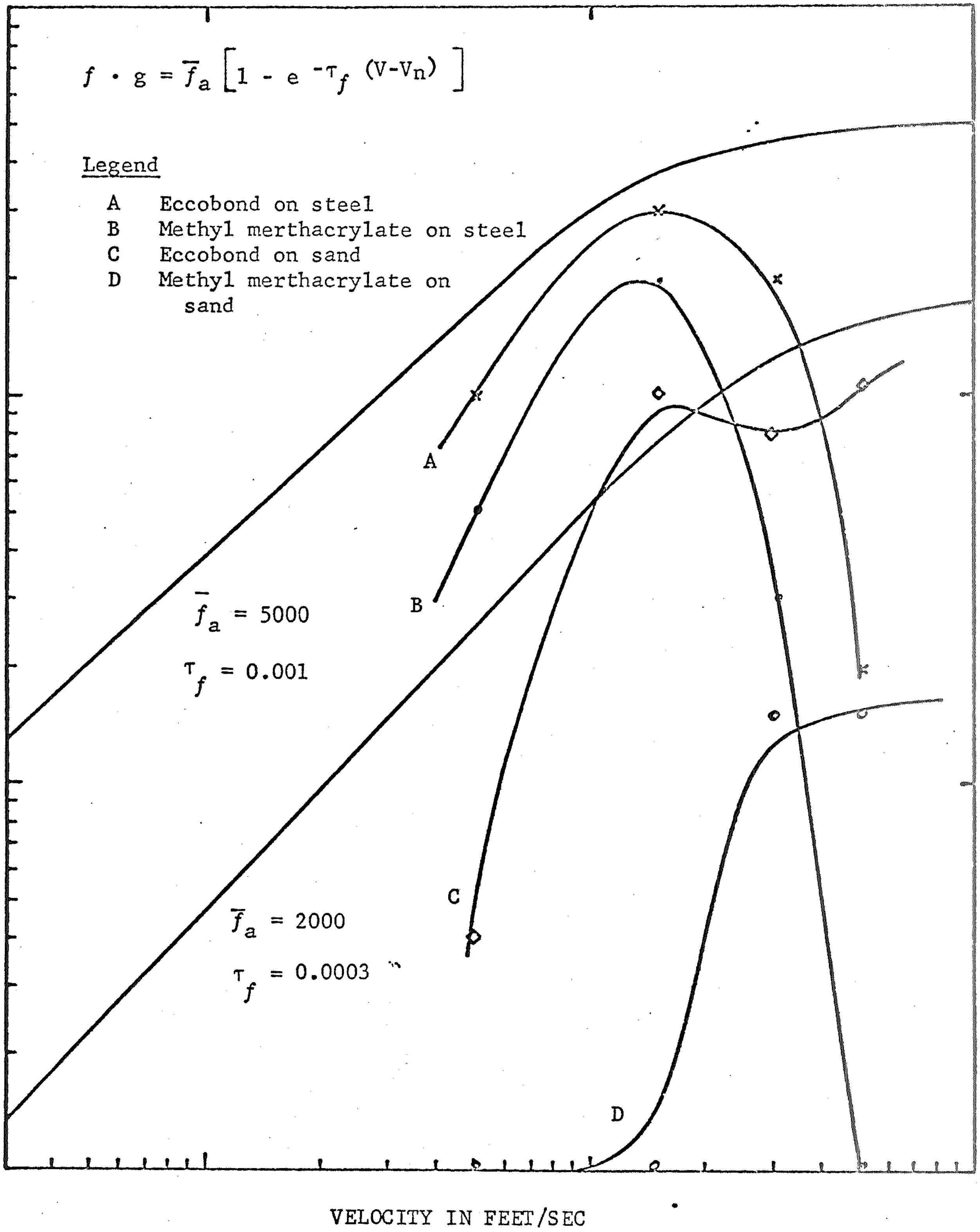
RELEASE BY IMPACT

- PROBABILITY THAT A FRACTURING IMPACT OCCURS P (V_I)
- THE IMPACT VELOCITY (V_I)
- THE DEGREE OF BREAK UP (f) — FUNCTION OF V_I
- PROBABILITY THAT MICROORGANISM SURVIVES IMPACT (g) — FUNCTION OF V_I
- LINEAR DEPTH IN MATERIAL FROM WHICH A MICROORGANISM CAN ESCAPE (λ)

VELOCITY DISTRIBUTION



FRACTURING FACTOR



RELEASE BY IMPACT

$$P_B\,(rI) = \lambda \int_{V_n}^{\infty} \overline{f}_a \left[1-e^{-\tau_f (V-V_n)}\right] \tau_I\, P\,(V_I) e^{-\tau_I (V-V_n)}\, dV$$

$$= \lambda\, \overline{f}_a\, P\,(V_I) \cdot K_V$$

$$\text{where} \quad K_V = \frac{\tau_f}{\tau_f + \tau_I}$$

IMPACT PARAMETER VALUES

		MEDIAN	MAX. ADVERSE	LEAST CONSERVATIVE
λ	Depth Coefficient	2×10^{-6}	4×10^{-6}	2.5×10^{-6}
$\bar{f}_a$	Fracture Factor	2×10^{3}	5×10^{3}	2.6×10^{3}
τ_f	Fracture Velocity Exponent	3×10^{-4}	2×10^{-2}	2.6×10^{-4}

$$P_B(rI) = \lambda \cdot P(V_I) \cdot K_V$$

$$= 6.5 \times 10^{-3} \cdot P(V_I) \cdot K_V$$

$$K_V = \frac{2.6 \times 10^{-4}}{2.6 \times 10^{-4}\ \tau_I} \leq 1$$

EFFECT OF MISSION PARAMETERS ON RELEASE BY IMPACT

$$P_B\,(rI) = 6.5 \times 10^{-3}\ P\,(V_I) \cdot K_V$$

		MAX. ADVERSE*	MOST PROBABLE*	MAX. FAVORABLE*
$P\,(V_I)$	RELIABILITY FACTOR	10×10^{-2}	2×10^{-2}	1×10^{-2}
K_V	VELOCITY FACTOR	1	0.6	0.03
$P_B(r_I)$	RELEASE/IMPACT	6.5×10^{-4}	7.8×10^{-5}	2×10^{-6}

*Estimates based on preliminary mission analysis

PROPOSED APPROACH

- ASSUME WORST CASE FOR VELOCITY FACTOR, VIZ.

$$K_V = 1$$

- ESTABLISH CONSTRAINT ON CUMMULATIVE PROBABILITY OF ACCIDENTAL IMPACT

$$P\ (V_I) \leq 10^{-1}$$

$$P_B\ (r) = 2.3 \times 10^{-3} + 6.5 \times 10^{-3} \times 10^{-1}$$

OR

$$P_B\ (r) = 3 \times 10^{-3}$$

CONCLUSIONS

- PROBABILITY OF RELEASE OF BURIED ORGANISM DEPENDS PRIMARILY ON RELEASE BY EROSION.

- IF JUDGMENT FACTORS INVOLVED IN ARRIVING AT VARIOUS PROBABILITY ESTIMATES ARE ACCEPTED, THEN

$$P_B(r) = 3 \times 10^{-3}$$

SUBJECT TO THE CONSTRAINT ON THE FLIGHT MISSION THAT

$$P(V_I) \leq 10^{-1}$$

APPENDIX B

ESTIMATION OF BURIED MICROBIAL BURDEN

by

Robert G. Lyle
Exotech Systems, Inc.
Washington, D.C.

Presented

AIBS Semi-Annual Spacecraft Sterilization Technology
Seminar

Seattle, Washington
June 1971

CONSTRAINTS ON CONTAMINATION BY BURIED MICRO-ORGANISMS

$$\boxed{m_B\,(0) \cdot 10^{-t_B/D_B} \cdot P_B\,(r) \cdot P_g \leq R_B}$$

R_B	ALLOCATION OF MISSION CONTAMINATION PROBABILITY TO BURIED LOAD
$m_B(0)$	NUMBER OF VIABLE MICRO-ORGANISMS PRIOR TO STERILIZATION (at $t_B = 0$)
t_B	NUMBER OF HOURS OF HEAT STERILIZATION
D_B	RESISTANCE OF MICRO-ORGANISMS TO HEAT STERILIZATION
$P_B(r)$	PROBABILITY THAT A BURIED ORGANISM WILL BE RELEASED ON PLANET SURFACE IN VIABLE STATE
P_g	PROBABILITY THAT A RELEASED ORGANISM WILL CAUSE PROLIFERATION OF TERRESTRIAL BIOTA ON MARS

$$m_B(0) = V \cdot d_V \cdot 10^{-t_x/D_x} + A \cdot d_A \cdot 10^{-t_x/D_x}$$

WHERE:

V = TOTAL VOLUME OF SPACECRAFT MATERIALS AND PARTS CONTAINING BURIED BIOBURDEN

A = TOTAL ENCAPSULATED SURFACE AREAS OF SPACECRAFT CONTAINING BURIED BIOBURDEN

d_V = DENSITY OF BURIED BIOBURDEN WITHIN MATERIALS COMPRISING V (SPORES/CM^3)

d_A = DENSITY OF BIOBURDEN BURIED AT ENCAPSULATED SURFACES COMPRISING A (SPORES/CM^2)

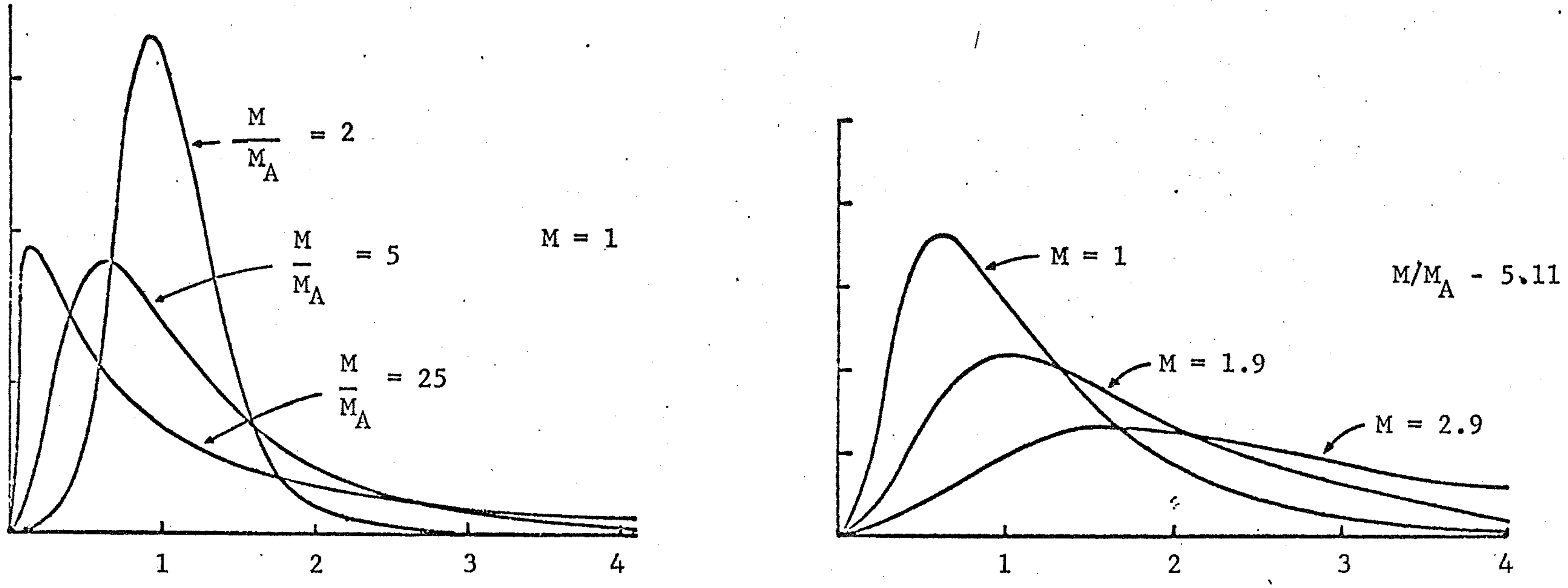
D_x = TIME IN HOURS REQUIRED AT A GIVEN TEMPERATURE TO DESTROY 90% OF A BURIED BIOLOGICAL POPULATION

t_x = TIME OF EXPOSURE AT THE STERILIZING TEMPERATURE ASSOCIATED WITH D_x

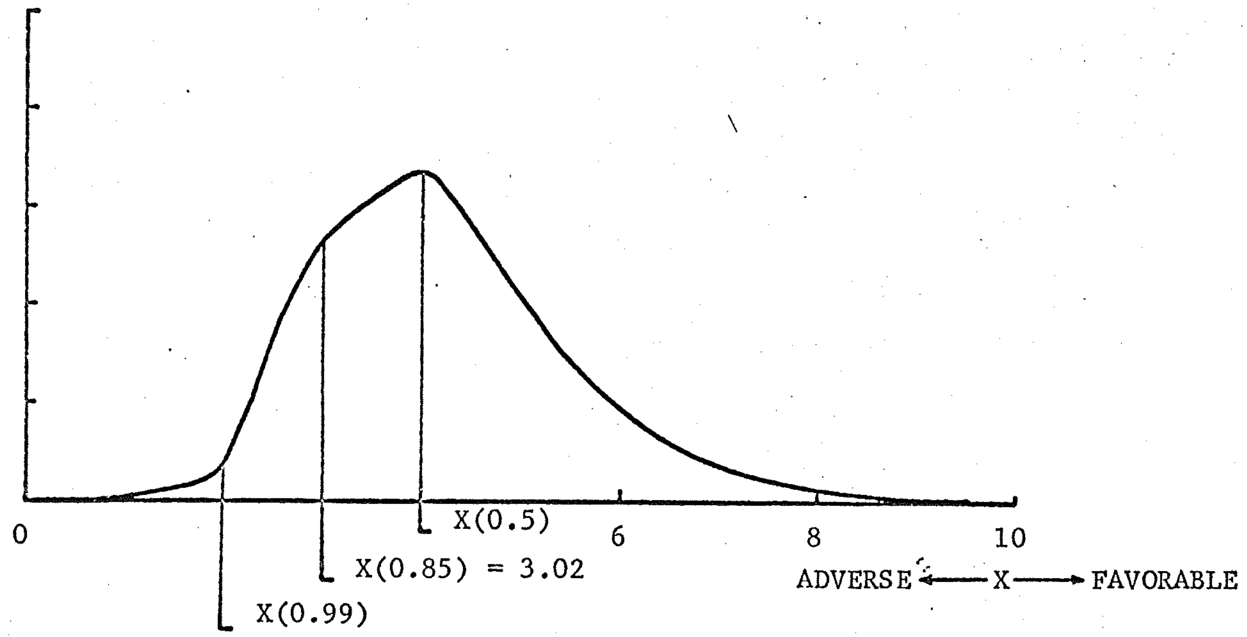
$$m_B\,(0) \;=\; 10^{-t_x/D_x} \sum d_{V_i} V_i + 10^{-t_y/D_y} \sum d_{X_j} \cdot A_j$$

WHERE THE VARIOUS SUBSCRIPTS REPRESENT THE FACT THAT AN ESTIMATE OF THE BURIED BIOBURDEN MAY BE DESIRED FOR SEPARATE SUBASSEMBLIES OR REPAIRED UNITS RATHER THAN FOR THE ENTIRE SPACECRAFT.

LOG-NORMAL DISTRIBUTION



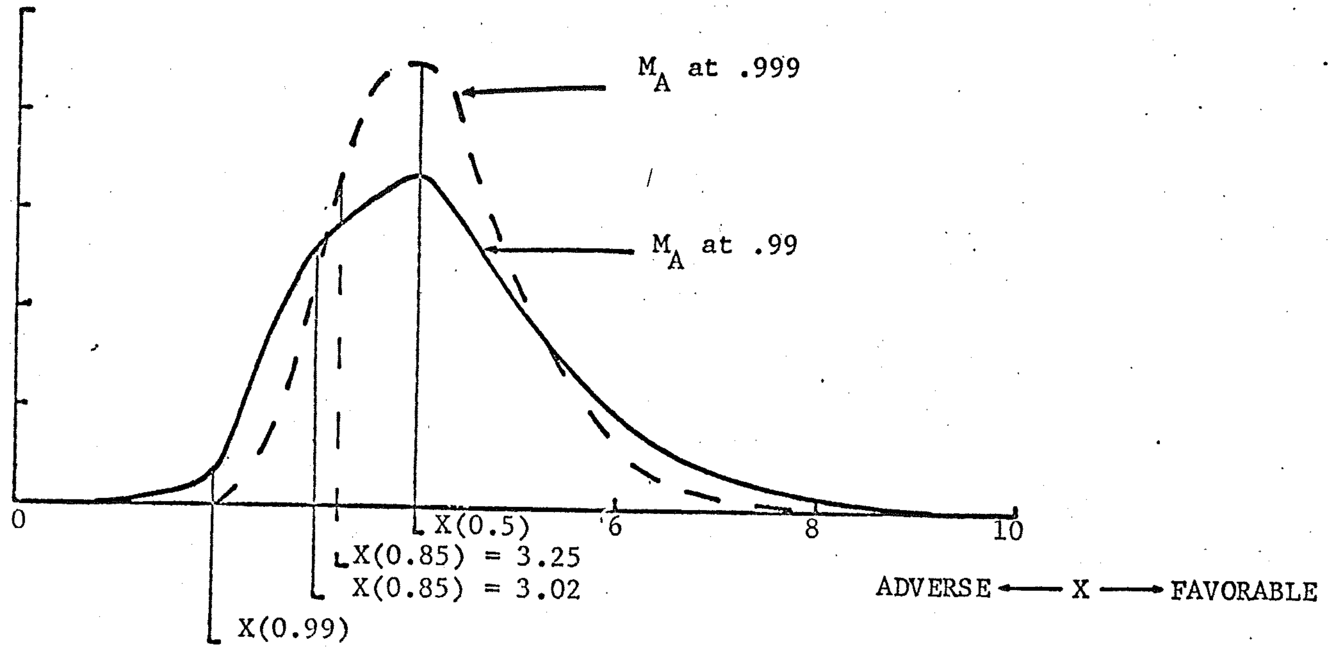
$LC = M(M_A/M)^{1/2.33}$



X(0.5) - MEDIAN (M) VALUE OF X

X(0.99) - MAXIMUM ADVERSE (M_A) VALUE OF X

X(0.85) - LEAST CONSERVATIVE (LC) VALUE OF X



X(0.5) - MEDIAN (M) VALUE OF X

X(0.99) - MAXIMUM ADVERSE (M_A) VALUE OF X

X(0.85) - LEAST CONSERVATIVE (LC) VALUE OF X

UNCERTAINTIES:

- ESTIMATE OF THE MEDIAN VALUE: IS IT REALLY THE 0.5 CONFIDENCE NUMBER?
- ESTIMATE OF THE MAXIMUM ADVERSE VALUE: IS IT REALLY THE 0.99 CONFIDENCE NUMBER?
- SHAPE OF THE DISTRIBUTION: IS THE LOG-NORMAL AN ADEQUATE REPRESENTATION?

COMPENSATING FACTORS:

- USING $P_g = 10^{-4}$ PROVIDES ABOUT THREE DECADES MARGIN IN THE ESTIMATION OF ANY ONE CONTAMINATION SOURCE.
- EACH PARAMETER IS ESTIMATED INDEPENDENTLY, IGNORING POSSIBLE CANCELLING EFFECTS.

- CRITIQUE THE SUBJECTIVE JUDGEMENTS INVOLVED IN THE APPROACH—IS THERE A CONSENSUS?

- DETERMINE WHETHER "RESIDUAL" SAFETY MARGIN OF 3 DECADES PER CONTAMINATION SOURCE IS APPROPRIATE.

- IF "RESIDUAL" MARGIN IS TOO LOW, ADJUST METHOD FOR CALCULATING LEAST CONSERVATIVE VALUE.

- IF "RESIDUAL" MARGIN IS TOO HIGH, ESTABLISH A LEAST CONSERVATIVE VALUE FOR P_g, RATHER THAN CURRENT MAXIMUM ADVERSE VALUE OF 10^{-4}.

- ESTIMATE PARAMETER VALUES BY:
  - (A) ESTABLISHING SUFFICIENT BASELINE DATA
  - (B) DEVELOPING CONSENSUS MEDIAN AND MAX. ADVERSE VALUES
  - (C) CALCULATING THE LEAST CONSERVATIVE VALUE.

APPENDIX C

SAFETY MARGINS AND THE IMPLEMENTATION OF PLANETARY QUARANTINE REQUIREMENTS

by

Samuel Schalkowsky
Exotech Systems, Inc.

Presented

AIBS Semi-Annual Spacecraft Sterilization Technology
Seminar

Seattle, Washington
June 1971

RECOMMENDATION OF COSPAR PANEL ON PLANETARY QUARANTINE

Leningrad, May 1970

"... the Panel wishes to call to the attention of COSPAR the desirability of improving the contamination model ... Recognizing that setting errors of estimation for the several relevant terms of the equation may be very difficult, the Panel notes:

a) Without estimating errors and their propagation one cannot defend the assumption that the overall chance of planetary contamination is in fact the value assigned.

b) A conscientious attempt to estimate all error terms will surely reveal specific sites of uncertainty better than can be done intuitively and indicate where renewed effort is warranted.

The Panel recommends that the equation referred to as the contamination model be up-dated by inclusion of error terms."

SPACE SCIENCE BOARD RECOMMENDATION

TO NASA, DECEMBER 1970

(Based on "Review of Sterilization Parameter: Probability of Growth (P_g)," by *ad hoc* Review Group, July 1970)

	Even-Odds Estimate	0.999 Confidence Factor – Upper Limit Estimate
P_g	3×10^{-9}	1×10^{-4}

"Predictably, the estimate of the probability of growth increases significantly with the requirement for high confidence in the individual estimates. This change is largely a reflection of our lack of knowledge of the Martian surface environmental conditions. In view of these uncertainties the review group recommends that NASA use the value of $P_g = 1 \times 10^{-4}$ for its spacecraft sterilization allocation model, at least until further data from planetary flights justify a re-evaluation. However, NASA should also recognize the conservative nature of this value for P_g when considering safety factors in the estimation of other sterilization parameters, so as to avoid excessive safety margins in the implementation of planetary quarantine requirements."

PLANETARY QUARANTINE REQUIREMENTS

COSPAR	RECOMMENDS AN UPPER BOUND FOR THE PROBABILITY THAT PLANET WILL BE CONTAMINATED FOR AN ASSUMED (ESTIMATED) NUMBER OF MISSIONS AND STATED PERIOD OF TIME.
NASA	SPECIFIES AN UPPER BOUND FOR THE PROBABILITY THAT A PARTICULAR FLIGHT MISSION WILL CONTAMINATE THE PLANET.
FLIGHT PROJECT	ALLOCATES TO FLIGHT ELEMENTS AN UPPER BOUND PROBABILITY OF CONTAMINATION.
IMPLEMENTATION	ANALYSIS OF INDIVIDUAL CONTAMINATION SOURCES (e.g., ENCAPSULATED ORGANISM) TO DEFINE PRECAUTIONS TO BE TAKEN (e.g., HEAT STERILIZATION) TO ASSURE THAT ALLOCATED UPPER BOUND IS NOT EXCEEDED.

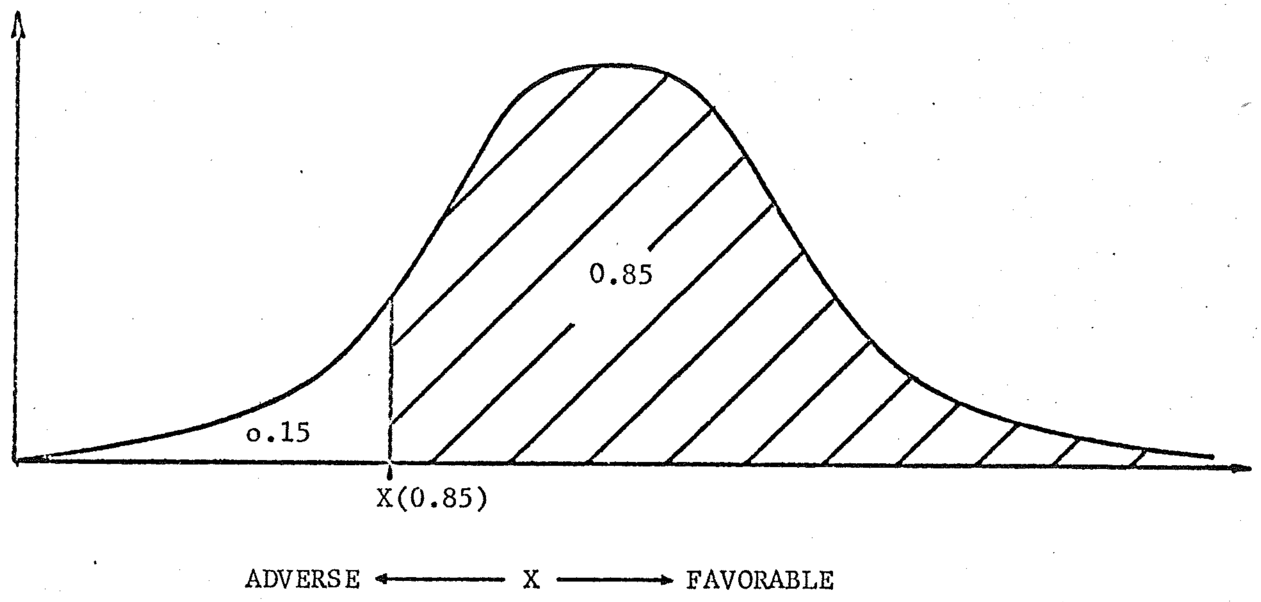
CONSTRAINTS ON CONTAMINATION BY

BURIED MICRO-ORGANISMS

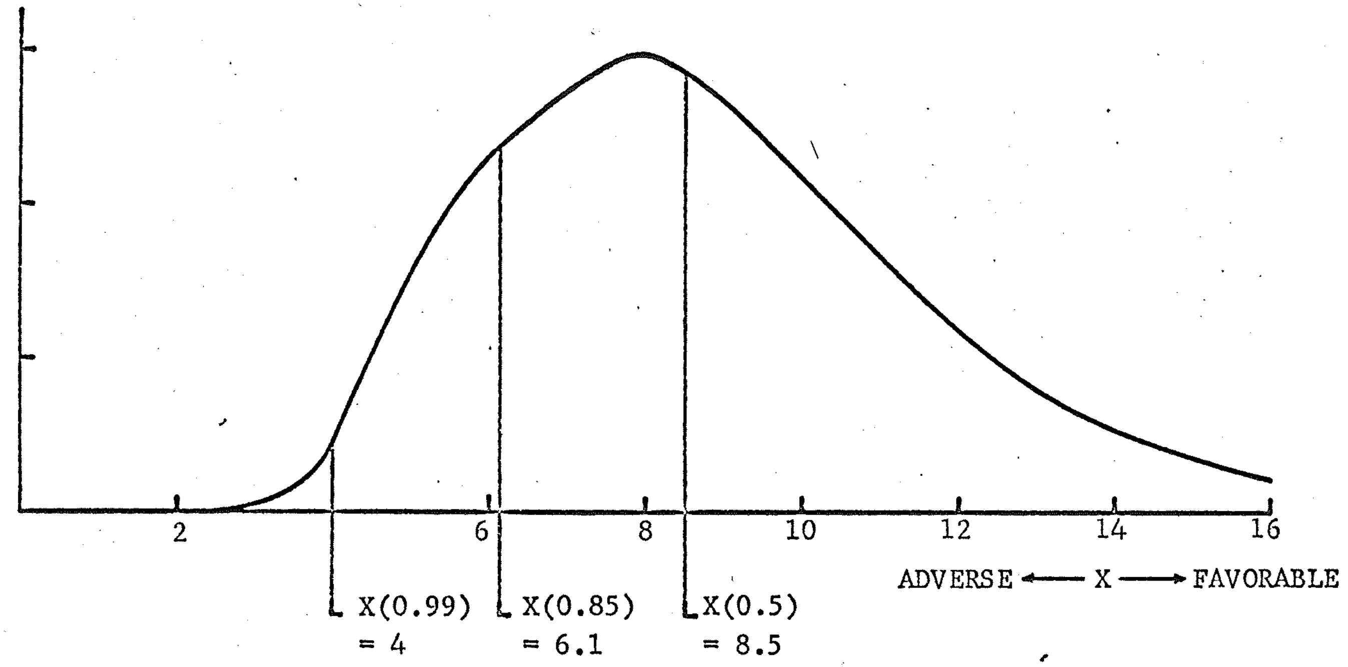
$$m_B(0) \cdot 10^{-t_B/D_B} \cdot P_B(r) \cdot P_g \leq R_B$$

R_B	ALLOCATION OF MISSION CONTAMINATION PROBABILITY TO BURIED LOAD
$m_B(0)$	NUMBER OF VIABLE MICRO-ORGANISMS PRIOR TO STERILIZATION (at $t_B = 0$)
t_B	NUMBER OF HOURS OF HEAT STERILIZATION
D_B	RESISTANCE OF MICRO-ORGANISMS TO HEAT STERILIZATION
$P_B(r)$.	PROBABILITY THAT A BURIED ORGANISM WILL BE RELEASED ON PLANET SURFACE IN VIABLE STATE
P_g	PROBABILITY THAT A RELEASED ORGANISM WILL CAUSE PROLIFERATION OF TERRESTRIAL BIOTA ON MARS

ASSUME DISTRIBUTION IS KNOWN



X(0.85) HAS THE PROPERTY THAT IT ASSURES US OF NOT EXCEEDING THE INEQUALITY CONSTRAINT WITH MINIMUM MARGIN.



DEFINE:

X(0.5) - MEDIAN (M) VALUE OF X
X(0.99) - MAXIMUM ADVERSE (M_A) VALUE OF X
X(0.85) - LEAST CONSERVATIVE (LC) VALUE OF X

METHODOLOGY

1. OBTAIN BASELINE DATA

2. DEFINE PERTINENT FACTORS WHICH WILL PERMIT GENERALIZATION FROM BASELINE DATA TO SPACECRAFT ENVIRONMENT.

3. SELECT
   - A) MEDIAN VALUE (0.5 CONFIDENCE)
   - B) MAX. ADVERSE VALUE (0.99 CONFIDENCE)

4. ESTABLISH LEAST CONSERVATIVE VALUE AS FINAL RESULT.

EXPERIMENTAL CONSIDERATIONS

$\hat{\rho}_\mu$ — estimated mean number of viable micro-organisms per cubic / cm

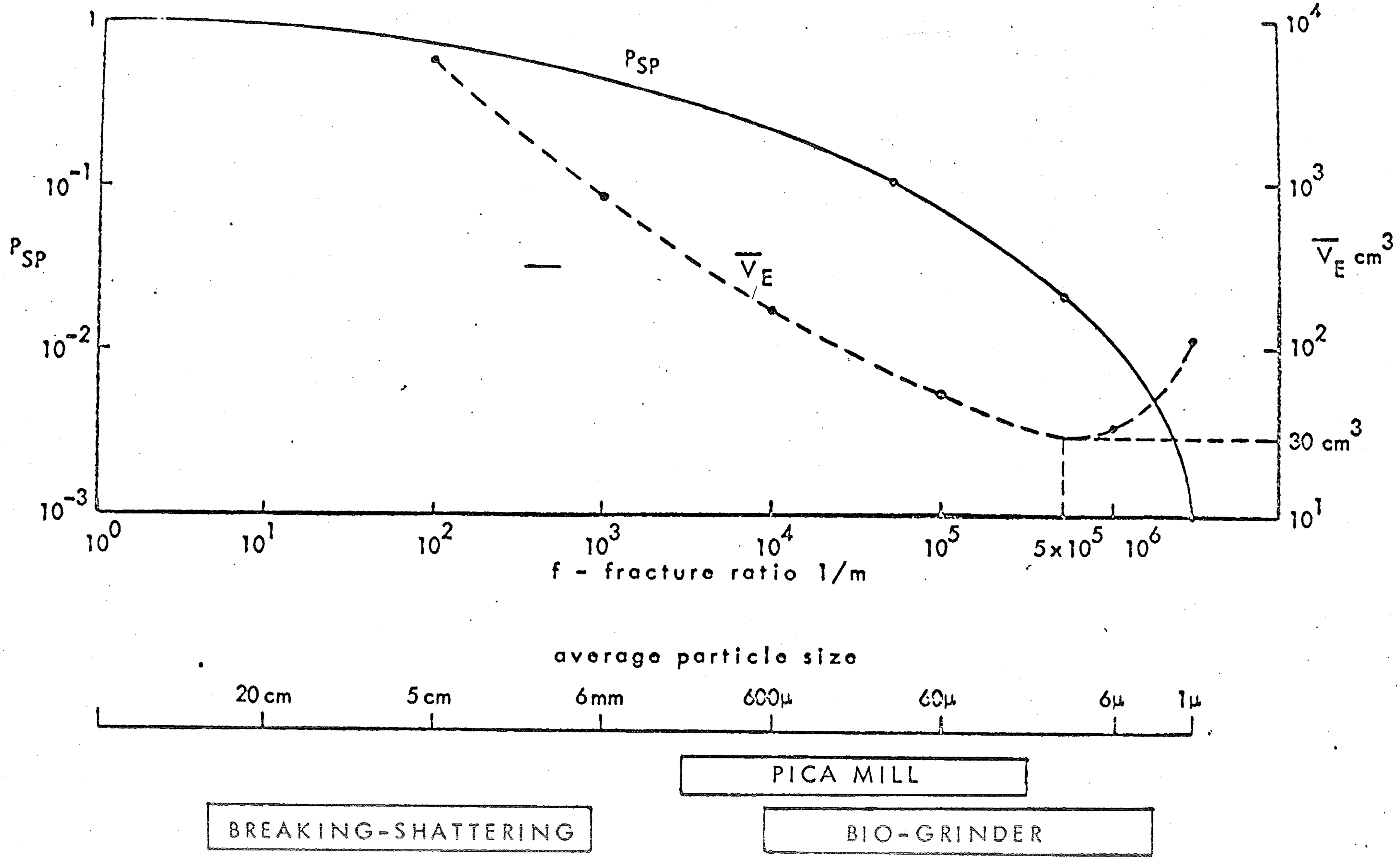
f — fracture ratio $= \frac{A_E}{V_E}$

A_E — newly exposed area of experimental material volume V_E

P_{SP} — probability of surviving fracturing process

λ — exposure depth coefficient $= 3 \times 10^{-6}$ m

ΣX_i — number of positive samples in V_E



$\overline{V}_E$ - normalized volume of experiment material: volume in cm^3 which will produce an estimated mean number of 1 organism/cm^3 for each positive sample observed.

Exotech Systems, Inc.

CALCULATION OF d_V

$$d_V = \frac{\Sigma x_i + \sqrt{\Sigma x_i} + \frac{1}{2}}{P_{sp} \lambda \Sigma A_i}$$

where:

x_i	1, if sample i yields positive 0, otherwise
P_{sp}	probability of surviving process of releasing spores
A_i	area exposed in i th sample
λ	depth of exposure $(2 \times 10^{-4}$ cm.)
Σ	summation over all samples

EXAMPLES FROM SURVEY OF EXPERIMENTAL DATA

Investigator/ Organization	Assay Item	No. Items	Total Volume $V_E(cm^3)$	Fracturing Procedure	Est. f	Est. P_{SP}	No. of Positives ΣX_i	d_V (organisms/cm^3) 85% confidence
Phillips & Hoffman Fort Detrick (October 1960)	capacitor (1 in. dia., 2.5 in. length)	62	32.8	not specified 50 ft^2 exposed (probably disassembled)	4×10^4	1	13	4.2
Portner & Hoffman Fort Detrick (Nov. 8, 1961)	solid propellant	37 cubes	8.2	"minced" (into cubes)	10^3	10^{-1}	0	0
Peterson & Favero PHS/Phoenix (1970-1971)	resistor fixed, composition .855 cm^3	40	34	broken in half exposed 40 cm^2	45	1	0	
	semiconductor rectifier }	10	14	broken in half exposed 19.5 cm^2	1.4	1	0	
	semiconductor rectifier }	30	42	pulverized	10^4	5×10^{-1}	1	3.2
	coil, adjustable core (7.8 g; 4.0 cm^3)	40	160	pulverized	$\approx 10^4$	5×10^{-1}	0	0
	resistor fixed wire wound (4.8 g; 2.5 cm^3)	27	68.5	disassembled	10^4	1	3	2.3
	capacitor, mylar/aluminum foil (3.5 g; 2.2 cm^3)	27	59.4	disassembled	10^5	1	1	0.1

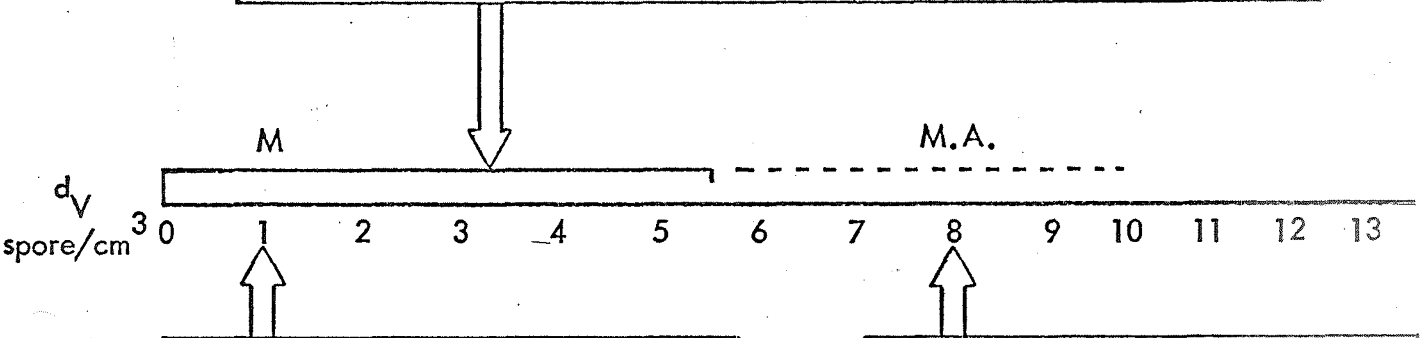
EXAMPLES FROM SURVEY OF EXPERIMENTAL DATA

Investigator/ Organization	Assay Item	No. Items	Total Volume V_E (cm^3)	Fracturing Procedure	Est. f	No. of Positives ΣX_i
Portner & Hoffman Fort Detrick (April 1960)	Electronic Piece-Parts					
	capacitor	8	not specified	broken and ground as far as possible (Particle size not specified)		6
	resistor	5	"			1
	transistor	4	"			1
	output transformer	1				1
Portner & Hoffman Fort Detrick (April 1960)	Solar Panel 9 cm^2 (assume 10 mill thick)	2 cells each in 5 tests	0.15	cross-sectioned to hexagonal cells (4 mm x 15 mm)	14	4 tests
J.T. Cordaro Aerospace Med. Div. Brooks AFB (August 1962)	capacitors	101	not specified	disassembled		9
	resistors	45	"	"		0
	diodes	5	"	"		0
	tubes	5	"	"		0
	relays	2	"	"		0
	transformers	4	"	"		1
	magnetic mod.	1	"	"		1
	micropositioner	1	"	"		0
	potentiometers	2	"	"		0

ESTIMATION OF d_V

BASELINE DATA

- Positives predominantly in sealed parts with encapsulated areas (laminations or windings)
- Some materials show positives (carbon, fiberglass, semi-conductor materials)
- Much of the past data not useful because of inadequate test and/or reporting procedures



MEDIAN — 0.5 CONF.

- Sealed parts (showing positives) are a small fraction of volume considered (ΣV)
- Materials which show positives are also small fraction of ΣV
- Many parts and materials show no positives
- High positive counts are from older data of questionable applicability

MAX. ADVERSE — 0.99 CONF.

- Lethality of assay process may be larger than found in control materials
- Sample of materials tested not fully representative

TENTATIVE ESTIMATE OF d_V

MEDIAN VALUE — 1 spore/cm^3

MAX. ADVERSE VALUE — 8 spores/cm^3

LEAST CONSERVATIVE VALUE: $d_V = 2.5$ spores/cm^3

ILLUSTRATIVE APPLICATION:

- ASSUME APPLICABLE MATERIAL VOLUME OF SPACECRAFT IS $V = 10^5 cm^3$
- UPPER BOUND ESTIMATE OF BURDEN BURIED WITHIN MATERIALS $= 2.5 \times 10^5$

EXCLUSIVE OF ALLOWANCES FOR STERILIZING EVENTS IN THE COURSE OF SPACECRAFT MANUFACTURE, ASSEMBLY AND TEST.

EXAMPLE OF EXPERIMENTAL DATA FOR d_A

ENVIRONMENT	SWAB EFFICIENCY	MICROORGANISMS/CM^{2}*
Very Clean**	33.33%	1.16 — 8.78
Controlled**	***	.807 — 1.56
10 k to 100 k Clean Rooms	***	.775 — 3.735
Class II Clean Rooms (1-11 viable particles/ft^{3} of air)	***	10.76 — 107.6
Class III Clean Rooms (0-0.2 viable particles/ft^{3} of air)	***	.043 — .43
Class IV Clean Rooms (0-2 viable particles/ft^{3} of air)	***	.15 — .516

* Spores generally assumed to be 10% of total microorganisms

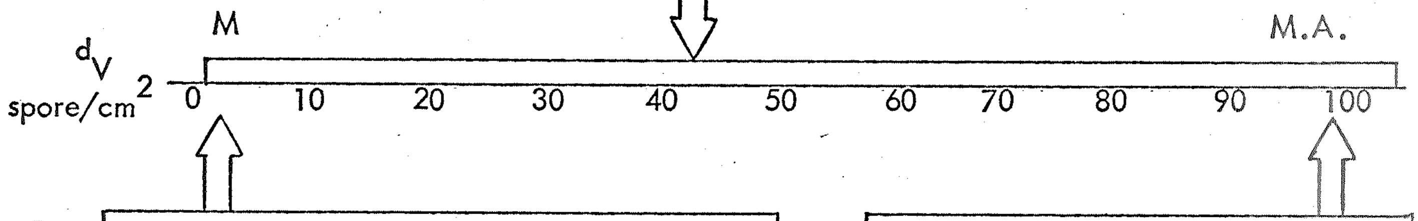
** Not otherwise specified

*** Swab efficiency not given but accounted for

ESTIMATION OF d_A

BASELINE DATA

- Principally fall-out data as measured in various environments
- Some data reflects handling of materials
- Assay of swabbing



MEDIAN – 0.5 CONF.

- Controlled environments for manufacture assembly, repair, etc. of electronic equipment
- Lethality of encapsulation procedures including surface preparation
- toxic constituents of coating materials
- Spores generally assumed not more than 10-15% of total microorganisms

MAX. ADVERSE – 0.99 CONF.

- Uncertainty in efficiency of swabbing
- Unknown environmental conditions in some manufacturing facilities
- Unknown degree of handling
- Uncertainty because of irregular surfaces (e.g., crevasses)

TENTATIVE ESTIMATE OF d_A

MEDIAN VALUE — 2 SPORES/CM^2

MAX. ADVERSE VALUE — 100 SPORES/CM^2

LEAST CONSERVATIVE VALUE — 12 SPORES/CM^2

ILLUSTRATIVE APPLICATION:

- ASSUME APPLICABLE ENCAPSULATED SURFACE AREA OF SPACECRAFT (CIRCUIT BOARDS, ETC.) IS

  $$A = 10^5 \text{ cm}^2$$

- UPPER BOUND ESTIMATE OF BURDEN ENCAPSULATED ON SURFACES

  $$1.2 \times 10^6$$

EXCLUSIVE OF POSSIBLE ALLOWANCES FOR DECONTAMINATING AND/OR STERILIZING EVENTS IN THE COURSE OF SPACECRAFT MANUFACTURE, ASSEMBLY AND TEST.