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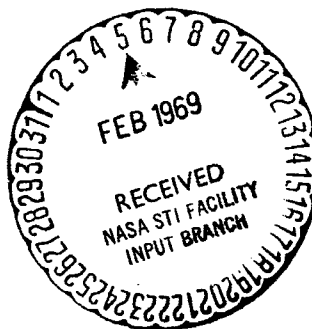
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A Study Program on the Development of a Mathematical Model(s) for Microbial Burden Prediction

Final Report

Volume I
Technical Report

DECEMBER 1968

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MARTIN MARIETTA CORPORATION

A STUDY PROGRAM ON THE DEVELOPMENT OF MATHEMATICAL

MODEL(S) FOR MICROBIAL BURDEN PREDICTION

JPL Contract 952028

Final Report

Volume I, Technical Report

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ABSTRACT

This report describes the work performed to develop and
build the Microbial Burden Prediction Model. The contract
period was divided into three (3) phases of program activity.
In Phase I, systems and detailed functional analyses were
performed on a typical Capsule Bus system portion of a plane-
tary probe (Voyager type). In Phase II, the results of the
Phase I analyses were reviewed to identify potential sources
of burden accumulation, the parameters associated with those
sources and the manner in which these parameters would influence
burden accumulation. Mathematical expressions were formulated,
as a predictive technique, to describe the burden accumulation
process. In Phase III, the computer model was developed and
checked out, using the Capsule Bus assembly and test sequence,
derived during Phase I, as the demonstration test case.

FOREWORD

This document represents the final technical report on JPL Contract 952028, <u>A Study Program on the Development of Mathematical Model(s) for Microbial Burden Prediction</u>. This report was prepared in accordance with the requirements established by the subject contract. The final report is submitted in three (3) volumes:

Volume I   Technical Report

Volume II   User's Manual for the Microbial Burden Prediction Program

Volume III   Appendices

CONTENTS

CONTENTS (Continued)

ILLUSTRATIONS

DEFINITIONS

1) <u>Planetary Vehicle</u> - A spacecraft designed to explore the planets. It consists of a probe system and a bus system.

2) <u>Capsule Bus System (or Bus System)</u> - The portion of a planetary vehicle that delivers the probe system to the vicinity of the planet and then flies by.

3) <u>Probe (or Probe System)</u> - The portion of a planetary vehicle that includes all subsystems that land on the planetary surface or directly support such landing; i.e., the canister and all subsystems contained within it.

4) <u>Probe Assembly</u> - The combination of parts and/or subassemblies of one capsule subsystem that are connected together or packaged together to form an item that is directly removable from a probe subsystem. This would normally represent the entity delivered to the probe system integration area.

5) <u>Probe Subsystems</u> - The probe subsystems are the canister, the lander, the maneuvering system, and the entry subsystem.

6) <u>Major Module</u> - A term used interchangeably with the term probe subsystem.

7) <u>Exterior Exposed Surfaces</u> - Those surfaces of an assembly, subsystem, or system that would be illuminated if placed at the center of an inwardly directed luminous sphere.

8) <u>Exterior Exposed Surface Burden</u> - The viable organisms existing on the exterior exposed surface of an item.

9) <u>Mated Surface Burden</u> - The viable organisms trapped between mating surfaces such as under screws and in joints.

10) <u>Occluded Surfaces</u> - Those surfaces of an assembly, subsystem, or system that are not exterior exposed surfaces but which would get wet if the item were immersed in a fluid.

11) <u>Zone</u> - A portion of the probe that may be uniquely identifed by consideration of such things as functional attributes of a subsystem, geometry, and thermal behavior. (The zones eventually will be the

thermal process units of the probe system on which the lethality cal-
culations will be based.)

12) Biologically Significant Zone - A zone for which the burden accumulation
process differs considerably from that of other zones due to differences
in orientation, surface material, contact, etc.

13) Assembly Initial Burden - The burden present on an assembly at the time
the assembly is integrated to its zone. The assembly initial burden is
a function of its history for the period from completion of the FA steri-
lization test to, but not including, integration of the assembly to its
zone during probe buildup.

14) Flight Acceptance Heat Sterilization Test (or FA Sterilization Test) - A
test that subjects hardware to a time-temperature cycle exceeding that
expected during terminal sterilization.

15) Assembly-Level Flight Acceptance Environmental Tests - Tests used to
demonstrate the ability of the equipment to satisfactorily perform in
selected environments at least as severe as flight. The flight accep-
tance tests may be limited to environments in which equipment enivon-
mental strength shows large variation, or to environments that have
historically been indicators of equipment quality. These environments
include vibration, shock, electromagnetic compatibility, thermal vaccum,
pressure transients, and surface pressure.

16) Interval Concept - A numerical technique for performing arithmetic
operations of addition, subtraction, multiplication, and division on
histograms (probability density functions) that are not necessarily
from identical underlying distributions. For the purposes of this con-
tract, the histograms (probability density functions) include, but are
not limited to, representation of the probability of occurrence versus
the number of microorganisms. If the probability density function is
continuous, discrete approximations are used.

17) Level of Activity - One of four levels of detail in the representation
of an assembly and test sequence; these levels, in order of increasing
detail, are:

First level   (STAGE)

Second level (TASK)

Third level (SUBTASK)

Fourth level (OPERATION).

18) <u>Clean Room</u> - A room provided with special air filters to reduce air-
borne particles; special clothing is also required to reduce the shedding
of particles from skin and hair. Clean rooms are usually classified
according to the maximum number of allowable particles (0.5 micron and
larger) per cubic foot of air; Class 100 and Class 100,000 are most
common. A laminar flow clean room has a relatively high airflow in
one direction only; such flow can be either crossflow (from one end of
the room to the other) or downflow (from ceiling to floor). See Ref 37
for more details.

CONTRACT REQUIREMENTS

This document is the final technical report on JPL Contract 952028,
A Study Program on the Development of a Mathematical Model(s) for Microbial
Burden Prediction. The contract period of performance was eight months from
contract go-ahead on 8 August 1967 to approximately 8 April 1968. The material
reported in this document describes the work performed by the Martin Marietta
Corporation to fulfill the requirements established in the subject contract.
To clarify specific contract requirements and identify the major tasks per-
formed, portions of the contract were excerpted and are presented below.

I. As Phase I, Integration and Test Sequences,

    A. Determine a generalized assembly and test sequence appli-
cable to several different types of probes or different
assembly and operation plans. The sequence shall commence
at the completion of the Assembly Level Flight Acceptance
Heat Sterilization Test and shall continue up to terminal
heat sterilization.

    B. Identify assembly operations that are frequently repeated
during probe buildup and test.

II. As Phase II, Parameterization of the Microbial Burden Prediction
problem,

    A. Identify parameters that significantly influence the
microbial loading of a probe that is assembled and
tested according to the sequence developed in Phase I.
It is assumed that the Assembly Level Flight Acceptance

Heat Test sterilizes each assembly to a probability of survival of micro-organism of 10^{-5}.

B. Formulate mathematical expressions for each parameter as a function of time, assembly or test procedure, and environment at time of assembly er test. The mathematical expressions shall include, but not be limited to, formulation of probability density functions usirg the interval concept for each parameter. All computer programs are required to run on a JPL IBM 7094-7044 Direct Couple System, Version 13 IBSY Monitor, IBJOB Fortran IV.

In support of Tasks II.A-B, the Contractor shall:

1. Search the literature.
2. List and explain all assumptions with appropriate references.
3. Identify all experiments necessary to verify the assumptions.

C. Determine criteria and expressions for the weighting of the parameters to measure the relative impact of each parameter on the total microbial burden on the probe.

D. Develop the Phase III model logic based on, but not limited to, utilization of inputs and outputs consisting of probability density functions using the interval concept.

III. As Phase III, Construction of Mathematical Models and Computerization,

A. Estimate the microbial burden on each zone of the probe using the interval concept.

1. Determine the criteria for the division of the probe into zones.

2. Estimate the assembly initial burden at the time the assembly is integrated into its zone.

3. Identify the assembly initial burden as being external surface burden, mated surface burden, or occluded surface burden.

4. Estimate the burden increment during assembly and test as a function of the sequence established in Phase I, time, assembly initial burden, and the parameters identified in Phase II.

5. Determine the exposure distribution of micro-organisms, i.e., determine the number of micro-organisms present on the zone as a function of the exposed surface area, mated surface area, and occluded surface area immediately prior to terminal heat sterilization.

6. Determine the genotype distribution at terminal heat sterilization; i.e., determine the number of micro-organisms expected on each zone by classifying the micro-organisms into categories defined by their resistance to dry heat.

B. Estimate the microbial burden on the probe using the interval concept,

1. Estimate the microbial burden at each stage of assembly and test; i.e., sum item under Paragraph III-A.4 over the "n" zones, or portions thereof.

2. Determine the exposure distribution on the probe at terminal heat sterilization; i.e., sum item under Paragraph III.A.5 over the "n" zones.

3. Determine the genotype distribution on the probe at terminal heat sterilization: i.e., sum item under Paragraph III.A.6 over the "n" zones.

C. Determine the uncertainty in the total microbial load as a function of the uncertainty in the input parameters.

D. Determine the number of assays that would be required to identify the burden level on each zone to any given confidence level; the expression shall include a factor accounting for the relative accuracy of various assay techniques.

I. INTRODUCTION

A mathematical model and associated computer programs were developed under this contract to predict the number of viable micro-organisms accumulated by the biologically significant zones of a planetary probe or spacecraft at selected points in the assembly and test sequence. The model supplements biological assays of the probe by simulating the microbial burden accumulation processes during periods when assays are not taken. An important application of this model is to predict the microbial loading on a probe immediately prior to terminal heat sterilization.

The burden prediction model developed by Martin Marietta under this contract is applicable to any probe or spacecraft; this is assured by the flexibility of the inputs to the computer program and by the care with which a suitably general test case was selected. The model uses the interval concept (see Definitions) to permit uncertainties in the burden prediction process to be treated stochastically; i.e., as random variables. Hence the microbial burden predictions are probability distributions (histograms), from which statistical limits can be determined for the burden.

The burden prediction mathematical model was developed in three phases:

> Phase I   -   Selection and analysis of a typical assembly
>   and test sequence;
>
> Phase II -   Parameterization of the microbial burden
>   prediction problem;
>
> Phase III -   Computer programming and test case.

(This list differs slightly from the Contract Requirements because the mathematical modeling was performed in Phase II instead of Phase III.)

In Phase I, the first task was to generate a general assembly and test sequence that could be applied to any space probe (e.g., Mariner-Venus 67, Capsule System Advanced Development (CSAD), Ranger). A Voyager-type Capsule Bus system was selected as the probe for which the generalized sequence would be developed. System functional analysis was then performed on the Capsule Bus system to identify the major probe subsystems to be assembled into the probe flight configuration. After the major subsystems were identified (e.g., deorbit module, lander module, parachute truss), a detailed functional analysis of each subsystem was performed. This analysis was made to derive and study the assembly and test sequence in sufficient detail to identify the sources of burden accumulation and to relate these in a one to one manner to the specific activities performed.

Consider, for instance, the insertion of a bolt (this activity is representative of the lowest level of operation considered in the analysis). In such an operation, a worker in a specified environment would insert (handle) the bolt; this activity would result in contact with the hardware and would require a given amount of time. Thus a one to one relationship was established between the operation (bolt insertion) and the sources of burden accumulation (environment, personnel, and contact). To provide the required detail, the Capsule Bus system was analyzed to four levels (identified as the STAGE, TASK, SUBTASK, and OPERATION in the burden prediction model).

The activities described at the first level of operation identify the major assembly and test activities required to build the Capsule Bus (e.g., vernier module or deorbit module assembly and test). Based on this analysis, a generalized assembly and test sequence was derived for each subsystem and for the integrated Capsule Bus. In each of these sequences, the activities

to be performed were expanded into subordinate, more detailed activity packages. Activity at this second level is typified by the positioning of a subsystem such as the lander module. Second-level activities were analyzed further to provide the third-level activities. Activity at this level is typified by the maneuvering required to position a subsystem. Finally, activity at the third level was expanded to the fourth level. At the fourth level appear the basic operations that would be performed to assemble the probe; activity at this level is typified by the installation or tightening of screws. It was at the fourth level of detail that the one-to-one relationships were established between burden accumulation and assembly operations.

In addition to identifying the four levels of operation, the analysis results identify the work location (e.g., Pasadena), the major module (e.g., vernier module), the subsystem (e.g., structure and mechanisms), and the hardware (e.g., vernier structure).

The operations identified at the fourth level represent discrete procedural steps in the assembly and test sequence for which personnel, time, hardware, and equipment requirements could be described. Generally, these operations were found to be repetitive, which made it possible to define a minimum number of generic operations that could be used to describe any activity performed in the assembly and test of the Capsule Bus system. These generic operations represented the modular elements used to develop the burden model.

In Phase II, the relationship between the generic assembly operations and burden accumulation was studied and quantified. The fourth-level (repetitive) operations were analyzed to identify the microbial parameters (e.g., assembly environment, time to perform, number of personnel, surfaces

being contacted) that would characterize each operation; by this means a list
of significant microbial parameters was compiled. Mathematical expressions
were then developed to represent the processes of burden accumulation and to
reflect the effects of the parameters on each process. Three burden accumula-
tion processes and one burden reduction process were identified:

1) Environmental fallout;
2) Personnel and equipment fallout;
3) Contact by tools or personnel;
4) Decontamination.

Due to uncertainties in parameter values and initial microbial burdens,
it is necessary to treat these quantities as random variables. This is ac-
complished in the burden prediction model by the interval concept. Uncertain
quantities are represented by histograms, which associate a probability with
each interval in the range of the variable. For example, in the histogram in
Figure 1, the burden has a 0.2 probability of being in the interval from 0 to
50 organisms, 0.4 probability of being between 50 and 100 organisms, etc.
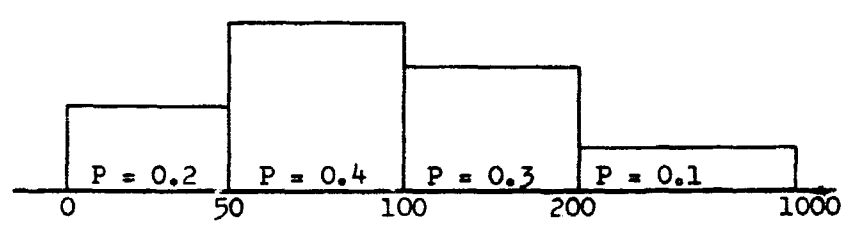
Figure 1
Example of Burden Histogram

The essence of the interval concept is the use of histograms in place of
numbers in the evaluation of mathematical expressions. One of the major tasks
of this contract was the development of a satisfactory way to perform the neces-
sary arithmetic operations on histograms.

After mathematical expressions had been derived for the burden accumulation processes, the logic was developed for the microbial burden prediction computer program. This logic was based on five considerations:

1) The ability to simulate the assembly and test sequence of any probe or spacecraft, where the sequence of activities is described at the four levels of detail;

2) The ability to simulate the burden accumulation and reduction processes using the interval concept and the mathematical expressions developed in Phase II;

3) The requirement to compute and maintain statistics that describe the burden accumulated by each biologically significant zone at selected points in the activity sequence;

4) The ability to maintain separate statistics for four surfaces (top, exterior, mated, and occluded) of each part or zone;

5) Input and output requirements.

The program logic was developed to make it possible to describe the activity flow at each of the four levels of activity. These levels provide the basis for sequencing the computer program. The actual burden computation is performed at the operation level; the higher levels (subtask, task, and stage) control reading of parameters and printing of output. The computer program simulates all operations in the first subtask, proceeds to the operation of the next subtask, etc. Simulation is terminated when the final operation of the last stage has been completed. Although the computer proceeds sequentially, parallel activities can be simulated by specification of prerequisites

at the task or subtask levels.

In Phase II, the computer program for the microbial burden prediction model was coded in FORTRAN IV language and then checked out using an abbreviated test case. Figure 2 illustrates the gross logic employed in the burden prediction model.

The input data required to drive the computer program consist of the burden parameters and the assembly and test sequence. The following inputs are supplied at appropriate activity levels:

1) Part numbers of hardware being manipulated;

2) Hardware area changes (e.g., the change from external to mated caused by joining two parts);

3) Environment designation;

4) Number of personnel;

5) Time to perform;

6) Initial burden on hardware and tools;

7) Burden retention factors for hardware and tools;

8) Prerequisite activities.

For example, the number of personnel must be supplied for each operation, whereas the introduction of a new environment is infrequent and can be done at the task level.

The computer prints out the burden histogram for each surface of each part or zone whenever it is affected by an operation. Burden totals for each surface are printed at the end of each task unless a complete listing of burden histograms for each surface of every part and zone is requested.

INPUT DATA

SIMULATION

OUTPUT DATA

ASSEMBLY/TEST ACTIVITY
 • STAGES
 • TASKS
 • SUBTASKS
 • OPERATIONS

MICROBIAL PARAMETERS
 • TIME
 • PERSONNEL
 • ENVIRONMENT
 • HARDWARE

BURDEN HISTOGRAMS

BURDEN PREDICTION MODEL

 • Environmental Fallout
 • Personnel and Equipment Fallout
 • Contact
 • Decontamination

 • MICROBIAL BURDEN
 • ACTIVITY SEQUENCE
 • COMPLETION TIMES
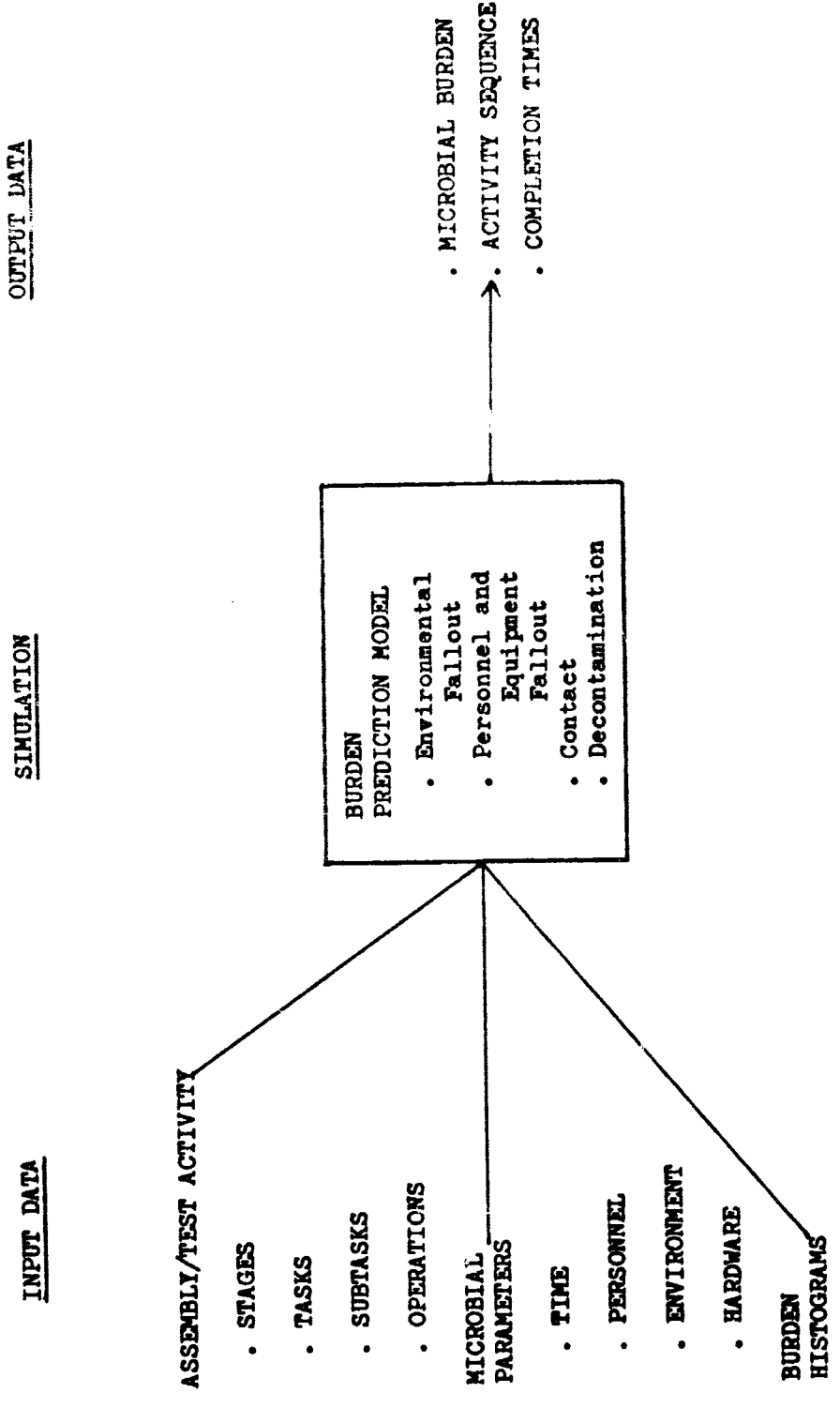
Figure 2

Gross Logic for the Microbial Burden Prediction Model

After the program checkout was completed, a final test of the burden prediction computer program was performed using the assembly and test sequence of the Voyager-type Capsule Bus system as developed in Phase I. Simulation of this sequence on the IBM 7094 computer system at JPL completed Phase III of the contract.

II. TECHNICAL DISCUSSION

A. PHASE I

1. Capsule Bus Assembly and Test Sequence

Phase I of the contract was devoted to the selection and analysis
of a space probe typical of those planned for future planetary exploration.
The requirement was to select such a probe, identify its major elements,
and review these elements in detail to determine how the probe might be
assembled and tested. Several probe classes were considered - Ranger
Block III, Mariner C, and a Voyager-type Capsule Bus system. Analaysis of
Ranger Block III and Mariner C-type probes indicated that the lander portion
of these probes was not sufficiently complex to represent the probes to be
developed for planetary missions. For this reason, a Voyager-type Capsule
Bus system was selected for analysis. This probe was felt to be more typical
of the probe class to be built in the future because such a Capsule Bus system
would consist of several major subsystems (e.g., vernier module) whose test
and integration sequences would typify the diverse problems that would be
encountered. Figure 3 portrays the typical flow of activities that would be
required at the subsystem level to assemble a Voyager-type Capsule bus system.

The period during which burden predictions were to be made was defined
as the period commencing immediately after the flight acceptance (FA) heat
sterilization test of hardware, at no lower a level than a subassembly, and
terminating immediately before terminal heat sterilization of the integrated
Capsule Bus system. Since the assembly and test of the Capsule Bus, per se,
does not begin immediately after FA heat sterilization, it was necessary to

Note: The arrows indicate prerequisites (as in PERT); all activities leading up to a block must be completed before the activity in that block can start.

A. Vernier Module Assembly and Test

B. Deorbit Module Assembly and Test

C. Aeroshell Assembly and Test

D. Canister and Adapter Assembly and Test

E. Parachute Truss Assembly and Test

F. Lander Module Integration and Test

G. Descent Module Integration and Test

H. Entry Module Integration and Test

I. Preseparation Flight Capsule Integration and Test

J. Launch/Cruise Flight Capsule Integration and Test

K. Flight Capsule System Integration and Test

W. Flight Capsule System Receiving Inspection

X. Planetary Vehicle Marriage

Y. Flight Capsule System Explosive-Safe Area Assembly and Test

Z. Preparation of Flight Capsule for Terminal Sterilization

Figure 3 First-Level Activity Flow Simulated in the Test Case

identify and predict the burden accumulation during activities performed
after heat sterilization and immediately before start of the assembly and
test sequence. These activities and their relationship to the generalized
assembly and test sequence are shown in Table 1.

Table 1 Capsule Bus Hardware Preassembly Sequence

```
1.  Flight Acceptance Heat Sterilization Test
        :
        :
2.  Flight Acceptance Environmental Tests
    A.  Vibration Tests
    B.  Thermal Vacuum Chamber Tests
        :
        :
3.  Storage (As Required)
        :
        :
4.  Capsule Bus Assembly and Test
    A.  Vernier Module Assembly and Test
        :
        :
```

The Capsule Bus system was analyzed at the subsystem (e.g., vernier
module) level. This analysis involved identification of the subsystem, the
major assembly, and the test activities that would be performed to build the
Capsule Bus. Based on this analysis, a generalized assembly and test sequence
was derived for each subsystem and for the integrated Capsule Bus system. The
results of the analysis are presented in Tables 2 and 3. Table 2 identifies
the test and integration activities at the subsystem (e.g., vernier module)
level; this is the first (highest) level of assembly and test activity. Typi-
cal activities at this level would be vernier module assembly and test, and
Capsule Bus system receiving and inspection at the launch site. Activities

Table 2   Generalized Capsule Bus System Assembly and Test Sequence (First Level)

Major Level Operation Description		First Level Operation Description
I - Contractor Facility Operations	A	Vernier module assembly and test
	B	Deorbit module assembly and test
	C	Aeroshell assembly and test
	D	Canister and adapter assembly and test
	E	Parachute truss assembly and test
	F	Lander module (vernier module, ESP, SL simulator and parachute truss) integration and test
	G	Descent module (lander module and aeroshell) integration and test
	H	Entry module (descent module and deorbit module) integration and test
	I	Preseparation flight capsule (entry module, aft canister, and adapter) integration and test
	J	Launch/cruise flight capsule (preseparation flight capsule and foreward canister) integration and test
	K	Flight capsule surface laboratory integration and test
II - Launch Site Operations	W	Flight capsule receiving inspection
	X	Plentary vehicle (flight capsule and spacecraft) marriage
	Y	Flight capsule explosive-safe area assembly and test
	Z	Preparation of flight capsule for terminal sterilization

Table 3 Generalized Capsule Bus System Assembly and Test Sequence (Second Level)

First Level Operation Description		Second Level Operation Description
E - Parachute Truss Assembly and Test	1	Parachute truss positioning
	2	Cabling subsystem preparation
	3	Cabling subsystem installation
	4	Cabling subsystem/OSE interconnection
	5	Cabling subsystem checkout
	6	Cabling subsystem/OSE disconnection
	7	Pyrotechnic subsystem (simulated squibs) preparation
	8	Pyrotechnic subsystem (simulated squibs) installation
	9	Pyrotechnic subsystem (simulated squibs)/ OSE interconnection
	10	Pyrotechnic subsystem (simulated squibs) checkout
	11	Pyrotechnic subsystem (simulated squibs)/ OSE disconnection
	12	Thermal control subsystem preparation
	13	Thermal control subsystem installation
	14	Thermal control subsystem/OSE interconnection
	15	Thermal control subsystem checkout
	16	Thermal control subsystem/OSE disconnection
	17	Aerodynamic decelerator simulator preparation
	18	Aerodynamic decelerator simulator installation
	19	Aerodynamic decelerator simulator/OSE interconnection
	20	Aerodynamic decelerator simulator checkout
	21	Aerodynamic decelerator simulator/OSE disconnection

that could be performed at the Integration Contractor's facility are separated from those that would normally occur as launch site operations. Since the results of the analysis at the second level were voluminous, Table 3 describes the assembly, test, and integration activities for a typical subsystem, namely the parachute truss. Typical activities at this level would be subsystem check-out, functional tests, and subsystem/CSE interconnection. A complete description of second level activity for the Capsule Bus system is presented in Appendix 3.

The need to expand the Capsule Bus system analysis to include more detailed activity levels beyond the second level was dictated by a desire to establish a one-to-one relationship between the activities performed and the sources of burden accumulation. To establish this relationship, the assembly and test sequence was further detailed to the third and fourth levels. At the third level, the activities are specific to certain hardware (e.g., "Install boost damper on solar panel V".) but still consist of several operations (e.g., "position damper", "install screws"). At the fourth level of activity, these operations are defined in sufficient detail to evaluate the parameters that determine the microbial burden. (These parameters are discussed in Chapter II.B.2.) Therefore it is at the fourth level that a one-to-one relation can be established between the activities performed and the burden changes that they cause. Typical fourth level operations are activities 1.1.1 through 1.1.5 in Table 4.

Table 4   Typical Results of the Functional Analysis

Indenture Level/Meaning	Functional Analysis
1. Work site	I Contractor Facility Operations
2. First level activity	A Vernier Module Assembly and Test
3. Module	A1 Vernier Module
4. Subsystem	L Structure and Mechanisms Subsystem
5. Hardware	L1 Vernier Structure, Lander Legs, and Propulsion Subsystem
6. Second level activity	1 Subsystem Positioning
7. Third level activity	1.1 Maneuver
8. Fourth level activity	1.1.1 Open Door of Sterilization Chamber
Fourth level activity	1.1.2 Enter Door of Sterilization Chamber
Fourth level activity	1.1.3 Remove Module, in its Fixture, from Sterilization Chamber
Fourth level activity	1.1.4 Position Overhead Crane
Fourth level activity	1.1.5 Lower Crane to Allow Attachment of Sling to the Mobile Service Platform Fixture
7. Third level activity	1.2 Attachment
Third level activity	1.3 Transport
Third level activity	1.4 Detachment
Third level activity	1.5 Inspection
4. Subsystem	M Propulsion Subsystem
5. Hardware	M1 Vernier Propulsion Subsystem Components
6. Second level activity	4 Subsystem/OSE Interconnection
7. Third level activity	4.1 Airborne Subsystem/OSE Electrical Interface

To identify any activity and its associated considerations (location, major module, hardware), an indenture system was adopted. Each of the eight indenture levels identifies an activity level or one of the considerations associated with the assembly and test sequence. A portion of the functional analysis is presented in Table 4. This table shows how the indenture system was used. Indenture level 1 identifies the site at which the work is being performed. Indenture level 2 identifies the first level of activity in the Capsule Bus system general sequence. Indenture level 3 identifies the module being assembled. Indenture level 4 identifies the subsystem on which work is being performed. Indenture level 5 identifies the hardware being used in the module assembly. Indenture levels 6-8 identify the second, third, and fourth levels of activity identified from the general sequence. With this indenture system, the activity level, work location, major module, subsystem, and hardware involved can be determined at any point in the assembly and test sequence. The complete assembly and test sequence for the Capsule Bus system is shown in Table III.3 of Volume III of this report.

2. Repetitive Operations

Once the analysis was extended to include the fourth level, each type of activity that would be performed to assemble and test a Capsule Bus system could be identified. The repetitive nature of many of these operations indicated that they could be represented as generic operations whose specific performance requirements could be described by text identifiers (e.g., "vernier module assembly and test", "subsystem preparation") and that could be assigned specific variable values (e.g., 2 men, 1.5 hours to perform, class 100,000 clean room, etc). All operations identified at the fourth level were reviewed to derive a list of generic operations that would describe all assembly and test activity. The nineteen generic operations that were identified are presented in Table 5.

Table 5   Repetitive Operations Identified in the Assembly and Test Sequence

No.	Operation
1.	Move assembly manually (lift, carry, and set down)
2.	Position overhead crane
3.	Attach crane hooks
4.	Take up chain slack; hoist module with crane
5.	Move module with crane
6.	Lower module with crane; slacken the chain
7.	Detach crane hooks
8.	Inspect module/assembly and approve
9.	Lift assembly with mobile service platform fixture (MSPF)
10.	Place assembly in handling container
11.	Move in handling container
12.	Connect test cables (hoses, harnesses, cables, etc)
13.	Disconnect test cables (hoses, harnesses, cables, etc)
14.	Perform test
15.	Insert screw, bolts, etc
16.	Tighten screw, bolts, etc
17.	Loosen screw, bolts, etc
18.	Remove screw, bolts, etc
19.	Decontamination (cleaning)

B. PHASE II

1. Literature Search

Much of the work performed during Phase II was based on a search of available sterilization literature. The literature search was facilitated by three sets of abstracts:

1) Technical Abstract Bulletins (TAB);

2) Scientific and Technical Aerospace Reports (STAR);

3) Sterilization Literature Abstracts (ER 14111), prepared and revised by the Martin Marietta Corporation.

Documents reviewed during the literature search are identified in Appendix II of Volume III, Appendices.

The purpose of the literature search was to

1) Identify parameters that would directly or indirectly influence the accumulation of microbial burden during the assembly and test of a space probe;

2) Help formulate mathematical expressions to describe the burden accumulation processes;

3) Identify sources of empirical data in an attempt to validate assumptions made in constructing or exercising the burden prediction model.

Considerable time was spent in attempting to identify all significant factors that could affect the microbial burden on hardware. General information was obtained on:

1) Movement of organisms present in the air;

2) Deposit of airborne organisms onto surfaces,

3) Attachment of organisms to surfaces;

4) Survival of organisms;

5) Redispersion of surface organisms;

6) Transfer of organisms by contact.

Many of the references cited only provided background information and therefore contributed mainly to the development of the list of parameters that influence the microbial burden accumulation. References that fall into this category are; 9-16, 18, 20, 23-26, 28-31, 33, 37-40, and 42-45. Some of these references also contributed to development of the burden prediction formulas (particularly the fallout formula). However, to test ideas gathered from general reading, quantitative results from experiments designed to study the accumulation of organisms on surfaces were needed. The most basic (and most popular) experiment consisted of exposing sterile strips to an environment and determining the accumulated burden at intervals of weeks or months. The almost universal occurrence of a burden "plateau" suggested the first-order model used in predicting fallout accumulation. Once this model was formulated, it was necessary to obtain values for the parameters that occurred. Reference 34 was very useful in this respect since air samples, fallout rate, and burden accumulation on stainless steel strips were recorded simultaneously over a period of one year. Thus in addition to the parameter values, this experiment also provided a check on the validity of the first-order model. (Agreement was very good, with a correlation coefficient of 0.91). References 17, 19, 21-22, 27, 32, 35-36 provided numerical values and/or data on the range of variability of parameters used in the burden accumulation formula.

Burden addition by personal contact is treated to some extent in Reference 35, which formed the basis for assumptions and parameter values in the contact formula.

The list of generic operations (discussed in Chapter II.A.2) was developed from study of References 1-8. References 4-8, being specific to the test case, supplied the actual "catalog" of operations and also provided the sequence of operations, subtasks, etc, used in the test case.

2. Burden Parameter Identification

As a preliminary to the development of the burden prediction model, a list of parameters that could affect burden was prepared. (See Table 6.) These parameters generally pertained to one of four characteristics of a given activity:

1) The environment in which it is performed;
2) The personnel performing the work;
3) The type of work being performed;
4) The types of organisms being considered.

The rule used in compiling Table 6 was to include all parameters that could reasonably be expected to have some effect. Since experimental demonstration of these effects was not required, it is likely that some of the listed parameters may later prove to be unimportant. However, the care with which the list was prepared makes it unlikely that any significant parameter has been omitted.

Preparation of the list of parameters was done to some extent during, but mostly after completion of the literature search. The literature search provided an understanding of the various processes that could influence burden; these processes were then analyzed to identify the significant parameters and the manner in which they could affect the burden. Although other processes may exist that influence the accumulation of burden, the following were selected as most important:

Table 6 Parameters That Affect Microbial Burden

1.   Environment
Clean Room Specifications

Temperature
    Humidity
    Ingress and egress
    Airflow velocity
    Personnel cleanliness
    Clothing

Number of People in the Room
Room Size (floor area, volume)
Organisms/cu ft of Air
2.   Personnel
General Biota-Contributing Tendency

Shedding (hair, skin)
    Breath
    Touch
    Clothing

Personal Affectations (head scratching, etc)
Amount of Movement and Level of Exertion
Mental Attitude
3.   Operations
Type of Operation
Biota Level on Tools and Equipment
Area of Contact
Type of Contact (pressure, rubbing, etc)
Position of Worker (above, beside, or under the work)
Orientation of Surfaces
Surface Materials and Finishes (tools and work) including Any Chemical Treatment
Number of Men Required
Number of Times This Operation is Repeated
Any Special Requirements (such as protective covers)
Time Required to Perform the Operation
4.   Types of Organisms
Spores/Vegetative Organisms
Aerobes/Anaerobes

1) Environmental fallout;

2) Personnel and equipment fallout (shedding);

3) Contact by tools or personnel.

These processes are discussed in detail in Chapter II.B.3.

The parameters "personal affectations" and "mental attitude" were not used in formulating the mathematical expressions for burden accumulation due to lack of quantitative data. Certain other parameters (e.g., the clean room specifications) appear only indirectly in the derived parameters (Chapter II. B.3.). The extent to which the derived parameters affect the total burden on a spacecraft will be discussed in Chapter III.C.3.c.

3.   Mathematical Analysis

As mentioned in Chapter II.B.2, three process were selected as most significant in the accumulation of microbial burden:

1) Enviromental fallout;

2) Personnel and equipment fallout (shedding);

3) Contact by tools or personnel.

Each process was analyzed to determine its pertinent parameters and to derive mathematical expressions for their action. It will be seen as a result of the analysis   that certain of the parameters identified in Chapter II.B.2. have been combined to form other, derived parameters. The reason for this is that the derived parameters are more easily measurable with standard equipment than the original parameters.

In addition to the three burden accumulation processes, a mathematical expression was developed to represent burden reduction. This process is termed "decontamination", and includes physical removal of organisms (e.g., by vacuum cleaning) as well as destruction of organisms (e.g., by acids and solvents).

a. Burden Accumulation by Fallout

The processes of environmental fallout and personnel and
equipment fallout are closely related; both are discussed in this
section.

In a given environment, it is assumed that the number of organisms
in the air can be estimated with air samplers. These organisms tend
to settle on exposed surfaces and hence continually add to the burden
on the surface. If there were no loss of these organisms (due to
death or physical removal), the surface burden would increase steadily
as long as the surface remained in that environment. It was assumed,
however, that a burden equilibrium or "plateau" is reached in a given
environment after approximately one week. This assumption was based
on the experimental results reported in References 17 and 22 (Appendix
II). The experiment involved placing a tray of sterile stainless steel
coupons in the desired environment and assaying a portion of these at
selected intervals. In nearly every instance where this was done, it
was clear that after a week the coupons had reached a burden "plateau".
The only change observed in later samples was attributed to statistical
fluctuation. This implies the existence of a mechanism that tends to
decrease the number of organisms.

During any short period of time dt, organisms will be deposited on
the surface from the air; let R be the rate of deposit $\frac{organisms}{sq\ ft\text{-}hr}$.
Since dt is small, R will be constant over this interval of time.

---

* Major assumptions have been underlined; a detailed list of the
assumptions appears in Table 10.

During dt there is also a loss of organisms due to an undetermined mechanism. If it is assumed that organisms remain on the surface an average of v hours, then 1/v of the population is lost each hour. Thus, letting b(t) be the number of organisms/sq ft present on the surface at time t, we have $\frac{db}{dt} = R - \frac{1}{v} b$. If the initial (t = 0) burden concentration (organisms/sq ft) is denoted by b_o, then this equation has the solution

$$b(t) = b_o e^{-t/v} + Rv(1 - e^{-t/v}) .$$

This is the basis of the formula used in the burden prediction model to predict the surface burden that accumulates from the environment.

There remains the problem of assigning values to the fallout rate R as a function of time, position in the room, activity level, etc. Since air samplers are customarily used in clean rooms, considerable data are now available on the concentration of organisms in the air (organisms/cu ft). These data have been obtained in several geographic locations, several different environments (from Class 100 to open factory), and with varying levels of activity (Ref. 17 and 22). For the present it will be assumed that the fallout rate R is given by R = g (surface) x f_i (airflow) x (concentration). The function f_i represents the fallout velocity (ft/hr) of airborne organisms due to airflow and gravity settling. No other mechanisms seem effective for particles larger than 0.5 micron (Ref 41). The subscript on f_i can assume the value 1 or 2. Two values of f_i are included because there is generally a significant difference in burden accumulation between

horizontal and vertical surfaces (e.g., Ref 35). This is perhaps due to the lack of gravity settling on the other surfaces.) Thus f_1 will be used for surfaces facing up and f_2 for other surfaces. These two functions will be assumed constant in a given environment and will be assumed measurable. The function g represents the portion of particles striking the surface that actually adhere. This function will probably depend on the nature of the surface in question, but will be assumed independent of other factors.

The concentration of airborne organisms (organisms/cu ft) can be measured at a given point in an environment as mentioned above. The normal variability in contamination corresponding to different levels of activity must also be measured. At present it will be assumed that such differences can be measured in a meaningful way.

A change in notation and inclusion of the area of the surface gives the following formula for the effects of fallout from environment, equipment, and personnel:

$$B' = Be^{-t/v} + AvR (1-e^{t/v})$$

where $\quad R = f_i \, g(c+Qe^{-\lambda d})$,

B' is the resulting burden (organisms),

B is the initial burden (organisms),

$e = 2.71828 \ldots$,

t is the time for the operation (hr)

v is the "average lifetime" (hr)

A is the area of the surface (sq ft),

R is the fallout rate $\dfrac{\text{organisms}}{\text{sq ft-hr}}$,

f_1 is the fallout velocity ($\frac{ft}{hr}$)

(f_1 for the horizontal surfaces, f_2 for other surface attitudes),

g is the surface retention factor (dimensionless),

c is the environmental airborne concentration ($\frac{organisms}{cu\ ft}$),

Q is the personnel airborne concentration ($\frac{organisms}{cu\ ft}$),

d is the distance from the worker to the surface (t),

λ is a distance reduction factor ($\frac{1}{ft}$),

(The quantities B', B, t, v, c, and Q are represented by histograms in the burden prediction model.)

The contamination increase attributed to personnel and/or equipment fallout is given by the expression:

$$Qe^{-\lambda d}$$

where Q is the contamination rating of the individual, (if several workers are present, Q should represent their total effect) d is the distance from the surface in question, and λ is a suitable constant. The introduction of two variables, namely Q and λ , was necessary to reflect the fact that the burden contributed by a worker depends both on how much he sheds and how close he is. For the purpose of this discussion, it was <u>assumed</u> that the variables Q and λ could be measured. The same model will be used to predict the burden increments that result from the proximity of contaminated tools or equipment. In laminar flow rooms, it will perhaps be better to add an increment only if the contamination source is "upstream" from the surface in question.

b. Contact

Normal physical contact is sufficient to remove (or deposit) organisms from a surface. However the available experimental data is insufficient to provide a mathematical expression for this process. Until the necessary experimental work is done, the following model will be <u>assumed</u> to predict the transfer of burden through the contact mechanism:

$$B' = B\left(1 - \frac{aS_2}{2A}\right) + \frac{b_t aS_1}{2}$$

where

B' is the final burden on the surface (organisms),

B is the initial burden on the surface (organisms),

a is the area touched (sq ft),

S_2 is the retention factor of the tool or hand,

A is the area of the surface (sq ft),

b_t is the contamination ($\frac{organisms}{sq\ ft}$) on the tool or hand, and

S_1 is the retention factor of the given surface.

The factors S_1 and S_2, for various materials, have been <u>assumed</u> to range from zero for nonsticky surfaces to one for sticky surfaces. Due to lack of experimental data, S_1 and S_2 are input as histograms. [Note that since the burden accumulation formulas are applied in succession, the initial burden (B) for any formula is the final (B′) from the previous formula.]

c. <u>Decontamination</u> -

In order to account for the effects of washing, wiping, vacuum cleaning, etc, the model permits specification of a removal fraction k ($0 \leqslant k \leqslant 1$):

$$B' = B (1 - k),$$

where B' is the resulting burden (organisms),

   B is the initial burden (organisms),

   k is the removal (kill) factor (dimensionless).

d.   Summary of Parameters Used in the Model

This section discusses the significance of the derived parameters in relation to the parameters in Table 6. The initial burden on a surface is a parameter in the sense that it is required in all burden accumulation formulas. However, the initial burden for a given surface need be input only once; from then on, this burden is retained in the model. For example, if a part was worked on in operation 1 of some subtask and if that part was also involved in operation 2, then its initial burden for operation 2 would be its final burden from operation 1. A similar situation occurs when the part is not worked on for some period of time; in this case, there is an intermediate application of the environmental fallout formula to update the burden on the part to the next time it is worked on. In either case the burden formulas are applied in sequence, with the final burden B' of each formula becoming the initial burden B of the next.

The area of a given surface is another parameter that needs to be input only once; i.e., when that surface is first introduced. The area is retained thereafter except for changes that may be deliberately introduced (e.g., when a part is removed).

The two fallout processes share the parameters t, v, f_1, f_2, c, and g. The operation time t is one of the original parameters in Table 6. v, f_1, and f_2 represent the effects of the environment (except for the number of organisms in the air), the type of operation, and the orientation of the surface. c, the number of organisms in the air when no personnel are present, is an original parameter.

The additional burden contributed by personnel working nearby (but not touching) is represented by the parameters Q, d, and λ. The "dirtiness" of personnel is represented by Q. The parameters d and λ together represent both the position of the worker(s) in relation to the surface and any characteristics of the environment (e.g., air currents) that influence the transfer of organisms from personnel to hardware.

The contact formula requires parameters a, S_1, S_2, and b_t. Both a and b_t are present in Table 6. S_1 and S_2 represent the surface materials of hardware, tools, and hands (gloves).

Decontamination requires only specification of the fraction of the burden that was removed or killed; it is determined by the type of operation.

The category of organisms being considered is implicit in the parameters v, c, Q, and b_t, since these can be expected to vary for different organisms.

e) Illustrative Example

The following example has been prepared to illustrate the application of the formulas to an operation performed during the assembly and test of a typical spacecraft. The conditions of the example are self-explanatory.

Typical Operation: Move Assembly, Manually

Personnel Involved: 1 Man

Environment: Class 100,000 Clean Room

Formulas Used: Burden Accumulation by Fallout and Contact.

For fallout, the fallout rate is first calculated:

$$R = fg(c + Qe^{-\lambda d}) = 14.79 \; \frac{\text{spores}}{\text{sq ft-hr}}$$

where: $f = 4.8$ ft/hr, $Q = 5.0$ spores/cu ft,

            $g = 0.5$, $\lambda = 0.46$ 1/ft,

            $c = 3.0$ spores/cu ft, $d = 1$ ft.

This value of R is then used in the accumulation formula:

$$B = Be^{-t/v} + AvR(1-e^{-t/v}) = 799.2 + 1.2 = 800.4 \text{ spores}$$

where: $A = 0.8$ sq ft, $v = 100$ hr,

            $B = 800$ spores $t = 0.1$ hr.

(Note that in this short time there was almost no change.)

The contact formula is then applied

$$B' = B \left(1 - \frac{aS_2}{2A}\right) + \frac{aS_1}{2} b_t = 790.4 + 60 = 850.4 \text{ spores},$$

where $B = 800.4$ spores (as above),

          $a = 0.1$ sq ft,

          $S_2 = 0.2$,

          $A = 0.8$ sq ft (as above),

          $S_1 = 0.8$,

          $b_t = 1500$ spores/sq ft.

Single values have been used to illustrate the effects of the
parameters on the burden accumulation. In practice, the uncertainty
in the data will require that certain variables (e.g., burden distri-
butions, and time) be represented as histograms. In such cases, both
input and output data will appear in this form.

4.   The Microbial Burden Prediction Model

a.   <u>Model Description</u> - The Microbial Burden Prediction Model is used
to determine the probability distributions for the number of organisms
that have accumulated on each surface at each step in the assembly and
test of a spacecraft. This model simulates the gain and loss of microbes
through the mechanisms of environmental fallout, operational fallout,
contact, and decontamination and keeps a running count of the burden on
each of four distinct surfaces (top, exterior, mated, and occluded) of
up to 120 separate parts.

The assembly and test sequence is organized in four levels of
activity. These levels, in order of decreasing comprehensiveness, are
the STAGE, TASK, SUBTASK, and OPERATION; i.e., a computer run consists
of the activities in a group of stages (20 or fewer), a stage is a group
of tasks (100 or fewer), a task is a group of subtasks (20 or fewer),
and a subtask is a group of operations. In addition to these grouping
characteristics, the levels are significant in terms of the kinds of
inputs and outputs associated with each level.

All inputs describing environments, parts, operations, and distri-
butions are made at the task level. Changes in the part or surface
designations (e.g., due to assembly or disassembly) or in the environ-
ments or retention factors of any part are made at the subtask level.
The coefficients that describe the effect of each burden gain or loss
mechanism are input at the operation level.

The actual gain and loss of microbial burden is computed at the
operational level and the new burdens on the affected parts are output

at this level. The subtask level output is the time distribution at which the subtask is completed. The task level output is the Task Summary which includes the time distributions for completion of the task, the total burden distributions by surface type and for the entire assembly, and, if desired, the burden on each surface of each part that has been involved in the assembly and test sequence. The stage level output is the Stage Summary that gives the mean burden and variance for each task of that stage. Burden differences, i.e., the burden accumulated between steps in the sequence, can be determined between the completion of any two tasks, not necessarily in the same stage.

A further distinction is made on the basis of prerequisite activities. Operations within a subtask are assumed to follow sequentially, i.e., the second operation commences when the first is completed, etc. Subtasks, however, may be performed concurrently and must have any prerequisite subtasks specified where such specified prerequistes must belong to the same task. Tasks also need not be consecutive and must have any prerequisite tasks specified. These prerequiste tasks, moreover, need not belong to the same stage. In the case of tasks and subtasks, up to two prerequisites may be specified and the start time distribution is based on the probability of having finished the prescribed prerequisite or prerequisites.

A more detailed description of the capabilities, simulation mechanisms, inputs, and outputs is given in Volume II of this final report.

b. The Interval Concept - Since many of the variables involved in the simulation of burden accumulation are not known exactly, the predicted burden on each surface of each part is best described in terms of a

probability distribution. In this program, such distributions are re-
presented by histograms, which associate a constant probability with
each interval in the range of the variable. This is equivalent to
using a series of straight-line segments to approximate the cumulative
probability curve. This provides a straightforward approach to deter-
mining the straight-line approximations to the distributions for the
random functions $z = c + y$, $z = x - y$, $z = x \cdot y$, $z = x/y$, and $z =$
max (x,y) where x and y are random variables. Before proceeding to
a consideration of this approach, appropriate comments should be made
concerning two of these functional relationships.

In the program, the relation $z = x - y$ is always used to find the
distribution of z that leads from a distribution of x to a distribu-
tion of y; i.e., x and y are not independent so that special care must
be taken. This is more fully described in Volume II. The function $z =$
max (x,y) may be better understood by considering the specific case
where the function is used. Suppose x and y represent the random
finish times of two prerequisite activities. Then, for every pair x,
y the maximum value $z = $ max (x, y) is defined and the probability dis-
tribution for z is the probability that both prerequisites have been
completed.

Using the interval concept, it must be pointed out, is an approxi-
mation. In the first place, if x and y are random variables whose
probability distributions are accurately represented by histograms (i.e.,
the probability is constant over each interval), the random function z
for any of the above operations will not in general have a distribution
accurately represented by a histogram. Furthermore, if the histogram

representation were accurate (the probability constant over each interval), the number of intervals for z must necessarily be a product of the numbers of intervals for x and y except where such intervals accidentally have the same end points. In spite of these disadvantages, the histogram approach provides a procedure for determining the random functions, and the inaccuracies can be reduced by increasing the number of intervals considered.

To illustrate the procedure used, consider the random variables x and y and their sum z = x + y. Let x and y have the probability distribution

$$P \ (1 \leq x < 5) \ = 0.4,$$

$$P \ (5 \leq x < 9) \ 2 \ 0.6,$$

$$P \ (1 \leq y < 3) \ = 0.4, \ \text{and}$$

$$P \ (3 \leq y < 6) \ 2 \ 0.6.$$

Then the probability that z will lie in a certain range interval is equal to the combined probability that a point represented by a pair x, y lies in the region for which z = x + y takes on values in that interval. This is shown in Figure 4.

Note that the z lines are drawn through the intersection of the x and y lines since these intersections represent abrupt changes in the probability levels. The probabilities that the points x and y lie in each region are given in the region. The resulting probabilities for the z intervals are

$$P\ (2\leq z<4)\ =\ 0.04,$$
$$P\ (4\leq z<6)\ =\ 0.12,$$
$$P\ (6\leq z<7)\ =\ 0.095,$$
$$P\ (7\leq z<8)\ =\ 0.115,$$
$$P\ (8\leq z<10)\ =\ 0.26,$$
$$P(10\leq z<11)\ =\ 0.13,$$
$$P(11\leq z<12)\ =\ 0.105,$$
$$P(12\leq z<15)\ =\ 0.135.$$

These probabilities are exact if it is assumed that the input probabilities are exact. However, one can easily see that the distribution over each interval is not linear and that a histogram representation is not exact. Also, the number of interva must be reduced, or after a few such computations, it will become prohibitively high.
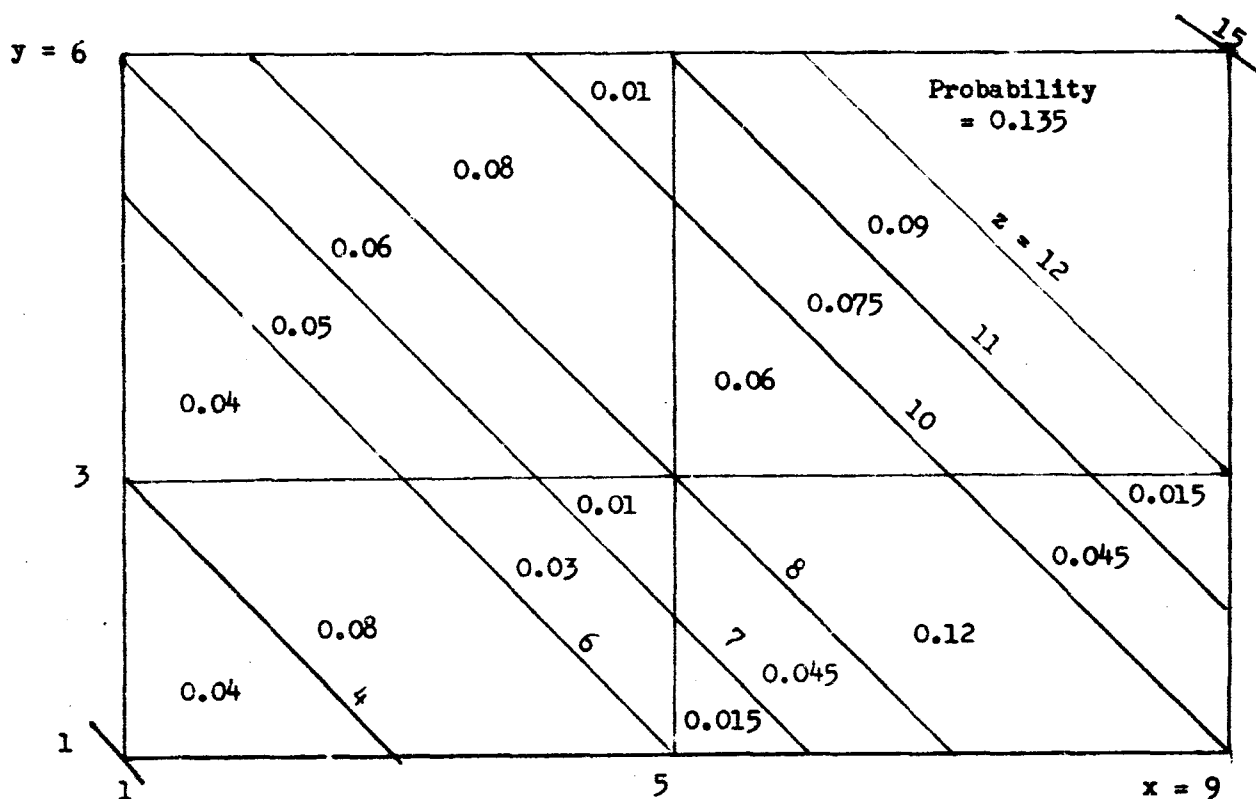

Fig 4   Typical Arithmetic Operation Using the Interval Concept

To keep the number of intervals within reason, the program calcu-
lates as many z values as the maximum of the number of x or y
values. These z values are chosen at the intersections most likely
to represent the most abrupt changes in probability level. In particular,
the range limits are always retained. In the above example, the z
values kept would be 2, 8, and 15, and the resulting histograms would
be as shown in Figure 5.

The example used here typifies the addition of two histograms. The
other histogram arithmetic operations (multiplication, subtraction,
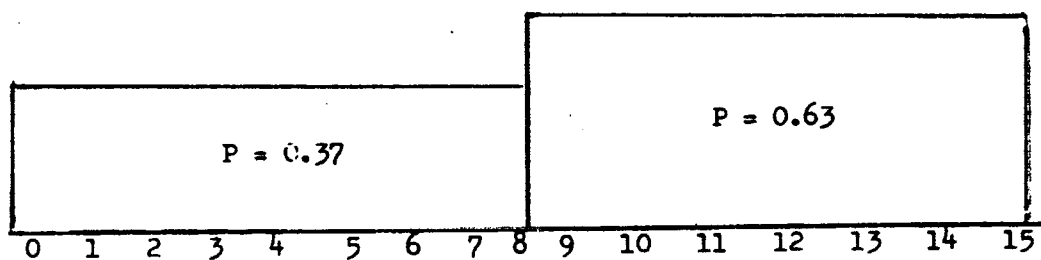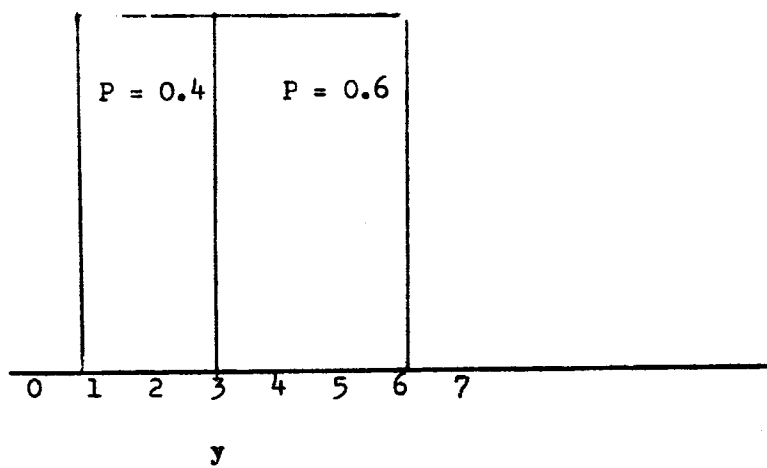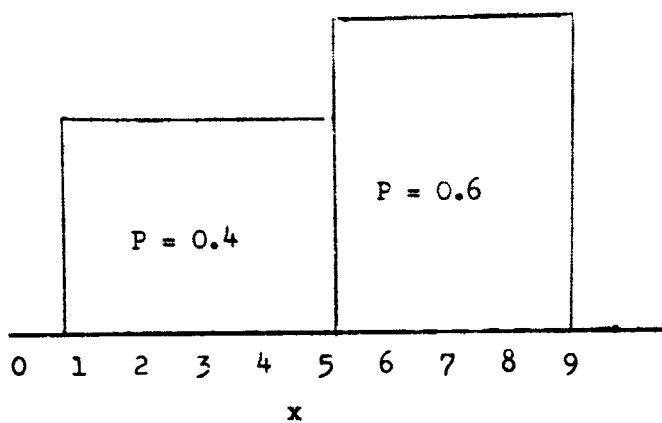division) are performed in an analogous manner.

Fig 5 Addition of Two Histograms Using the Interval Concept

c.   <u>Model Logic</u> - The following discussion describes the sequence of
logic steps by which the burden prediction model simulates the assembly
and test of any spacecraft. Figure 6 shows the macro logic of the model;
the detailed logic is presented in Volume II of this report. Execution
of the burden simulation is initiated and advanced by the reading of
control cards. These control cards determine the level of operation to
be performed next. If a previous stage has been performed, a data summary
for that tape is written on magnetic tape. If no previous stage has been
performed, the program can execute any one of seven options, depending
on the value of control variable KK. For KK = 0, the program will
terminate the simulation; this will occur only when the entire assembly
and test sequence has been simulated. Special program options are ex-
ecuted when KK = 4, 5, or 6. For KK = 4, the program will compute
and write burden increments on tape; these increments represent burden
added for a recently completed stage, task or subtask. For KK = 5, the
program will read in zone definitions, if they are required. For KK = 6,
the program will call the restart subroutine. This routine is used when-
ever the simulation is terminated prematurely and statistics compiled
previously are to be stored for a subsequent restart from the point of
termination.

Actual simulation of the spacecraft assembly and test sequence is
controlled and advanced when KK = 1, 2, or 3. For KK = 1, the program
reads a run description card that identifies the run to be made. (The
model can process several unrelated simulations in one submittal to the
computer.) After a run description card has been read or if KK = 2,
the program reads a stage description card. This card identifies the

Fig. 6 MACRO LOGIC FLOW CHART OF THE COMPUTER PROGRAM

next stage to be performed. After a stage description card has been read or if KK = 3, a task description card is read. The program then executes one or more options depending on the value of a control card parameter IK:

> IK = 1   Read new environments,
>
> 2   Read new operations,
>
> 3   Read new parts,
>
> 4   Read new distributions,
>
> 5   Read description card.

Next the program determines if all subtasks in the current task have been performed. If they have, the program writes a task summary on magnetic tape and then returns to the beginning to read another control card and reenter the loop. If all subtasks have not been performed, the program selects the next sequential subtask. The area, environment, and surface retentivity factor changes, if required, are read in for the subtask. Next the program reads in an operation index number (identifier) and modifiers. If all operations for the current subtask have been performed, the program returns and reads the next subtask card. If all operations have not been performed, the part(s) to be affected in the next operation are identified.

Next, the program determines which burden accumulation formulas are required in this order - - decontamination, fallout, then contact. When any or all of these equations are required to represent performance of the given operation, the formula(s) are evaluated and new burden is predicted and written on magnetic tape. At this point, the program determines if all parts affected by the current operation have been considered.

If they have, the next operation card is read and the program advances through the loop just described. If they have not, however, the additional parts affected by the operation are identified and the new burden is predicted for them.

d. Model Output - The data presented in Table 7 represent partial results obtained during the simulation of a Voyager-type Capsule Bus system. The heading located in the upper left-hand corner of the page identifies the run, stage, task, and subtask being performed. The starting time for subtask is provided as a mean time and in the form of a histogram. The headings "From, To, and Prob." identify the range of time (in hours) during which the subtask may start and the probability that it will start during that interval. For instance, there is a probability of 0.0079 that subtask 1 can start in the interval between 5.764 and 25.190 hours. The output for operation 13 (i.e., disconnect test cables) is shown next. This operation is being performed in Environment 1 (i.e., hibay area) and requires 1.07 hours to perform. Part 11 is being handled during this time. The data indicate that 1.0 square foot of Surface 1 (i.e., top external area) and 5.0 square feet of Surface 2 (other external area) for Part 11 were subjected to fallout. The new burden that resulted is shown in the two histograms at the right. These histograms are identified as Distributions 25 and 26 for Surfaces 1 and 2, respectively. Surface 1 was also contacted by the person performing the operation (i.e., 1.0 sq ft was contacted). The results of fallout and contact on Surface 1 were combined, effectively added, and stored as Distribution 25; this histogram is shown in the bottom right-hand corner of the page.

Table 7   Typical Output Format

Microbial Burden Prediction Model
Run 1, Voyager Test
Stage 1, A Vernier Module Assembly and Test
Task 10, 6 Subsystem/OSE Disconnection
Subtask 1, 6.1 A/B S/S-OSE E/DCCN

Subtask Start Time Distribution					From	To	Prob
Mean Time = 60.39 hr					5.764E 00	2.519E 01	0.0079
					2.519E 01	4.104E 01	0.1333
					5.104E 01	6.676E 01	0.5949
					6.676E 01	8.222E 01	0.1717
					8.222E 01	1.035E 02	0.0564
					1.035E 02	2.188E 02	0.0358

Microbial Burden Buildup (Operational Level)

Operation 13

Environment 1
Time in hrs, from 60.39 to 61.46

Parts Affected by Operation -

Part	Surf	Dstr	Area	Source	From	To	Prob
11	1	25	1.000E 01	Fallout			
					6.741E 01	8.457E 01	0.0000
					8.457E 01	8.949E 02	0.0013
					8.949E 02	8.023E 03	0.1703
					8.023E 03	4.091E 04	0.6595
					4.091E 04	1.250E 05	0.1213
					1.250E 05	8.535E 05	0.0476
					2.106E 05	1.432E 06	0.0460
11	2	26	5.000E 01	Fallout			
					1.452E 00	1.677E 02	0.0000
					1.677E 02	1.646E 03	0.0016
					1.646E 03	1.391E 04	0.1772
					1.391E 04	6.931E 04	0.6558
					6.931E 04	2.106E 05	0.1194
					2.106E 05	1.432E 06	0.0460
11	1	25	1.000E-01	Contact			
					5.576E 00	9.404E 01	0.0000
					9.404E 01	9.159E 02	0.0015
					9.159E 02	8.028E 03	0.1703
					8.028E 03	4.080E 04	0.6593
					4.080E 04	1.246E 05	0.1213
					1.246E 05	8.502E 05	0.0476

C. PHASE III

1. Division of the Capsule Bus into Zones

The prediction technique used in the burden model includes an extensive bookkeeping system that monitors the status of hardware to reflect the buildup of burden at selected points in the assembly and test sequence. When the complete assembly and test sequence has been simulated, a set of statistics is available to describe the location (in terms of the biologically significant zones) and the magnitude of the accumulated burden. Before the probe enters the terminal heat sterilization cycle prior to launch, knowledge of the location and magnitude of predicted burden will be used to determine the characteristics of the heat cycle needed to sterilize the space probe. To make this determination possible, the biologically significant zones must be grouped in terms of thermal zones into which the probe will be divided as a result of thermal process analyses.

During Phase II, the assembly and test sequence of the Capsule Bus was reviewed at the third and fourth levels of operation. The purpose of this review was to

1) Establish criteria for regrouping biologically significant zones into thermal zones;

2) Determine a suitable means of implementing these criteria as a bookkeeping technique in the burden prediction model.

The identification of biologically significant zones was based on the hardware used in the assembly and test sequence for the Capsule Bus, and the way in which the hardware was assumed to be assembled. Zones were identified by tracing the hardware through the assembly steps and visualizing how the

finished product, at any given point, would look. In developing a test case to be used to demonstrate the burden model, criteria were established to identify biologically significant zones for the Capsule Bus. These criteria are shown in Table 8; they represent a reasonably comprehensive list of biological considerations that could be applied to any space probe configuration.

The method employed in the burden model to regroup biologically significant zones in terms of thermal zones permitted the biologically significant zones to be independent of the thermal zones into which the probe would finally be divided. The problem of zone regrouping became one of determining how biological zones and the burdens associated with these zones could be regrouped so that, at the end of the assembly an test sequence simulation, burden could be printed out for thermal zones.

Table 8 Criteria for the Definition of Biologically Significant Zones

1. Types of surfaces formed during the assembly process.

    Examples - mated surfaces, external surface areas
         exposed to the environment, etc

2. Material(s) present in newly formed surfaces or assemblies.

    Examples - Stainless steel, paint, insulating materials,
         etc.

3. Location of newly formed surfaces or assemblies.

    Examples - Recessed receptacle for connectors, proximity
         to heat-generating hardware, etc

4. Geometry of newly formed surfaces or assemblies.

    Examples - A hemispheric assembly mounted in a base
         frame, cabling assemblies, etc

The most practical method of providing this capability was to relate the thermal zones to those portions of the biologically significant zones of which they are composed. Thus, whenever it is desired to print out the burdens on the thermal zones, a set of cards is input defining for each thermal zone the surfaces (or portions of surfaces) that are to be included from each biologically significant zone. Thermal zone printouts do not affect the biologically significant zones already present in the model; thus it is not necessary to make further zone changes in order to continue with the simulation.

2. **Test Case**

a. **Description** - After the construction of the burden prediction model was completed, a deck of input data was prepared to simulate the assembly and test sequence for the Capsule Bus system. This input included parameter values, histograms to represent required burden and time distributions, and detailed instructions to portray the sequence of activity at each of the four levels of operation. The simulation was performed to:

1) Demonstrate the capability and flexibility of the burden prediction model;

2) Provide a framework in which to study the effects of various parameters on the burden predicted.

The test case consisted of 15 stages of assembly and test activity, representing the Martin Marietta Corporation's preferred configuration of the Voyager Capsule Bus system. The activities simulated are described in Appendix III, Section 2. The first level (stage) activity flow is presented in Figure 3. The 15 stages represent activity performed immediately after flight acceptance heat sterilization tests and extending to, but not including terminal heat sterilization of the integrated Capsule Bus system at the launch site.

b. __Data__ - A complete listing of the input data values is presented in
the documentation supplement provided with Volume II of this report.
The input data will be discussed in the order in which they appear in
the data deck. All data are for aerobic spores. Data were derived
from two sources:

1) Reference 17, 21, and 22 identified in Appendix II;

2) Estimates based on the assumptions identified in
   Appendix I.

All basic data relating to environments, operations, and biologically
significant zones were supplied at the beginning of the data deck. Gen-
erally used histograms (e.g., three titled Narrow, Medium, and Wide) and
histograms representing the surface areas and initial burdens of the
biological zones were also input at the front of the data deck.

The three environments were specified by the mean values of certain
parameters:

Environment	c	v	λ	f_1	f_2
1 Class 100 Laminar Tent	0.7	100	2.3	4.2	1.4
2 Class 100,000 Clean Room	3.0	100	0.46	4.8	1.6
3 Test Facilities	7.0	100	0.46	4.8	1.6

For c and v, the values were obtained from References
17, 21, and 22

These mean values are used in the model to construct histograms having
the same mean and a shape determined by a specified histogram. The
histogram for v was constructed from what little data could be found;
the histogram for c was chosen arbitrarily from the standard histograms,

Narrow, Medium, and Wide. The mean value supplied for the parameter v was modified to reflect differences in its value for the four surfaces by multiplying by 1, 1, 10, and 10 for surfaces 1 through 4, respectively.

The catalog of generic operations supplied to the model is the same as Table 5. Three histograms are specified for each operation to determine the shapes of the t, Q, and b_t histograms prepared in the model; these were selected arbitrarily from the standard histograms.

The selection of biologically significant zones was somewhat arbitrary since detailed information about which areas would be frequently touched was not obtainable. In general, the zones were selected to correspond to discrete pieces of hardware and hence may also represent thermal zones. Areas for all zones and parts were estimated from the Voyager specifications. Initial burdens were all zero since the parts had just emerged from the flight acceptance heat tests. The surface retention factors g and S_1 were arbitrarily chosen in the following ranges:

Smooth metal surfaces   0.1 to 0.5;

Skin or cloth   0.6 to 0.9.

To represent electrostatic effects on plastic surfaces, a value of 1.5 was used for g.

The functional analysis discussed in Chapter II.A.1. determined the remainder of the data for the Voyager simulation. Prerequisites were specified where necessary to assure the correct sequence of activities. Parts data were input as required, and the areas and

burdens modified as determined by the activities being performed. The time and the number of men required for each operation were estimated during the functional analysis; the parameters Q, a, and b_t were estimated from the number of men working and the type of work being performed.

3. Interpretation of Model Output

The computer model produces a microbial burden prediction in the form of a histogram with probability P_i assigned to each interval (x_{i-1}, x_i); a typical burden histogram is portrayed in Figure 7.
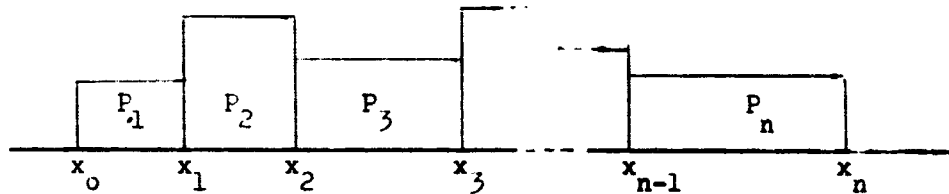

Figure 7   Typical Burden Histogram

Two questions naturally arise:

1) Does this output accurately represent the microbial burden?

2) What statistically valid conclusions can be drawn from this output?

a.   Output Accuracy - In a given application, the correspondence between the model prediction and the actual microbial burden is affected by the accuracy of the burden prediction formulas, the accuracy of the input data, and the accuracy of the calculations in the computer.

The burden prediction formulas, one for contact and one for fallout, were chosen to provide a good fit with the experimental data available.

Even if the exact formulas were used, the output would be worthless unless the inputs were accurate. One input required to predict the burden on a given assembly is the burden on each component part at the time it is added to the assembly. It is also necessary to input certain parameters (e.g., the number of organisms per cu ft of air) that represent

the environment and treatment of the assembly from its origin. However, due to random fluctuations (e.g., in the air currents), or inexact measurements (e.g., bioassays), most of the necessary data can only be estimated. This is done by taking representative samples, for example, spot assays on a large structure. It is, of course, essential that these samples be taken in such a manner that every portion of the structure has the same chance of being selected. The accuracy of the inputs clearly depends on the size of the sample; the larger the sample (assuming that it is representative), the more that is known about the attribute being sampled and the smaller the chance of a peculiar sample's leading to an incorrect estimate. For instance, if the sample mean is used to estimate the value of a certain input parameter, the probable error decreases as the square root of the sample size. (Of course, the sampling should not be so extensive that it disturbs the attribute being sampled; e.g., swabbing the entire surface of a part only measures the burden on that part before the assay was made.) Thus, within certain limits, the size of the sample taken to measure a given parameter is a measure (not necessarily linear) of the accuracy of the input for that parameter.

Having obtained a sample for a certain parameter, a statistical estimate could then be made of the "true" value of that parameter; for example, the average number of organisms per square foot on the structure. However, the computer model is designed to accept the sample itself; it is only necessary to group the sample points into suitably chosen intervals and then to reduce the number of points in each interval to a percentage (or probability). In this way certain assumptions usually made about the sample (e.g., normality) are avoided.

Finally, there is the question of calculation errors, especially cumulative errors. Since the sum, product, etc of two histograms is not (in general) a histogram, there is an error involved in changing the result back to a histogram. However, for "reasonable" distributions (roughly equal intervals and only one or two modes), this approximation causes almost no change in the mean and will only increase the variance, thus giving a conservative answer. (The variance increase runs from 0 to 10% per histogram combination.) Computer round off error has negligible effect on output accuracy since it is many orders of magnitude below the effect of the histogram approximation error.

Thus the model prediction is at least as accurate as the data provided in the inputs with the exception of a calculation approximation which tends to give a conservative result.

b.　Statistical Inference - Having determined the accuracy of the output, there remains the problem of drawing valid conclusions from it. A simple approach would be to regard the output histogram as an approximation to the probability density function of some ideal population of microbial burdens. This will provide a rough estimate of limits for the actual burden. (A tolerance interval is constructed to contain a given portion of the population with specified confidence. This should not be confused with a confidence interval, which is constructed to contain some population parameter with specified confidence.) This can be seen by considering two identical histograms, one prepared from a sample of size 4 from some population, and one from a sample of size 4000 from a different population
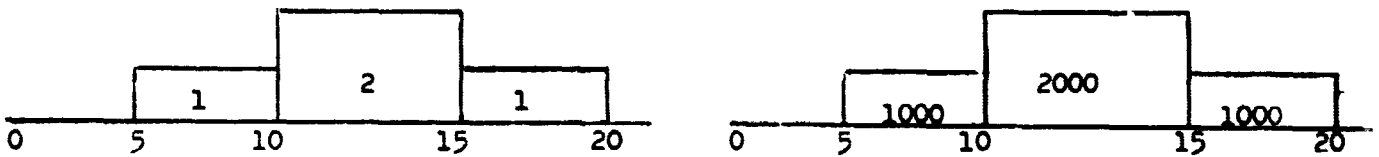
If the interval of interest is from 5 to 20, it is clearly safer to say that an item drawn from the second population will lie in the interval; a history of only 4.

It is seen that something more than the histogram itself is needed. A statistically valid interpretation is to regard the histogram as the result of a ramdon sample drawn from the set of all possible microbial burdens. To do this, the sample size must be known and this is related to the size of the samples (assays) used in preparing the inputs to the model. Consider samples from the two populations:

$$X = 1,4,5 \quad \text{and} \quad Y = 1,4,5,5,7,8 .$$
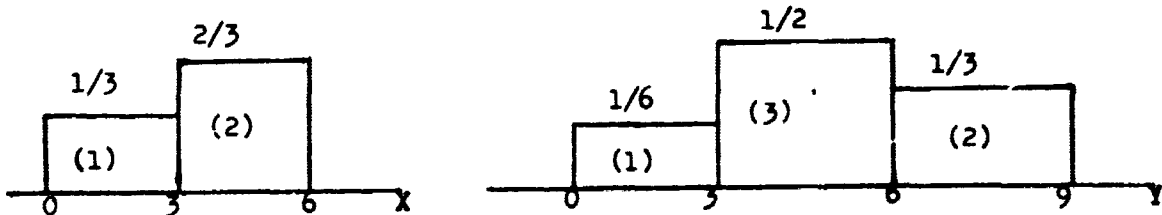
The computer model would calculate the histogram approximation to the distribution of the sum $X + Y$ as:

0.19444   0.35111   0.44444

```
   0        6        9              15          X+Y
```
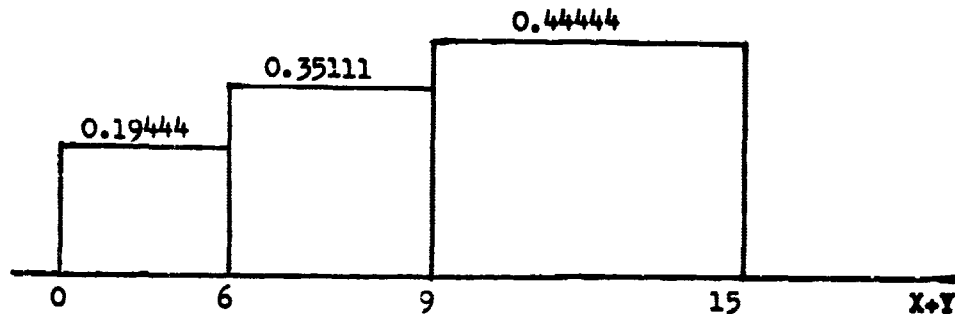
But what is the corresponding sample size? This question cannot be answered without further study; however, a conservative answer is that it represents a sample of at least three, the smaller of the two input samples. It is fairly clear that if the Y-values were actually 1000 times larger than those given above, the addition of X would have almost no effect. In this case the sample size would be that of Y instead of X. Since similar results hold for other histogram operations (multiplication, exponentiation, etc) used in the computer model, it is safe to regard the sample size of the output histogram as that of the smallest input sample.

Although it is safe to use the smallest sample size, it may require excessive work to make this number sufficiently large. (A sample size of about 100 would be desirable for the output.) It should be clear that the accuracy of some inputs has little effect on the accuracy of the output. For example, the contamination rating (Q) for a certain worker would be of little importance if that worker approached the spacecraft only once and then came no closer than 10 feet. Thus some measure of the sensitivity of the output to the various input parameters is needed.

c.   Sensitivity Analysis - The sensitivity of Y to X may be defined as $S_X^Y = \frac{\% \text{ change in } Y}{\% \text{ change in } X}$. Thus a sensitivity of zero means that Y is not

affected by X (over the range considered), and a sensitivity of one inficates that a small change (say 5%) in X causes an equal change (5%) in Y. A negative sensitivity means that an increase in X causes a decrease in Y. For differentiable functions, the sensitivity can be calculated using the partial derivative dividied by the nominal Y/X ratio. (This is valid only if Y is not zero; it is meaningless to talk of the percentage change in a variable whose initial value is zero.) The sensitivity is a dimensionless quantity and, by the chain rule for differentiation, we have $S_Z^Y = S_X^Y S_Z^X$ where Y is a function of X, which is in turn a function of z.

The formulas used in the burden prediction model are:

Fallout:

$$B' = Be^{-t/v} + AvR(1-e^{-t/v}),$$

$$R = f_i g(c+Qe^{-\lambda d}).$$

Contact

$$B' = B(1 - \frac{aS_2}{2A} + \frac{aS_1}{2} b_t,$$

where:

B′ is the resulting burden (organisms),

B is the initial burden (organisms),

e = 2.71828,

t is the assembly time (hr),

v is the "average lifetime" (hr),

A is the area of the given surface (sq ft),

R is the fallout rate ($\frac{organisms}{sq\ ft-hr}$)

f_i is the fallout velocity $(\frac{ft}{hr})$,

g is the fallout velocity $(\frac{ft}{hr})$,

c is the airborne contamination concentration $(\frac{organisms}{cu\ ft})$,

Q is the personnel "dirtiness factor" $(\frac{organisms}{cu\ ft})$

λ is a distance reduction factor $(\frac{1}{ft})$,

d is the distance from worker to surface (ft),

a is the area contacted (sq ft),

S_2 is the surface retention factor for the tool (dimensionless),

S_1 is the surface retention factor for the work (dimensionless),

b_t is the contamination desnity on the tool $(\frac{organisms}{sq\ ft})$.

Note that none of the above parameters is ever negative, and further-more, A and v must be non-zero. S_1 and S_2 are also restricted not to exceed 1. The parameter g is similar to S_1 and S_2 but may need to exceed 1 to include electrostatic effects. In the following discussion we have defined $b = B/A$ for convenience.

For the fallout formula we have

$$s_b^{B'} = \frac{b e^{-t/v}}{(b - v\lambda) e^{-t/v} + vR} \ .$$

If there are no airborne organisms (so R = 0), then $s_b^{B'}$ is always 1; otherwise $s_b^{B'}$ is 1 when t = 0 and decreases to 0 as t increases. This fact must be remembered when considering the effect of a sequence of operations; the burden on a part reflects only its recent (with respect to v) history.

$$S_R^{B'} = \cfrac{1}{1 + \cfrac{b e^{-t/v}}{vR(1 - e^{-t/v})}} \quad .$$

If the part was sterile initially (i.e., b = 0), then $S_R^{B'}$ = 1; otherwise $S_R^{B'}$ = 0 when t = 0 and increases to 1 as t increases.

$$S_t^{B'} = \frac{-t/v \ (b-vR) e^{-t/v}}{(b-vR) e^{-t/v} + vR} \quad .$$

$S_t^{B'}$ is greatest when t is approximately equal to v; it may be positive (b < vR) or negative (b > vR) and is identically zero if b = vR. $S_t^{B'}$ is zero when t = 0 and goes to zero again as t increases beyond v.

$$S_v^{B'} = \frac{(t/v)(b-vR) e^{-t/v} + vR (1 - e^{-t/v})}{b e^{-t/v} + vR(1 - e^{-t/v})} \quad .$$

For any values of the parameters except b 2 vR = 0 (in which case nothing is happening anyway), $S_v^{B'}$ = 0 when t = 0, and increases to 1 as t increases.

B' is of course sensitive to A ($S_A^{B'}$ = 1), but A can be measured as accurately as necessary and should not contribute to error in the output.

In conjunction with $S_R^{B'}$, the sensitivity of R to its parameters must be determined:

$$S_{f_i}^{R} = S_g^{R} = 1.$$

$$S_c^{R} = \frac{c}{c + Q e^{-\lambda d}}$$

S_c^R is close to 1 if c is large compared to $Qe^{-\lambda d}$ and is near zero if $Qe^{-\lambda d}$ is large compared to c.

$$S_Q^R = \frac{Qe^{-\lambda d}}{c + Qe^{-\lambda d}}$$

This has the opposite behavior of S_c^R.

$$S_\lambda^R = S_d^R = \frac{-\lambda d Q e^{-\lambda d}}{c + Qe^{-\lambda d}} \ .$$

If $Qe^{-\lambda d}$ is large compared to c, this is nearly equal to $-\lambda d$; in other cases, all parameters must be considered.

For the contact formula we have

$$S_B^{B'} = \frac{B(1 - \frac{aS_2}{2A})}{B(1-\frac{aS_2}{2A}) + \frac{aS_1}{2} b_t} \ .$$

Since S_1, S_2, and a/A do not exceed 1, this sensitivity is never negative and is zero only if B is zero. If the area contacted is relatively small (say a/A = 0.1) and b_t is approximately equal to B/A, $S_B^{B'}$ is nearly equal to 1.

$$S_a^{B'} = \frac{\frac{a}{2}(S_1 b_t - S_2 B/A)}{B + \frac{a}{2}(S_1 b_t - S_2 B/A)} \ .$$

S_a^B is small if a/A is small or if $S_1 b_t$ is nearly equal to $S_2 B/A$. $S_a^{B'}$ is close to 1 if B is much smaller than $\frac{1}{2} a S_1 b_t$.

$$S_{S_1}^{B'} = \frac{\frac{1}{2} a S_1 b_t}{B(1 - \frac{aS_2}{2A}) + \frac{1}{2} a S_1 b_t} \ .$$

$S^B_{S_1}$ is small if a/A is small and B/A is small compared to b_t; it is also small if b_t is much smaller than B/A.

$$S^{B'}_{S_2} = \frac{\frac{-aS_2}{2A} B}{B(1 - \frac{aS_2}{2A}) + \frac{aS_1}{2} b_t} \quad .$$

$S^B_{S_2}$ is never positive (an increase of the retention of the tool reduces the burden on the surface), and can approach -1 if B is large compared to $aS_1 b_t$ and if $S_2 = a/A = 1$.

$$S^B_{b_t} = \frac{\frac{aS_1}{2} b_t}{B(1 - \frac{aS_2}{2A}) + \frac{aS_1}{2} b_t} \quad .$$

$S^B_{b_t}$ is small if $(\frac{1}{2})aS_1 b_t$ is small compared to B; it approaches 1 when B is small compared to $(\frac{1}{2})aS_1 b_t$.

Table 9 summarizes the sensitivity analysis.

Table 9 Summary of Sensitivity Analysis

Parameter	Sensitivity of Burden to Parameter
Initial Burden, B	Varies from 1 to 0 as t increases
"Average lifetime", v	Varies from 0 to 1 as t increases
Fallout Velocity, f_1	Varies from 0 to 1 as t increases
Surface Retention, g	Varies from 0 to 1 as t increases
Airborne Concentration, $c + Qe^{-\gamma d}$	Varies from 0 to 1 as t increases
Area of Contact, a	Generally small unless a/A and/or b_t are unusually large, in which case this sensitivity approaches 1.
Surface	Generally small.
Tool Retention, S_2	Generally small (negative) unless a/A is unusually large in which case this sensitivity approaches -1.
Burden on hand or tool, b_t	Generally small unless a/A and/or b_t are unusually large, in which case this sensitivity approaches 1.

NOTE: This summary applies only to the case where airborne and surface organisms are present.

As can be seen from the above analysis, each parameter has a strong influence under some conditions but because of declining effect of the importance of the initial burden as t increases, only the more recent (compared to v) effects will affect the output.

There remains the problem of utilizing the sensitivity to reduce the sample size where possible. Although no statistical theory has been developed for doing this with maximum accuracy, an approximate method can be used. Suppose that a sample size of N is required for the output and it is desired to determine the sample size for the parameter Q when S_Q^B is known. If $S_Q^B = 1$, then clearly Q must be as accurate as the output and a sample of N for Q is required. If instead $S_Q^B = 0$, then Q need not be sampled at all. Between these extremes the relation is not determined but the obvious first approximation would be a linear one use a sample of size NS_Q^B for Q. A preliminary investigation indicates that this is conservative but the subject requires a thorough study before valid conclusions can be drawn.

d. Sample Calculation

As a numerical example to illustrate the above discussion, let the output histogram be:
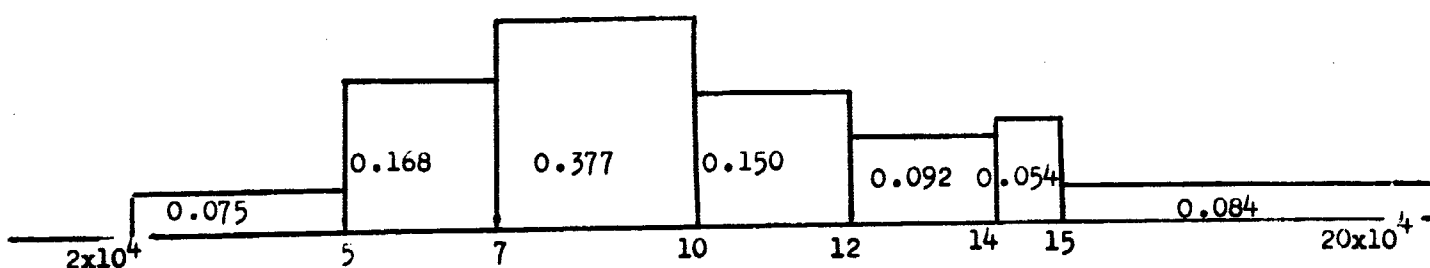
corresponding to a sample size of 135.

To determine actual burden on the spacecraft, tolerance limits on the population must be constructed. The procedure for this depends on whetnei or not the above distribution is regarded as normal. If the skewness is considered insignificant, methods assuming normality can be used. First calculate estimates $\bar{x}$ and s of the population mean and standard deviation. These are best obtained by treating the histogram as a continuous probability distribution:

$$\bar{x} = \sum_i P_i \; \frac{x_i + x_{i-1}}{2} = 9.574 \times 10^4,$$

$$s^2 = \left[\sum_i P_i \; \frac{x_i^2 + x_i \; x_{i-1} + x_{i-1}^2}{3} \right] - \bar{x}^2 = 13.98 \times 10^8.$$

(Alternatively, knowledge of the sample size could be used to convert the histogram to a discrete distribution and statistics derived as $\bar{x} = 9.574 \times 10^4$, $s^2 = 12.88 \times 10^8$. The former method is more conservative.)The tolerance limits are then given by $\bar{x} \pm Ks$, where K is a tabulated factor. (Ref. 42, p 4.6). For example, to be 95% confident that the tolerance limits cover 99% of the possible outcomes, the value of K for this sample size is 2.876. The tolerance limits are -1.19×10^4 to 20.33×10^4. (The negative lower limit casts doubt on the assumption that the distribution is normal.)

If the distribution is judged not to be normal (due in this case to the skewness), nonparametric methods should be used. Such methods will work for any distribution but generally give wider tolerance limits.

In the above example, the sample size was chosen so the largest and smallest values encountered (i.e., 2×10^4 and 20×10^4) are 99% tolerance limits with 95% confidence (Ref. 42, p 293). The nonparametric tolerance interval is slightly smaller than the one produced by assuming a normal distribution because of the conservative estimates of s.

For either estimate the sample size must be known; a sample of 100 or more seems necessary for a reasonably small tolerance interval. Of course, since the output of the model is to be used to determine sterilization requirements for interplanetary vehicles, it may be necessary to use tolerance limits for 99.9% of the population with 99.9% confidence or greater. This would require much larger samples to be taken. Assume for this example that the sample size of 135 produces an acceptable tolerance interval. If the sensitivity calculations show that the sensitivity of the value of the final microbial burden to a certain input parameter, say Q, is 0.015, then the number of assays required for Q is $N \, S_Q^B = (135)(0.014) = 1.89$; a sample of size 2 should thus be sufficient.

D. Suggestions for Verifying the Computer Model

Much of the microbiological and mathematical analyses performed during
Phase II to develop a predictive technique was based on assumption. These
assumptions were derived in three ways:

1) From the published sterilization literature,

2) From sterilization experience,

3) By judgment based on all available data.

The assumptions made during the program represent a base on which the bur-
den prediction technique and the biological significance of the assembly and
test activities were predicated. In any given situation, the assumptions made
represented an estimate of "real world" conditions. In many cases, because
of the absence of knowledge regarding a specific occurrence or environment, the
assumption represented a qualified judgment of the situation.

Exercises that have been performed using the burden prediction model have
done little to verify these assumptions because the data used were hypothetical.
Without empirical data obtained from monitoring an actual hardware assembly and
test sequence or results from experimentation, there is no reasonable way to
verify the model assumptions. Since the opportunity to monitor the assembly
and test large space probes is rarely available, the primary source of useful,
empirical data must be an experimental program designed to verify specific model
assumptions.

Many of the assumptions made in constructing and operating the model were
based on experimental results. These assumptions are considered to be valid,
and as such, will not need verification through further experimentation. Cer-
tain other assumptions, however, were based on intuitive judgment. These
assumptions should be verified.

The assumptions made during the model development program are listed in Table 10. They are organized into two groups, those that require and those that do not require validation through further experimentation. There is little practical value in describing an experimental program until an exhaustive search of the current technology has been completed to determine which experiments might contribute to the verification of assumptions. For this reason this report concerns itself only with the identification of assumptions that should be investigated; it defers consideration of an experimental program to a later date.

Table 10 Assumptions

Assumptions Needing Research
1. The sample size of the sum (product, etc) of two distributions is at least equal to the smaller of the two sample sizes. (A considerable savings in assay work is likely to result if the exact relationship can be determined.)
2. The sensitivity of the output to a given parameter can be multiplied by the desired output sample size to get an approximation for the sample size of the parameter. (Again, a savings in assay work is likely to result if the exact relationship can be determined.)
3. In order to simulate the "plateau" phenomenon, it was necessary to assume that organisms remain (alive) on a given surface a certain average length of time and then are (somehow) lost. A value of 100 hours seems approximately correct for exposed surfaces, but no data could be found for mated and occluded surfaces. The latter were assumed to be 1000 hours.
4. A first-order model was assumed for the fallout and "die-off" process on surfaces: $$R' = Be^{-t/v} + AvR(1 - e^{-t/v})$$
5. The formula for fallout rate $(R = f_i gc)$ has some experimental verification (Ref 34) but may not be appropriate in all circumstances.

Assumptions Not Needing Research

1. The computer program accounts for contact at the end
   of an operation even though the contact may actually
   have occurred at intervals throughout the operation.
   It is assumed that this difference is negligible.
   (If not, the operation should be separated into
   shorter operations.)

2. Contact is assumed to occur instantaneously.

3. It is assumed that merely keeping track of the total
   burden on each surface of each part (or zone) is
   sufficient; this burden is then considered uniformly
   distributed over that surface. (The zones must be
   chosen so small that this is acceptable.)

III.   PROGRAM SUMMARY AND CONCLUSIONS

The purpose of this program was to develop a methematical simulation model and associated computer programs to predict the accumulation of microbial burden at any point during the assembly and test of any spacecraft. Such a model was developed by the Martin Marietta Corporation for the Jet Propulsion Laboratory. The model has several outstanding features:

1) The model is flexible in that it may be used to simulate the assembly and test of any spacecraft. During this program, a Voyager-type Capsule Bus system was simulated using the model;

2) The model provides the capability to analyze assembly and test operations in terms of discrete procedural steps (i.e., similar to a time-and-motion study). The Capsule Bus system was analyzed to identify its assembly and test operation requirements at a level at which it was possible to describe discrete, repetitive procedures. To achieve this, four levels of operation were identified -- the Stage (first level of operations), the TASK (second level of operations), the SUBTASK (third level of operations), and the OPERATION (fourth level of operations). The operation was the lowest level of detail attained. The operations are basic, repetitive activities that would be performed to assemble and test a spacecraft (e.g., manually position a subassembly, solder, tighten a screw). 19 generic operations were identified for the Capsule Bus system. This subject is discussed in Chapter II.A.;

3) The model provides the capability to partition the spacecraft into zones and to predict the accumulation of burden on these zones. This feature complements the basic capability of the model to predict burden at each point in the spacecraft assembly and test sequence. This subject is **discussed** in Chapter II.C.1;

4) The level of detail represented in the model makes it possible to establish a 1:1 relationship between assembly and test operations and the sources of burden accumulation; this relationship is established through microbial parameters that describe the conditions of the operation(s) being performed. For instance, the parameters would identify the following information concerning the operation being performed:

    a) Environment (hi-bay);

    b) Number of men;

    c) Time to perform;

    d) Hardware involved;

    e) Burden retention factors for hardware.

This subject is discussed in Chapter II.B.2;

5) The burden prediction technique consists of mathematical expressions that represent known burden accumulation mechanisms. Currently, four mechanisms are used in the model; additional mechanisms may be added as required. The mechanisms now in the model are environmental fallout, personnel and equipment fallout, contact and decontamination. This subject is discussed in Chapter II.B.3;

6) The model employs the interval concept to represent and manipulate burden probability distributions. In order to include the data uncertainty, the burden variables are represented by histograms. Histogram manipulation provides a straightforward approach for performing arithmetic operations on the probability distributions. This subject is discussed in Volume II of this report;

7) Data inputs to the model have been defined and arranged to provide flexibility and visibility. Assembly activities are input in the exact sequence to be simulated. Parts, distributions, etc are grouped into logical packages that relate directly to the sequence of operations to be simulated;

8) Data output has been provided describing detailed results of the simulation. The output identifies the operations performed in sequence, their time of performance, and the burden predicted as a result of that performance. The burden predicted is presented in histogram form. This subject is discussed in Chapter II.B.4.d.

IV RECOMMENDATIONS FOR PROGRAM CONTINUATION

The development of a microbial burden prediction model is a necessary step in the evolution of a program for planetary quarantine. Such a model should produce reliable burden estimates both for biological control during assembly and for determining the final microbial burden for quarantine and sterilization calculations. The model should be convenient to input, fast running, dependable, and should produce its output in a form suited to the uses that will be made of the burden estimates. These qualities are present to varying degrees in the model developed under this contract; further improvement must be based on experience with applications to actual hardware.

As a first step in this direction, the following tasks are recommended for continuation of the current contract:

1) Values should be determined for all parameters used in the
    model. Two purposes will be served by this work:
    a) the derived data will provide data for use of the
        model on hardware for which the necessary data are
        incomplete;
    b) The validity of assumptions about the measurability
        of the selected parameters can be checked;

2) A simulation should be performed of an assembly and test
    sequence (e.g., Mariner 67) for which detailed biological and
    assembly records have been kept. This will enable the pre-
    dictions of the model to be compared with assays of the hardware
    concerned so that adjustments can be made to the model as
    necessary.