

PERKIN-ELMER CORPORATION
R-3124-5

General Electric Letter 7/10/67 - IMBLMS

NASA RFP 10-1234

Partial Pressure Sensor for a Two Gas Atmosphere (Photometric)

- A. Metabolic and Nutritional Item: General Metabolism and Nutrition Evaluation.
Partial Sub-Item (a) Energy Metabolism at Various Levels of Activity (O_2 consumption, CO_2 Production, . . .)
Input Parameters: Partial pressures of O_2 , CO_2 , H_2O , N_2 or He, and total pressure.
- B. Description: The design utilizes two sensor channels and a total pressure transducer to provide five different measurements (partial pressures of O_2 , CO_2 , H_2O , N_2 or He, and total pressure) and electrical signals proportional to these measurements. The first channel measures the partial pressure of CO_2 in the infrared at 4.27 microns using a thin film interference filter to select this wavelength. The second channel measures the partial pressures of oxygen and water vapor by using the absorption characteristics of these gases in vacuum ultraviolet at 1470Å and 1750Å respectively. The values of these partial pressures are summed in an electrical analog system and subtracted from the total pressure to obtain the measure of the diluent gas (Helium or Nitrogen) partial pressure.
- C. 1. Voltage: 28 VDC
Power: less than 5 watts
2. Weight: less than 5 lbs.
3. Size: 3.5 x 3.9 x 8.0 inches
4. Environmental limitations: Manned Spacecraft application
5. Support Equipment: see attached
6. Output: 0 to 5 volts D.C. for each constituent and total pressure
- D. 3. Concept proven, but not fully developed.
Development tests being coordinated under NASA, Langley Research Center contract. Initial units, before flight qualification, to be delivered by end of calendar, 1967.

PERKIN-ELMER CORPORATION
R-3124-1

General Electric letter 7/10/67 - IMBLMS

NASA RFP 10-1234

Miniature CO₂ Sensor

- A. Metabolic and Nutritional Item: General Metabolism and Nutrition Evaluation.
Partial Sub-Item a. Energy Metabolism at Various Levels of Activity (. . . CO₂ Production, . . .)
Input Parameter: CO₂ partial pressure.
- B. Description: The CO₂ Sensor detects the infrared attenuation of the sampled atmosphere at two narrow wavelength intervals. One corresponds to an absorption band unique to CO₂; the other is located in a window where no normal atmospheric gasses absorb. By computing the ratio of the two attenuation values, the instrument develops an output proportional to the CO₂ concentration. A dual wavelength filter that alternately interrupts the infrared beam in the sample path is responsible for the highly selective response. (See attached).
- C. 1. Voltage: 28 VDC
Power: 1 watt
2. Weight: 2.6 pounds
3. Size: 1.5" x 4" x 7.5" approximately (40 cubic inches)
4. Environmental limitation: Manned spacecraft application
5. Support equipment: Essentially per attached
6. Output: 0 to 5 V.D.C.
- D. Space qualified for Bios-Satellite (Hamilton Standard ECS), Apollo (NASA, MSC, Crew Systems Div.), Apollo Command Module (NAA), Apollo Lunar Excursion Module (Grumman).

Estimated cost per unit:

Lot of 4 units - \$35,000 each
Lot of 20 units - \$20,000 each

PERKIN-ELMER CORPORATION
R-3124-2

General Electric Letter 7/10/67 - IMBLMS

NASA RFP 10-1234

Miniature CO₂ Monitor for Helmets, Space Suits, and Similar Applications

- A. Metabolic and Nutritional Item: General Metabolism and Nutrition Evaluation.
Partial Sub-Item (a) Energy Metabolism at Various Levels of Activity (. . . CO₂ production, . . .)
Input Parameter: CO₂ partial pressure
- B. Description: The CO₂ Monitor is a single beam, double wavelength, filter photometer with difference measurement. The unit consists of a source (small tungsten lamp), collimating lens, another lens which re-images the source on a detector and filters just ahead of a detector assembly. The source is operated from AC power at a slow rate thus providing an AC energy level at the detector and proportional AC signals from the detector. Two detectors are in the detector assembly and receive IR energy at 4.3 microns (CO₂ absorption band) on one and 4.0 microns (unaffected by CO₂) on the other by virtue of their respective filters. Computation of the rates of the two attenuation values gives an output proportional to the CO₂ concentration.
- C. 1. Voltage: 13.5 VDC
Power: 0.7 watts approx.
2. Weight: 1.0 lbs. approx.
3. Size: 4 x 4 x 1 inches approx.
4. Environmental limitation: EVA
5. Support equipment: essentially per attached
6. Output: 0 to 5 VDC
- D. 3. Concept proven, but not fully developed. Work in progress as part of a Spacecraft Cabin Analyzer for NASA, MSC, and Portable Life Support System for NASA, MSC being built by Hamilton Standard Division of United Aircraft Corp.

PERKIN-ELMER CORPORATION
R-3124-3

General Electric Letter 7/10/67 - IMBLMS

NASA RFP 10-1234

Oxygen Partial Pressure Transducer

A. Metabolic and Nutritional Item: General Metabolism and Nutrition Evaluation.

Partial Sub-Item (a) Energy Metabolism at Various Levels of Activity (. . . O_2 consumption, . . .)

Input Parameter: O_2 partial pressure

B. Description: The oxygen partial pressure transducer is a photometric device utilizing the absorption characteristic of oxygen in the ultraviolet region. It contains only three elements: a source, chopper, and detector. An essentially monochromatic source operating at $1470\text{\AA}$ provides a beam of energy which is directed to a sapphire chopper driven by a resonant tuning fork and received by a UV sensitive photomultiplier. These elements are hermetically sealed in a small diameter which may be exposed to the atmosphere being monitored. The complete unit also includes signal processing and power supply electronic circuits in welded potted modules in an environmentally sealed package.

To measure the partial pressure of oxygen using ultraviolet absorption techniques it is sufficient to merely utilize a source, sample path and detector. The source will limit the spectral bandwidth, the fixed path length of the sample cell allows the computation of oxygen concentration from the observed transmittance and the detector converts the transmitted energy to electrical signals for amplification and processing.

The sapphire chopper provides two channels for the signal. Long term stability is achieved by introducing the second signal channel which is used as a reference. By continually adjusting the gain of the reference to compensate for changes in the source detector or electronics, the original signal channel can be made insensitive to these changes. The only signal which the overall system can respond to then is changes in oxygen partial pressure.

- C. 1. Voltage: ± 10 VDC approx.
Power: 2.5 watts approx.
2. Weight: 1.4 lbs. approx.
3. Size: 1.7 x 2.3 x 6.25 inches approx.
4. Environmental limitation: Manned Spacecraft application
5. Support equipment: essentially per attached
6. Output: 0 to 10 VDC

- D. Concept proven, but not fully developed.

Laboratory tests in process. System based on prototypes delivered to NASA, Manned Spacecraft Center and O₂ channel of Two Gas Atmosphere Monitor (Photometric) currently under development for this same agency. Proposed for MOL and technically acceptable.

PERKIN-ELMER CORPORATION
R-3124-4

General Electric Letter 7/10/67 - IMBLMS

NASA RFP 10-1234

Two Gas Atmosphere Monitoring System (Mass Spectrometer)

- A. Metabolic and Nutritional Item: General Metabolism and Nutritional Evaluation.
Partial Sub-Item (a) Every metabolism at various levels of activity (O_2 consumption, CO_2 production, . . .)
Input Parameters: O_2 , CO_2 , H_2O , and N_2 (or He) partial pressures.
- B. Description: The sample gas is admitted to the mass spectrometer through the combination of a viscous flow pressure divider and a molecular leak. This reduces the gas pressure to a level compatible with the ion source operating pressure. Gas enters the ionizing chamber which is part of the ion source. The ion source supplies electrons from a hot wire filament through an electron gun to the ionizing region. Gas entering the ionizing chamber is ionized by electron bombardment and the resulting ions are accelerated out of the ionizing region through an ion focusing system and to an exit aperture. This exit aperture forms the "object" of the magnetic sector analyzer. This consists of a uniform magnetic field which is generated by a permanent magnet, and a set of four ion current collectors. A magnetic field permeates through the walls of the vacuum envelope in which the ions are traveling and causes them to bend in circular paths, the radii of which are dependent upon their mass-to-charge ratios. The ions are separated by this action and are then focused into collector buckets which are spaced out along the collector flange at distances proportional to mass. There are collectors for each ion species of interest. These are, in this case, oxygen, nitrogen, carbon dioxide, and water.

The vacuum envelope houses the ion source and the magnetic sector. It is typically a thin walled stainless steel housing which is electrically accessible through feedthroughs. Multiple pin headers introduce voltages

from the ion source electronics and feed them to the filaments and to the various focusing electrodes, while single pin feed throughs transmit the ion currents from the ion current collectors to electrometer amplifiers which amplify the small ion currents to the levels required for output.

In addition to the electrometer amplifiers the support electronics consist of only three modules: a filament supply and emission regulator which senses the ionizing current and controls the filament current to keep emission current constant; electrode bias supplies which provide the necessary voltages to the focusing electrodes; and the detector power supply which provides voltages required for the electrometer amplifiers.

- C. 1. Voltage: 28 VDC
Power: 3.7 watts
- 2. Weight: 6.5 lbs.
- 3. Size: 4.8 x 6.5 x 5.5 inches
- 4. Environmental limitation: Manned Spacecraft application
- 5. Support equipment: essentially per attached
- 6. Output: 0 to -5 VDC
- D. 2. Completely packaged but not flight qualified.

Estimated cost per unit: approx \$30,000 each
in small quantities

C.4. VENDOR EVALUATION CRITERIA

TITLE		NUMBER	
Program Plan		GE-MOL-M-115-1	
USE		DATE	
1. For evaluation of proposal.		23 June 1966	
2. For determining the approach for development of equipment.		OFFICE OF PRIMARY RESPONSIBILITY	
3. The plan, when approved, will form the basis of the program and a baseline from which to audit the program for conformance.		Major S/C Program Operations	
		REFERENCES (Authority - Regulation, etc.)	
		AFSCM 310-1	
		S-5-14.0	
		M-1-14.0	
INTERRELATIONSHIP			
See DRL and GE-MOL-E-109 for submittal instructions. Other plans which may or may not be required by the subcontract:			
GE-MOL-C-103	L-107	P-103	P-105 R-108 S-131
F-102	M-114	P-104	R-107 S-110 T-101
PREPARATION INFORMATION			
The Subcontractor shall prepare a Program Plan for managing and administering performance of the tasks defined by the Work Statement. Whenever possible, the copies of existing procedures, manuals, etc., should be furnished in lieu of discussion of intent. This plan shall be written in accordance with the following guidelines: 1. Organization - A description of the Subcontractor's corporate and division(s) organization, the MOL program management organization and how it relates to the present organization; indicating cross flows to top management level. Indicate the names of key management, scientific and engineering personnel who would be assigned to this program; give the following information on each: a. Experience of personnel. b. General qualifications of these personnel, including education. c. Percent of total time each will be available for this program. Included with this organization information should be a description of responsibilities and authorities. 2. Program Control - A Subcontractor shall define his management system to be used for defining, planning, budgeting, and scheduling the work to be accomplished, and for surveillance, monitoring, evaluating and controlling work performance, costs, status, and applied			

manpower against the program plans, schedules and budgets.

3. Intercompany Liaison - Discuss the coordination procedures to be used in relation to interdivisional activities. Will common forms and procedures be used? Is it expected that the other divisions will establish parallel structure and procedures? Will similar echelons report directly or through the program director? What problems are anticipated and how is it proposed to handle them?

4. Scheduling

a. The Program Plan shall include the following two (2) items:

- (1) A program milestone schedule, including the proposed schedule for major activities.
- (2) A Program Management Network depicting significant events for accomplishing the overall program for which the subcontractor is responsible, consistent with the above milestone schedule and tasks defined in the Work Statement. The network shall have an Event Dictionary (List) to identify events and for each event, the dictionary shall have an event number, event title, and event description (including condition of each event upon its completion).

b. Overall Schedule Control - Discuss the relationship of scheduling to other control procedures you will use. Outline how scheduling information will be used and by whom, how often and in what form. Discuss review of changes or slippages, how these are reviewed, and rescheduling accomplished. Discuss your scheduling organization, where they get the information, how often and the extent of verification.

c. PERT - If a PERT System is required by the Work Statement, discuss the implementation of PERT systems and their utilization as management tools for program evaluation and control by the subcontractor. (PERT is required only if Exhibit P1001 is required by the Work Statement.)

- (1) Discuss the compatibility of the subcontractor's PERT system with USAF/Time/Cost Description Manuals.

Volume I	USAF PERT Time System Description Manual
Volume II	USAF PERT Time System Computer Handbook
Volume V	USAF PERT Implementation Manual

5. Cost Control

- a. Discuss the plan for controlling costs throughout the program.
 - b. Discuss the place of cost control in the subcontractors' organization.
 - c. Include planned formats for use in reporting the following financial data required by GE-MOL-A-106 (indicate which formats are in use at present by the subcontractor):
 - (1) Financial Data
 - (2) Manpower Data
 - (3) Financial Summary Report
 - (4) Value of Work Performed
 - (5) Expenditure and commitment curve by task
 - (6) Summary and expenditure and commitment curve
6. Other Plans - If a requirement exists in the work statement or exhibits for any of the disciplines listed below, but a separate plan is not specifically required in the Program Plan section of the Work Statement, a brief discussion of the subcontractor's planned implementation approach shall be provided for each as part of this plan. This brief discussion shall include for each applicable discipline the place of the discipline in subcontractor's organization and the planned approach to meet requirements, referencing existing procedures or existing methods for implementing requirements of the work statement.

Disciplines:

- a. Manufacturing (also discuss difference in manufacturing flow for flight and development hardware and, if applicable, normal vs. contamination controlled areas).
- b. Procurement (also describe preliminary make or buy plans and differences in procurement procedures for major subcontracts and parts/materials procurements).
- c. Engineering
- d. Safety
- e. Maintainability
- f. Data Management
- g. Configuration Management

- h. Logistics (also discuss procedural support data, training plans, support at GE or launch site, and plans for factory repair of failed items, as applicable).
- i. Human Engineering
- j. Electromagnetic Compatibility (Interference Control)
- k. Mass Properties Control

TITLE		NUMBER
Integrated Test Plan		GE-MOL-T-101-1
USE		DATE
1. To evaluate subcontractor's proposed test plans. 2. To monitor his actual operations for conformance to the plan.		7 July 1966
		OFFICE OF PRIMARY RESPONSIBILITY
		Major S/C Program Operations
		REFERENCES (Authority - Regulation, etc.)
INTERRELATIONSHIP		
Program Plan, GE-MOL-M-115 Facilities & Equipment Plan, GE-MOL-F-102 Reliability Plan, GE-MOL-R-107 Safety Plan, GE-MOL-S-131 See DRL and GE-MOL-E-109 for submittal instructions		
PREPARATION INFORMATION		
The Integrated Test Plan shall be prepared in accordance with the following instructions and outline. The outline below may cover areas of testing which are not required by the Work Statement, but it should not be construed to be a requirement for such testing; however, the subcontractor may elect to propose and describe tests additional to those specified in the Work Statement and include description of these tests in the plan. 1. The Integrated Test Plan shall define the total test program (AVE and AGE) and shall include all testing. The plan shall define the following for each test: A. Hardware item to be tested. B. Quantity to be tested. C. Test requirement, with appropriate Work Statement or specification paragraph number reference. D. Test objective. 2. The Plan shall be prepared in accordance with the following categorical outline: A. Development Tests 1. AVE 2. AGE B. Qualification Tests - AVE C. Validation Tests - AGE		

- D. Acceptance Tests
 - 1. AVE
 - 2. AGE
- 3. The integrated test plan shall describe how each of the following tests or verifications are integrated with development, qualification, acceptance and validation tests as applicable:
 - A. Electromagnetic Compatibility
 - B. Reliability
 - C. Safety
 - D. Maintainability
 - E. Human Engineering
- 4. A Test Program Summary Matrix shall be included as part of the Integrated Test Plan. The matrix shall be constructed listing the hardware to be tested (test specimens) vertically, and the types of testing horizontally, with column intersections marked with the number of test specimens proposed for each test.
- 5. An integrated test program schedule shall be included showing the plan for conducting all tests as a function of weeks after go-ahead. The schedule shall include:
 - A. Preparation and Approval of Test Plan
 - B. Preparation and Approval of Test Procedures
 - C. Test Equipment Design, Fabrication, and checkout.
 - D. Test Setup
 - E. Testing
 - F. Quick-Look Test Reports
 - G. Test Reports

TITLE		NUMBER
Procurement Plan		GE-MOL-P-105-1
USE		DATE
1. To evaluate proposal and determine subcontractor's ability to handle his procurements.		22 April 1966
2. To determine methods by which subcontractor will pass on critical requirements to his suppliers.		OFFICE OF PRIMARY RESPONSIBILITY Major S/C Program Operations
3. To obtain information required by ASPR and other government regulations.		REFERENCES (Authority - Regulation, etc.)
INTERRELATIONSHIP		
Program Plan, GE-MOL-M-115		
See DRL and GE-MOL-E-109 for submittal instructions.		
PREPARATION INFORMATION		
The Subcontractor shall prepare a Procurement Plan including:		
1. Procurement organization, authorities, responsibilities, & interaction with other organizations.		
2. Procurement policies and procedures to be applied to this subcontract, including differences in procedure between major subcontracts and parts/materials procurements.		
3. Source selection procedures and criteria for selection of bidders, evaluation of proposals, and selection of suppliers.		
4. Make or Buy		
A. Decision process and criteria.		
B. Preliminary Make or Buy Plan		
(1) Estimated percentage of the program cost to be expended in procurement.		
(2) List major items to be procured (estimated price in excess of \$100,000 or 5% of the proposed subcontract price, whichever is less) and high risk items, regardless of price. (Consider hardware supplied by other divisions of the subcontractor's company as procurements for purposes of preparing this list.)		
(3) Identify potential subcontractors for the items listed and the characteristics of the procurement (complete R&D program, design and production, production only, testing only, etc.)		
5. Subcontract management and control, including methods used or to be used in cost, schedule, and performance evaluation and control.		
6. Subcontract technical direction, including the methods used in providing detail direction and assuring that requirements are complied with by the Supplier.		

TITLE Logistics Plan		NUMBER GE-MOL-L-107-2
USE 1. To evaluate the subcontractor's proposed logistics effort. 2. Determine his understanding of the requirements. 3. For use as a baseline for audit for conformance.	DATE 4 October 1966	
	OFFICE OF PRIMARY RESPONSIBILITY Major Subcontract Program Operations	
	REFERENCES (Authority - Regulation, etc.)	
INTERRELATIONSHIP Procedural Support Data, GE-MOL-L-102 Spare Parts List, GE-MOL-L-104 Program Plan, GE-MOL-M-115 See DRL and GE-MOL-E-109 for submittal instructions.		
PREPARATION INFORMATION The Subcontractor shall submit a logistics plan for performing the requirements of the Work Statement. The logistics plan shall include the following when the items are required by the Work Statement:: 1. <u>Field Engineering Support Plan</u> A recommended plan for support of the deliverable hardware from delivery through flight including: A. Maintenance Plan B. Modification Control and Repair of Items Returned to Subcontractor. C. Procedural Support Data Updating D. Failure Reporting 2. <u>Emergency Support Plan</u> This plan shall include, but is not limited to a list of key technical and management personnel and alternates who are to be contacted in the event of an emergency; this list shall indicate both business and home phone numbers. 3. <u>Training Plan</u> The training plan will describe the training necessary to qualify personnel, designated by GE, to receive, checkout, install operate and		

maintain the end item(s) of AVE and AGE supplied under this contract to the extent specified in the Work Statement.

Subcontractor will make maximum use of Procedural Support Data, recommended below, in the support of his training program. Any additional material required will be identified and justified by the subcontractor.

The plan will specify the training courses to be conducted; the training material applied to each course; an outline of each training course; schedules of courses; type of examinations to be given; and method of evaluation to determine whether each course accomplishes its objectives.

4. Procedural Support Data Plan

A time-oriented plan describing recommended procedural support data including the following types, as applicable:

- A. Ground system test procedures for AGE end item installation and checkout.
- B. Test procedures for functional checkout of the AVE.
- C. Preventive maintenance data for inspection and replacement instructions.
- D. Corrective maintenance data for malfunction localization, peculiar calibration and repair instructions.
- E. Handling procedures for transportation, assembly or disassembly.
- F. Operating procedures for the equipment and accessories.
- G. Installation procedures for the equipment.

TITLE		NUMBER	
Maintainability Program Plan		GE-MOL-R-108-1	
USE		DATE	
1. To evaluate subcontractor's proposal and ability to meet maintainability requirements.		22 April 1966	
2. To define specific tasks to be carried out by subcontractors and methods to be used.		OFFICE OF PRIMARY RESPONSIBILITY	
3. To serve as a baseline to audit for conformance.		Major S/C Program Operations	
		REFERENCES (Authority - Regulation, etc.)	
		MIL-M-26512	
INTERRELATIONSHIP			
Program Plan, GE-MOL-M-115			
Integrated Test Plan, GE-MOL-T-101			
See DRL and GE-MOL-E-109 for submittal instructions.			
PREPARATION INFORMATION			
The Subcontractor shall prepare a description of his proposed maintainability program. This plan shall:			
a. Identify and define the elements comprising the proposed plan.			
b. Identify and define the time-phasing of each element.			
c. Identify and define the activity (work to be accomplished) programmed for each element.			
d. Identify the organization responsible for implementing and performing each maintainability program element.			
e. Indicate the lines of communication between personnel responsible for maintainability elements and design engineering, manufacturing, field engineering or support, reliability and human engineering, etc.			
f. Recommend appropriate maintainability program milestone review points.			
g. Identify maintainability goals which indicate the necessary progress toward the achievement of the maintainability requirements.			
h. Describe the maintainability program control techniques to be employed.			
i. Identify and define the maintainability records to be established and maintained.			
j. Describe methods and procedures to be used to predict maintainability and demonstrate that maintainability requirements have been achieved.			

TITLE		NUMBER
Safety Engineering Plan		GE-MOL-S-131-1
USE		DATE
1. To evaluate subcontractor's proposal.		7 July 1966
2. Determine adequacy of his plans to meet safety requirements of the deliverable hardware.		RESPONSIBILITY
3. Serve as a basis to audit subcontractor for conformance.		Major S/C Program Operations
INTERRELATIONSHIP		REFERENCES (Authority - Regulation, etc.)
Program Plan, GE-MOL-M-115		MIL-S-38130
Safety Engineering Report, GE-MOL-S-109		AFSCM 310-1
Hazard Reports, GE-MOL-S-128		S-19-17.0
Integrated Test Plan, GE-MOL-T-101		
See DRL and GE-MOL-E-109 for submittal instructions.		
PREPARATION INFORMATION		
1. The subcontractor shall prepare a plan which outlines the methods and techniques by which safety engineering concepts will be implemented. In addition, the plan shall give the subcontractor's safety engineering policies and objectives and shall list the safety milestones to be integrated with program milestones. The plan shall include, but not be limited to, coverage of the following items where they apply to the subcontract:		
a. <u>Safety Analyses</u>		
1. These analyses are in accordance with MIL-S-38130 and include consideration of single-mode-of-failure as a minimum.		
2. The procedures in this section shall show how these analysis are tied in with systems analyses and shall assure accomplishment of hazard analyses.		
3. The procedures will also show how the results of analyses are used and how hazardous conditions will be rectified.		
b. <u>Test Program</u>		
1. This section will show the methods by which safety engineering monitors the test plans, procedures, and reports as well as those methods assuring consideration of safety engineering aspects in developing test procedures.		

b. Test Program (Cont'd.)

2. The procedures assuring feedback of test information for use in design modification will also be included.

c. Safety Reports

This action shall describe the safety reports to be submitted, such as progress, hazard, accident/incident, and deviation.

d. Data Control

This section shall include the methods used to control the disposition and use of safety information.

e. Audit

This section shall contain procedures for audit to measure the effectiveness of the safety engineering program.

f. Ground Handling and Transportation

This section shall include methods assuring the development of special safety procedures required for ground handling and transportation. They shall also show how these procedures will be included in appropriate documents.

g. Training

Procedures shall be included to assure identification of special training requirements and the accomplishment of this training by the subcontractor's training department, if applicable.

h. Explosive Ordnance

When explosive ordnance is involved, this section shall contain procedures to assure development of the required technical data and compliance with appropriate Air Force and ICC directives. This includes determination of hazard, storage, and compatibility classifications.

2. Where data required by this plan is duplicative of data supplied in other plans or reports, the subcontractor's plan will reference but not duplicate the data.

Note: The subcontractor's plant or industrial safety practices or procedures are not to be included in this plan.

TITLE		NUMBER
SAFETY ENGINEERING PLAN		MSM-S-131
USE		DATE
1. To evaluate subcontractor's proposal.		28 March 1967
2. Determine adequacy of his plans to meet safety requirements of the deliverable hardware.		OFFICE OF PRIMARY RESPONSIBILITY
3. Serve as a basis to audit subcontractor for conformance.		Major S/C Program Operations
INTERRELATIONSHIP		REFERENCES (Authority - Regulation, etc.)
		MIL-S-38130 AFSCM 310-1 S-19-17.0
PREPARATION INFORMATION D. <u>SAFETY PLAN</u> - The subcontractor shall prepare a plan which describes the methods and techniques by which safety engineering concepts will be implemented. The plan shall give the subcontractor's safety engineering policies and objectives, and shall list the safety milestones to be integrated into detail milestone schedules. The plan shall include, but not be limited to, coverage of the following items where they are applicable to the subcontract: 1. <u>Safety Analyses and integration with testing.</u> The subcontractor shall show how safety analyses are tied in with other analyses; how the results of analyses are used, and how hazardous conditions are identified and considered in developing test procedures. The Methods shall be described to verify that safety requirements are met. Feedback of test information for use in design modification shall be described. 2. <u>Safety Reports.</u> The subcontractor shall describe the safety reports to be prepared and the disposition and use of safety information, including submittal to the subcontractor. 3. <u>Audit.</u> The subcontractor shall describe procedures for audit to measure the effectiveness of the safety engineering tasks. 4. <u>Ground Handling and Transportation.</u> The subcontractors shall describe the approach to develop special safety procedures required for ground handling and transportation, and how these procedures will be		

DATA ITEM

PAGE 1 OF 2 PAGES

Preparation Information (Continued)

included in procedural support data.

5. Training. Methods to identify special training requirements shall be described.

6. Explosive Ordnance. When explosive ordnance is involved, the subcontractor shall describe development of the required technical data and compliance with appropriate Air Force and ICC directives. This includes determination of hazard, storage, and compatibility classifications.

Note: The subcontractor's plant or industrial safety practices or procedures are not to be included in this plan.

TITLE		NUMBER	
Facilities and Equipment Plan		MSM-F-102	
USE		DATE	
1. To evaluate proposal and determine adequacy of available facilities and equipment, including special tools and test equipment.		6 April 1967	
2. List and define the facilities and equipment to be allocated to the subcontract.		OFFICE OF PRIMARY RESPONSIBILITY Major S/C Program Operations	
		REFERENCES (Authority - Regulation, etc.)	
INTERRELATIONSHIP			
PREPARATION INFORMATION			
The Subcontractor shall define the facilities and equipment required to implement the requirements of the Work Statement. The facilities and equipment plan shall be divided into the following categories: A. A breakdown of facilities by dollar value of Government owned facilities to be used in support of this program in accordance with Schedule I through Schedule IV, AFPI 13.2404. In the event a number of programs are being supported, the support of this program can be indicated as a percentage of the total. A breakdown of dollar value of the subcontractor owned facilities, presented in the same manner as the above, shall be included. B. An equipment list of existing subcontractor and government owned equipment which will be utilized in this program. This listing shall include the priority assignments that will be made by the subcontractor between this subcontract and other present or future subcontracts in case of conflicts. The present location (in plant, launch site, or other) will be given for each item. C. Those Facilities or equipment which the subcontractor owns and plans to modify or plans to build to implement the Subcontract.			

DATA ITEM

PAGE 1 OF 2 PAGES

C-55

D. Contractor or Government Facilities on which the subcontractor requests usage time to implement the subcontract. For facilities or equipment in these two categories, the subcontractor should include as applicable:

- a. Performance and design features required.
- b. Modifications and cost required to bring existing Contractor or Government facilities or equipment up to requirements.
- c. Present location of the facility or equipment and required location for use on the program.
- d. Usage dates required.
- e. For facilities planned for construction or under construction the detailed schedule for their design, construction and checkout.
- f. The plan and procedures in effect or which will be implemented to inspect, control, maintain and operate the Contractor or Government facilities and equipment to be used in performance of the subcontract.

TITLE Quality Program Plan		NUMBER GE-MOL-P-103-2
USE 1. To evaluate subcontractor's existing quality control system. 2. To determine subcontractor's understanding of quality requirements. 3. To serve as a baseline for audit of the quality program.	DATE 27 Oct. 1966	
	OFFICE OF PRIMARY RESPONSIBILITY Major S/C Program Operations	
	REFERENCES (Authority - Regulation, etc.) MIL-Q-9858 A MIL-C-45662 A ASPR 7-104.28 QA-1001	
INTERRELATIONSHIP Program Plan, GE-MOL-M-115 Quality Control Procedures, GE-MOL-P-102 See DRL and GE-MOL-E-109 for submittal instructions.		
PREPARATION INFORMATION The Subcontractor shall submit a plan defining his organization, procedures and methods for implementing the Quality Control requirements of the Work Statement. The plan shall provide evidence of an organized, systematic approach to all aspects of quality assurance in the Subcontractor's organization and with regard to procured hardware. It shall evidence economic planning and include definition of controls, inspections, workmanship standards, quality criteria, procedures, methods and techniques, using wherever possible the subcontractor's existing system. The Quality Program Plan shall include, but not necessarily be limited to the following: 1. Quality Assurance Organization 2. Quality Management and Control 3. Quality Assurance indoctrination and training 4. Flow Chart showing the proposed quality program operations from contract go-ahead through end item delivery. 5. Proposed changes to existing quality operations and the point of incorporating such changes with relation to the program plan. List of quality procedures critical		

CE-MOL-P-103-2
27 Oct. 1966

- or peculiar to the program.
6. Quality Design Review
 7. MRB Procedure
 8. Quality Inspection Plan
 9. Supplier/Subcontractor Quality Assurance Control
 10. Program for identifying and controlling critical components.
 11. Hardware production (Manufacturing) flow plan detailing the inspection and/or test points.

Copies of any existing Subcontractor procedures covering the above items should be included.

TITLE	NUMBER
Reliability Program Plan	GE-MOL-R-107-1
USE	DATE
1. To evaluate subcontractors' proposal and ability to provide a reliable product.	12 July 1966
2. To define specific efforts to be carried out by the subcontractor.	OFFICE OF PRIMARY RESPONSIBILITY Major S/C Program Operations
3. Serve as a baseline for audit for conformance	REFERENCES (Authority - Regulation, etc.) MIL-STD-785 AFSCM 310-1 R-1-17.0
INTERRELATIONSHIP	
Program Plan, GE-MOL-M-115 Integrated Test Plan, GE-MOL-T-101 See DRL and GE-MOL-E-109 for submittal instructions.	
PREPARATION INFORMATION	
A. The Subcontractor shall prepare a description of the planned reliability program, including a detailed listing of specific tasks and the general procedures to implement and control these tasks. These specific tasks shall include any parts improvement programs deemed necessary to meet reliability objectives. The listing and reporting of accomplishment of these tasks shall be in a form that permits technical auditing by the contractor and the contractor for contractual compliance. The reliability program plan shall provide for periodic reporting on the reliability activities. The program plan shall provide specific information as to how the subcontractor will meet specified quantitative reliability requirements during development and manufacture, including the design concepts to be utilized. The program plan shall (1) identify the organization and the personnel responsible for managing the over-all reliability program, and (2) shall clearly define its responsibilities and functions, including both policy and action. It shall stipulate the authority delegated to this organization to enforce its policies. The relationships between line, service, staff, and policy organization shall be identified. B. The Plan shall describe the failure reporting system, including analysis, feedback and corrective action.	

C. The Plan shall describe the following as required by the work statement or as planned by the Subcontractor:

1. Reliability Education
2. Performance of Reliability Figure of Merit Analyses
3. Operating Time Controls
4. Determination of Calendar and operating life of hardware
5. Program for control of parts, materials, and processes and their selection.
6. Failure Mode & Effects Analyses

D. (The following applies to all subcontracts except Aerospace Ground Equipment). The Subcontractor shall provide a listing by title and number of all standards utilized by the subcontractor (or if more convenient, only those applicable to this program), including the following:

Engineering Standards
Manufacturing Standards
Quality Control Standards
Reliability Standards

Examples of typical standards include:

Design Standards for Microelectronics
Printed Circuit Standards
Soldering Criteria
Wiring and Harness Standards
Manufacturing Instructions
Selected Parts List

Existing Company indices may be submitted if convenient for the Subcontractor. Later updating of this plan shall identify those standards directly applicable to this subcontract.

TITLE Engineering Plan	NUMBER GE-MOL-S-110-2
USE To evaluate subcontractor's proposed approach to achieve a design which meets the specified requirements. Note: This plan is not intended to duplicate the technical proposal but serves as a management supplement to it.	DATE 16 Jan. 1967 OFFICE OF PRIMARY RESPONSIBILITY Major S/C Project Engineering REFERENCES (Authority - Regulation, etc.) 1
INTERRELATIONSHIP Program Plan, GE-MOL-M-115 See DRL and GE-MOL-E-109 for submittal instructions.	
PREPARATION INFORMATION The implementation of the basic design approach shall be described in the form of an Engineering Plan which shall provide a description of the process of analysis, design and development tasks by which the basic design approach is translated into detail specifications and drawings in accordance with contract, system and design requirements. The Engineering Plan shall include: - A flow diagram shall be included which shows the sequential flow and all dependent relationships from award of contract through final design release. All Contractor/Subcontractor interfaces shall be identified. The Engineering Plan shall be completely compatible with, and show direct relationship with, the Integrated Test Plan, Reliability Program Plan, Quality Program Plan, Maintainability Program Plan, Facilities and Equipment Plan, and Manufacturing Plan (as applicable). - A description of the Subcontractor's design procedures and the roles played by each organizational function in the design process.	

TITLE Manufacturing Plan	NUMBER GE-MOL-P-104-2
USE 1. To evaluate the subcontractor's proposed manufacturing effort. 2. To determine subcontractor's understanding of peculiar manufacturing problems, such as contamination control, and evaluate his ability to meet the requirements. 3. To determine manufacturing areas and facilities allocated to the subcontract.	DATE 8 February 1967 OFFICE OF PRIMARY RESPONSIBILITY Major S/C Program Operations REFERENCES (Authority - Regulation, etc.)
INTERRELATIONSHIP Program Plan, GE-MOL-M-115. Manufacturing Processes and Procedures, GE-MOL-P-106. See DRL and GE-MOL-E-109 for submittal instructions.	
PREPARATION INFORMATION The subcontractor shall submit a Manufacturing Plan for performing the requirements of the Work Statement. The plan shall describe the procedures, constraints, requirements, and controls which will be implemented by the subcontractor throughout the contract. If different Manufacturing Standards are to be used for various kinds or classes of hardware, i.e., development hardware & flight hardware, then a clear distinction should be made in the manufacturing plan of the class of hardware to which various elements of the plan apply. Wherever they are applicable, copies of existing procedures should be submitted in lieu of plans. The following outline is to be used for the manufacturing plan: I. Introduction (Summary of plan accentuating key points). II. Approach - Recognition of Manufacturing problems and planned approach to each problem. III. Organization - General identification and description of manufacturing organization, including organization charts and charters (responsibilities). IV. Planning A. Scheduling - A description of proposed manufacturing scheduling system. B. Manufacturing Engineering, including producibility engineering, tool planning design, shop planning and methods, and equipment and facility planning. C. Tooling concept, including:	

1. Description of the tooling concept planned for this subcontract.
2. Special tools, jigs and fixtures required to accomplish this subcontract.
3. A schedule for all items of (2) above with emphasis on design data required to proceed with tool design and fabrication.

D. Repair and Rework - Methods for repair and rework of various classes of hardware, including tooling.

E. Manufacturing Flow.

1. Time-phased flow diagram for each deliverable item.
Show skills required in each stage of assembly and in-process testing.
2. Indicate variations for differences in:
Hardware Class (deliverable flight hardware vs. developmental)
Hardware Type (electronic, mechanical, propulsion, tooling)
Manufacturing Area (normal vs. contamination controlled area)

V. Control Techniques

- A. Production Control
- B. Selection, development, qualification, control and approval of new manufacturing processes.
- C. Method by which requirements in engineering documents are transposed into manufacturing, production or other "shop" documents.
- D. List, by job titles of occupations requiring training or certification and methods to be used.

VI. Coordination

- A. Manufacturing - How coordinated with other operations
- B. Coordination of effort with engineering, procurement, quality assurance, and reliability.
- C. Formal communications, including change orders, directives, reports and formal liaison meetings.

TITLE		NUMBER
Data Management Plan		GE-MOL-M-114-1
USE		DATE
1. To evaluate the subcontractor's proposed data management effort.		22 April 1966
2. To determine subcontractor's understanding of data management requirements.		OFFICE OF PRIMARY RESPONSIBILITY
3. To determine extent of existing data applicable to the program and resultant cost savings.		Major S/C Configuration & Data Management
INTERRELATIONSHIP		REFERENCES (Authority - Regulation, etc.)
Program Plan, GE-MOL-M-115		AFSCM 310-1
See DRL and GE-MOL-E-109 for submittal instructions.		
PREPARATION INFORMATION		
The Subcontractor shall prepare a plan defining his organization, procedures and methods for implementing the data requirements of the Work Statement. The plan shall designate the focal point having responsibility for data required by the subcontract. Plans shall be discussed for use of existing data applicable to this contract and subcontractor's policy regarding use, without cost, of available data from other programs or previous work. The plans shall describe proposed controls to prevent duplication in the preparation of data.		

TITLE Configuration Management Plan	NUMBER GE-MOL-C-103-1
USE 1. To evaluate proposal and determine subcontractors understanding of the Configuration Management Requirements. 2. To determine subcontractors methods of configuration identification, control and accounting and their compatibility with GE requirements. 3. For use as baseline for audit for conformance.	DATE 22 April 1966 OFFICE OF PRIMARY RESPONSIBILITY Major S/C Configuration & Data Management REFERENCES (Authority - Regulation, etc.) AFSCM 375-1 AFSCM 310-1 C-18-21.0 SCM 100
INTERRELATIONSHIP GE-MOL-M-115, Program Plan GE-MOL-C-101, Configuration Management Procedures E-2-11.0-1, Drawings, Standards, and Lists Other applicable GE-MOL-C-(items) See DRL and GE-MOL-E-109 for submittal instructions.	
PREPARATION INFORMATION The Subcontractor shall submit a Configuration Management Plan defining his organization, procedures and methods for implementing the requirements of the Work Statement. Copies of Subcontractor's existing procedures, manuals, policy directives, etc., where they satisfy the requirements, are preferable in lieu of a plan or portions thereof. The plan shall discuss or include the following: 1. Place of Configuration Management within the organization and relationship of Configuration Management to groups responsible for specification preparation, change control, engineering release, ECP preparation, and design reviews. 2. Control techniques as they apply to the Design Requirements Baseline and Product Configuration Baseline as defined in AFSCM 375-1. 3. Drawing requirements and their relation to Configuration Management 4. Specification Maintenance. 5. A Specification Tree showing interrelationship between all specifications to be prepared by the subcontractor and an approximate schedule for their completion, related to events such as PDR, CDR, etc. (if applicable). 6. Intended use of configuration identification index and configuration accounting report in the control of configuration. 7. Plans for implementing applicable configuration management requirements upon the subcontractor's suppliers.	

APPENDIX D
EXCERPTS FROM PRESERVATION OF BIOLOGICAL SPECIMENS STUDY
FINAL REPORT

APPENDIX D
EXCERPTS FROM PRESERVATION OF BIOLOGICAL SPECIMENS STUDY
FINAL REPORT

This appendix is comprised of selected excerpts from the final report on Contract No. NASW-1562, "A Study of the Collection and Presentation of Biological Specimens during Space Flight for Post-Flight Analysis" and includes the following information:

- D.1 Table of Contents
- D.2 Summary
- D.3 Conclusions and Recommendations
- D.4 Selected Charts and Diagrams

D.1 TABLE OF CONTENTS

<u>Section</u>		<u>Page</u>
1	SUMMARY	1-1
2	INTRODUCTION	2-1
	2.1 General	2-1
	2.2 Safety	2-3
	2.3 Why	2-5
	2.4 Measurement Criteria	2-6
3	ANALYTICAL METHODS	3-1
	3.1 Blood	3-1
	3.1.1 Bibliography for Blood Analyses	3-42
	3.2 Urine	3-51
	3.2.1 Correlation of Analytical Methods for Constituents Common to Blood and Urine	3-64
	3.2.2 Bibliography for Urine Analyses	3-65
	3.3 Feces and Sweat	3-77
	3.3.1 Bibliography for Feces and Sweat Analyses	3-80
4	MICROORGANISMS	4-1
	4.1 Sampling	4-2
	4.1.1 Sampling Sites	4-2
	4.1.2 Sampling Methods	4-3
	4.2 Analysis	4-5
	4.2.1 Gas Chromatography	4-6
	4.2.2 Mass Spectrometry	4-6
	4.2.3 Infrared Spectroscopy	4-7
	4.2.4 Fluorescent Antibody Technique	4-7
	4.2.5 Modification of Conventional Methods	4-8
	4.3 Media	4-8
	4.4 Preservation of Samples for Post-Flight Analysis	4-9
	4.4.1 Incubation	4-9
	4.4.2 Refrigeration	4-10
	4.5 Bibliography	4-10
5	PRESERVATION TECHNIQUES	5-1
	5.1 Summary	5-1
	5.1.1 Chemical	5-1
	5.1.2 Refrigeration (Chilling)	5-1
	5.1.3 Freezing	5-4
	5.1.4 Vacuum Distillation (Drying)	5-4
	5.1.5 Lyophilization	5-4
	5.1.6 Adsorption and Ion Exchange	5-4

D.1 TABLE OF CONTENTS (Cont)

<u>Section</u>	<u>Page</u>
5.2 Selection and Approach to Each Preservation Technique	5-4
5.2.1 Chemical	5-7
5.2.2 Refrigeration	5-9
5.2.3 Freezing	5-9
5.2.4 Vacuum Distillation	5-15
5.2.5 Adsorption and Ion Exchange	5-17
5.2.6 Lyophilization	5-17
5.3 Evaluation of Preservation Techniques	5-19
5.3.1 Chemical	5-19
5.3.2 Refrigeration	5-21
5.3.3 Freezing	5-30
5.3.4 Vacuum Distillation	5-47
5.3.5 Adsorption and Ion Exchange	5-54
5.3.6 Lyophilization	5-54
5.4 Biological Aspects of Preservation	5-63
5.4.1 Blood Preservation	5-66
5.4.2 Urine Preservation	5-73
5.4.3 Sweat and Feces	5-84
5.5 Trade-off Considerations of Biological Requirements versus Engineering Penalties	5-85
5.6 Rating of Preservation Methods	5-86
5.6.1 Rating of Preservation Methods on the Basis of Constituent Stability	5-86
5.6.2 Rating of Preservation Techniques in Terms of Safety and Ease of Performance of Procedures for Astronauts	5-96
5.7 Bibliography	5-98
6 COLLECTION AND HANDLING	6-1
6.1 Collection	6-1
6.1.1 Feces Sampling	6-1
6.1.2 Urine Sampling	6-6
6.1.3 Blood Sampling	6-15
6.1.4 Sweat Sampling	6-26
6.1.5 Bacteriological Sampling	6-35
6.2 Handling	6-42
6.2.1 Storage	6-42
6.2.2 Storage Module	6-45
6.2.3 Transportation	6-53
6.2.4 Trash Disposal	6-53
6.3 Bibliography	6-56

D.1 TABLE OF CONTENTS (Cont)

Section		Page
7	SAMPLING REGIMEN	7-1
8	TRAINING	8-1
	8.1 Training Program Outline	8-2
9	CONCLUSIONS AND RECOMMENDATIONS	9-1
	9.1 Conclusions	9-1
	9.1.1 Analytical Methods	9-1
	9.1.2 Microorganisms	9-2
	9.1.3 Preservation	9-2
	9.1.4 Collection and Handling	9-3
	9.1.5 Sampling Regimen	9-3
	9.1.6 Training	9-4
	9.1.7 Reliability as Related to Complexity from the Biological Viewpoint	9-4
	9.2 Recommendations	9-4
	9.2.1 Studies on Preserved Samples	9-4
	9.2.2 Laboratory Procedures	9-5
	9.2.3 Crew Selection	9-6
	9.2.4 Materials	9-6
	9.2.5 Safety	9-6
	9.2.6 Thermodynamic Properties of Biological Fluids	9-7
	9.2.7 Development of Freon Vapor Cycle Cooling Unit for Zero-G Operation	9-7
	9.2.8 Indigenous Microflora	9-8
	9.2.9 Thermodynamic Analyses of Spatial Heat Sinks (Radiators) for Specific Space Flight Missions	9-8
	9.2.10 Development of a Washing Machine for Use In Space Vehicle	9-8
	9.2.11 Centrifuge Development	9-8
	9.2.12 Trash Handling	9-9
	9.2.13 Experimental Design	9-9
	9.2.14 Experimenter's Handbook	9-9
APPENDICES		
A.	CLINICAL LABORATORY EVALUATIONS	A-1
B.	PRELIMINARY DESIGN FEATURES	B-1
C.	GENERAL GUIDELINE DESIGN INFORMATION	C-1

D.2 SUMMARY

This four-month study, Collection and Preservation of Biological Specimens During Space Flight for Post-Flight Analysis, performed under Contract NASW-1562, has included consideration of both the biological and engineering aspects of collection and preservation.

The philosophy underlying the approach taken by the General Electric Company is stated in Section 2. The guiding motive in this approach was to try to assure that analytical results would yield the best data possible in terms of physiological significance, accuracy, precision, and sensitivity. The need for good physiological data is self-evident: extended weightlessness may result in changes in the physiology of astronauts which may be deleterious either temporarily or permanently. Little information is available in regard to physiological changes which may take place in the course of space flight. All that we know is the result of before and after studies, for the most part, for the relatively short periods of the Gemini missions. Another consideration which has guided GE's approach has been the safety of the astronauts, who should not be exposed to hazardous chemicals and procedures.

Analytical methods for constituents of blood, urine, feces, and sweat are described in Section 3. These methods were chosen with a view to eliciting the most precise and accurate data possible from samples preserved during experiments planned by NASA. The question of possible preservation methods also played a role in the choice of techniques because some methods could not be used on preserved specimens; especially in the case of whole blood, in-flight determinations may have to be made since no adequate means of preservation was found. Another factor in the choice of analytical methods was their degree of acceptance and use by research and clinical laboratories. Some techniques which may yield excellent results have not as yet come into general acceptance and, because of this and intrinsic difficulty, their use may be limited to a few research institutions. The techniques chosen are summarized in Tables 3-1, 3-2, 3-3, 3-4, and 3-5.

Sampling and preservation of microorganisms are treated separately in Section 4 because so much of the methodology needs firmer definition, and the quantitation of microbiological data still eludes us. The problems of culturing microorganisms during flight and various techniques of preserving them for post-flight analysis are considered at length. Various old and new methods of sampling are also considered; development of new, and modification of currently used techniques are recommended. Methods of analysis and identification of microorganisms are also discussed. Automatic means of identification, such as gas chromatography, mass spectrometry, infrared spectroscopy, and fluorescent antibody technique which are in the development stage and may be available for routine use in the future are considered.

The engineering and biological aspects of preservation techniques are discussed in Section 5. Based on system weight and state of development, the order of engineering preference for biological sample preservation is rated "best to worst": chemical, refrigeration (chilling), freezing, vacuum distillation, lyophilization, and adsorption-ion exchange. A best approach is selected for each, and the weight, power, and volume penalties are discussed at length. The biological problems involved are considered separately for blood, urine, feces, and sweat. Feces and sweat appear to be the easiest to preserve reliably. Urine presents more difficulties, but most can be solved by several approaches. Blood, however, presents extremely difficult problems with respect to the preservation of some of its constituents. The only solution to some of these at present appears to be in-flight analysis. Other problems have no ready solution but would require laboratory developmental work. All preservation choices require experimental verification and establishment of standard base-lines for any changes in constituents which might occur as a result of a preservation method.

Collection and handling of the samples are discussed in Section 6. Each biological material is discussed separately, and approaches which take into account the absence of gravity and the necessity for scrupulous avoidance of spillage are presented. Several approaches are possible for each material and are described in detail. Some of these make use of designs

already developed by the General Electric Company. Other concepts were developed during the course of this study. Besides devices for collection and storage of the materials themselves, the need for an on-board centrifuge and washing machine is pointed out and preliminary concepts for these devices are shown. Sample containers for holding liquid bacteriological culture media, which permit the addition of samples, are discussed as are storage and transporting modules for all samples. A final sub-section treats the problem of trash disposal and describes a suggested approach.

Sampling regimens are presented in Section 7. Included are schemes for accommodating all the clinical evaluations listed in Appendix A as well as others which would provide a stepwise approach. Sample sizes have been determined so as to allow analyses in duplicate for the constituents of interest. Volume, weight, and power penalties for storing samples by the method of choice are also listed. In addition, clinical evaluations listed in Appendix A, plus others of possible interest have been ranked in groups on the basis of physiological importance and feasibility of performance. Volume, weight, and power penalties for these groups have been determined for the various preservation methods considered. The need for assessment of the relative importance of tests and final priority assignments based on a trade-off between priority assignment by scientific merit and feasibility ranking (by flight schedules, flight qualified hardware lead time, and crew skills required) is pointed out. The problem of physiological importance and feasibility of performance has also led to a tabulation of tests listed in Appendix A which could be omitted from the preservation regimen.

An outline of a training program for astronauts to prepare them for carrying out the procedures necessary for collecting, handling, and preserving biological specimens is described in Section 8. There are two approaches taken depending on whether a flight surgeon is a member of the crew. Also included is an estimate of clock-hours of classroom attendance needed to train a crew to the necessary level of proficiency.

Conclusions of this study and recommendations for future work are included in Section 9.

D.3 CONCLUSIONS AND RECOMMENDATIONS

After a four-month study of a multi-faceted problem containing dependent, independent, and confounding variables, it would be presumptuous to label the bulk of our conclusions as any thing other than "tentative". They are discussed below, as our recommendations for future study.

9.1 CONCLUSIONS

In a number of instances, a recommendation for work in a given area is the result of a conclusion that insufficient information is available.

9.1.1 ANALYTICAL METHODS

The analytical methods deemed best for each of the body constituents are described in Section 3. During the selection of these techniques, two suspicions were confirmed: 1) Precise, accurate, and sensitive tests of proven worth are readily available for elements, inorganic radicals, and relatively simple organic compounds; 2) for complex organic compounds ranging from steroids to proteins, precision and/or accuracy tend to diminish rapidly. Another drawback to many such tests is the large sample volume required.

Clinical tests on whole blood are for the most part approximations which are compared to an empirically obtained set of standards. A common determination such as a WBC differential is subject to considerable fluctuation even when done by the same technician on two samples of blood taken within a few minutes of each other from one person.

Platelet counts can and do vary to the extent of $\pm 35\%$. While such tests do supply qualitative information, their lack of precision and accuracy place them low on the priority list for inclusion in a set of flight experiments.

Urine analyses, with the exception of 17-hydroxycorticosteroids, aldosterone, serotonin, and vasopressin, can be done within the precision limits, set by NASA, of $\pm 5\%$. This is in keeping with the statement above regarding loss of precision in tests for the more complex organic compounds.

Feces and sweat electrolytes can be measured with comparative ease.

9.1.2 MICROORGANISMS

Disagreement is rife among biologists dealing with "locked flora", and microorganisms indigenous to the skin and gut over what constitutes a "normal flora", how "normal" should be defined, how measurements of changes in skin and gut microfloral populations should be made, how samples should be taken and incubated, and the roles of protozoa and particularly viruses in man's personal microorganisms. The unequivocal statement can be made that neither the theory nor the practice of microbiology has yet developed to a state where accurate precise quantitative data on changes in skin and intestinal microorganisms can be obtained on the ground, much less in orbit. Qualitative data though can be obtained but must be carefully interpreted.

9.1.3 PRESERVATION

By far and away, chemical preservation is the simplest and most economical method with minimum weight and volume and no power cost. Unfortunately, electrolyte determinations are the only accurate assays that can be made on samples preserved in this fashion. The handful of reports in which various assays were made on stored samples, preserved chemically by freezing and refrigeration, have proven of minimal value during this study. There is no body of literature devoted to clinical analyses on preserved and stored samples. A considerable amount of work has been accomplished in the freezing of blood for future transfusions, but not only is most of the preservation at dry ice (-78°C) or liquid nitrogen (-195°C) temperatures, (prohibitively low to reach and maintain within the biomedical experiment weight and power bogies shown in Appendix C), but the criteria for efficacy of preservation are concerned with the attribute of cell viability, not minimal changes in value of blood constituents.

For the analyses listed in Appendix A, freezing, refrigeration, and incubation will all be required, plus chemical preservation. For purposes of safety, it may be necessary to refrigerate chemically preserved specimens.

Lyophilization and vacuum distillation, with the exception of reducing wash water volume, are feasible but are considered inferior. Lyophilization is an excellent technique for preserving many sample constituents, but engineering penalties are severe, and freezing preserves these constituents just as well for flights of several months duration. Drying of samples over a desiccant looks good on paper, but no data on this method is available. Ion exchange resins, ring over chromatography, and other adsorption or absorption techniques are much too unwieldy for application to flight experiments.

9.1.4 COLLECTION AND HANDLING

Feces and urine can be collected automatically. There are no handling problems with the recommended systems.

Sweat, whether the collection bag or washing machine is used, will require a bit more effort on the part of the crew. Handling of the sample is quite straight forward.

Collection and handling of fecal samples, swabs, etc. for microorganism assay, though, is a different story. A highly motivated and well trained crew is mandatory if strict adherence to a sampling protocol is to be assured.

For proper collection and careful attention to the several blood handling schemes, a well trained and highly motivated crew is again mandatory.

Drawings of various pieces of apparatus for use during weightlessness are shown; all would require relatively short development times.

9.1.5 SAMPLING REGIMEN

The number of blood samples and their volumes, when taken on the 7-day rotating schedule (Table 7-2) which includes all the clinical evaluations in Appendix A, can be cut to a more reasonable number if those evaluations listed in Table 7-11 are omitted.

9.1.6 TRAINING

During a GE sponsored test, engineering personnel were trained within a week to draw blood from one another and did so for a month. During another company funded study, test pilots had a great deal of difficulty in using a spirometer. The difference between the two groups was not in intelligence or prior experience but in motivation; without a strongly motivated crew, the experiments will not be done properly, if at all.

9.1.7 RELIABILITY AS RELATED TO COMPLEXITY FROM THE BIOLOGICAL VIEWPOINT

In general the more complex a procedure is for collection, handling, or preservation, the less reliable. At every stage there is the possibility of operator error or system failure with resultant loss of sample and/or hazard to the astronauts. This is particularly true of some of the procedures necessary for handling blood samples. However, this problem has two sides to it. Some techniques and equipment may have to have complexity built-in to ensure greater reliability, especially with reference to stabilization of constituents. For example, serum or plasma has to be separated from blood for many analyses. In order to be able to do this in zero gravity, special containers must be developed and an on-board centrifuge will be necessary. A great deal of operator finesse will also be required. It would be desirable to simplify all techniques and equipment to increase reliability. But in order to perform some tasks at all during flight, a certain degree of complexity is unavoidable.

9.2 RECOMMENDATIONS

9.2.1 STUDIES ON PRESERVED SAMPLES

As has been mentioned several times, there are big gaps in our knowledge of how various constituents of biological materials hold up under various forms of preservation. A broad laboratory study of this problem utilizing various types of preservation is necessary to determine the best methods for various constituents. Data on stability is meagre. All types of preservation have not been followed experimentally in similar ways so some of the data which is available cannot be compared. This is especially true for duration of reliable storage. The gaps concerning these points can only be filled by extensive experimental studies.

One particular area where there exists little, if any, information is comparison of the efficacy of various temperatures of frozen storage. Those few studies which have dealt with the stability of biological constituents in the frozen state have only dealt with a single temperature of storage (with the exception of freezing erythrocytes for later transfusion). Rate of freezing has also received little discussion aside from its importance in preserving blood cells intact. These two areas, freezing rate and storage temperature, require a great deal more study to permit the choice of optimum conditions for this type of preservation.

If samples are to be preserved and stored for post-flight analyses, studies should be started now to develop standard curves for stored body fluid constituents of interest. Preservation by chemical means, refrigeration, and freezing are the prime candidates. Samples of urine, feces, sweat, whole blood, plasma, and serum should be stored for periods of time not less than twice the planned resupply interval. Chemical preservatives which do not pose a crew safety hazard should be sought. Refrigeration at various temperatures should be tried, 4°C seems to be a sacred number; whether 2°C or 7°C might be better is unknown. Freezing with controlled and uncontrolled rates of heat removal needs investigation as well as frozen storage at various temperatures. It must be emphasized that refrigerators and freezers made for home use, but which are routinely used in laboratories, are not satisfactory for these studies. Constant temperatures (± 0.5 to $\pm 1.0^\circ\text{C}$) should be maintained during storage, with a sensitive, precise, and accurate temperature sensor and recorder keeping track of temperature excursions.

9.2.2 LABORATORY PROCEDURES

Modifications of laboratory methods and equipment for easier use in weightlessness should be studied as soon as possible. Standardization of laboratory methods by the American Association of Clinical Chemists is a continuing process. The assistance of this and similar professional groups should be sought in an effort to ensure that laboratory procedures, whether on-board or performed post-flight, on preserved samples are as accurate, precise, and sensitive as possible.

The variation in test results among laboratories is too great to be ignored. Reference laboratories should participate in the planned experiments as a further check on accuracy and precision.

9.2.3 CREW SELECTION

The hypotheses that test pilots can be trained to perform experiments, and the converse, that scientists can be trained to fly the vehicle should be rigorously examined. The successful performance of tedious, sometimes odious, and occasionally complex laboratory procedures is totally dependent upon the crew. If the purpose of the planned missions is to obtain physiological and biochemical data, then highly motivated, well trained crews are essential.

Astronaut selection criteria should be re-examined and probably revised in order to obtain a crew possessing the mix of skills necessary for a top-notch laboratory.

Consideration should also be given to the inclusion of laboratory technicians in the crew. Many good scientists create the illusion that they have ten thumbs and two left hands when they work in a laboratory. The experiments for the AAP missions will be carefully planned with set schedules, thus requiring more doing than theorizing. A scientist-astronaut should be in charge of the laboratory and should make all major decisions, such as switching to an alternate schedule, omitting or adding a given procedure, etc.; but for routine tasks, and there will be many, a good technician would be preferable.

9.2.4 MATERIALS

Materials for use in a space laboratory must be chosen with care to avoid toxicity and/or fire hazards. A candidate list, from which materials for sample containers and handling equipment such as syringes, etc., can be fabricated, should be generated. These materials can then be tested for their applicability to laboratory usage. For example, the surface of plastics tends to be non-wettable. Surface etching may be required for tubes. The extent to which this changes the outgassing characteristics of the plastic is unknown.

9.2.5 SAFETY

During certain of the experiments, one or more of the astronauts will require some finite amount of time to disengage himself from apparatus (e. g., sweat test in Paragraph 3. 3). Should an emergency arise occasioning the need to don a pressure suit, time will be of the essence. Procedures should be developed which will permit the astronaut to rid himself of encumbrances (an equipment design criterion must be quick release) in as short a period of time

as possible. Because of the array of equipment contemplated, studies to determine these emergency procedures should be done in parallel with equipment design.

Another hazard is presented by chemicals which may be preservatives or reagents. Each on-board laboratory procedure should undergo a risk assessment as a separate task after a preliminary definition of what equipments and procedures will be included in the operation of the orbiting laboratory.

9.2.6 THERMODYNAMIC PROPERTIES OF BIOLOGICAL FLUIDS

Either as a part of the long-term sample preservation studies mentioned above, or as a separate study, the thermodynamic properties of biological fluids need to be determined. Freezing of blood for transfusion use is largely an "overkill" technique. More heat removal capacity is available than is known to be needed. Overdesign, with safety factor added on to safety factor added on to margin of error, imposes severe weight, power, and volume penalties. Since these penalties have not been of primary concern in research and eleemosynary institutions, the major users of blood freezing and storing equipment, little definitive work on the thermodynamic properties of blood has been done. With knowledge, from studies on blood preservation, of just how cold blood must be for storage, how fast it must be cooled and then knowing how much heat has to be removed at what rate, this becomes an area where spin-off from the space program could influence the design of blood-banking equipment. Smaller, more efficient preservation units would sharply reduce their cost.

For urine, feces, sweat, and blood (including whole, plasma, and serum) information on thermal properties coupled with data on the effects of long term storage would be applicable to the shipment of biological fluids; specimens, when preserved and packaged properly, could be sent to reference laboratories at any time with assurance that the analytical results could be evaluated.

9.2.7 DEVELOPMENT OF FREON VAPOR CYCLE COOLING UNIT FOR ZERO-G OPERATION

The advantages of this type of cooling unit are discussed in Section 5. However, such equipment has not been developed for space vehicles. A study should be undertaken to determine development time and application to uses other than sample preservation.

9.2.8 INDIGENOUS MICROFLORA

Changes in both skin and intestinal microflora during confinement and isolation are under study in our laboratory. Sampling and recovery of microflora from the skin and feces needs considerable study in order to know what the original population is and how it changes with time during isolation and confinement. Since a pathogen can become the dominant microorganism, the health and safety of the crew will be endangered. With the time before long term missions starting to grow shorter, better methods of controlling the microflora must also be found. Additional studies on sampling and recovery of microorganisms and on control of the indigenous microflora are urgently needed.

9.2.9 THERMODYNAMIC ANALYSES OF SPATIAL HEAT SINKS (RADIATORS) FOR SPECIFIC SPACE FLIGHT MISSIONS

During the performance of this study, a lack of information on spatial heat sinks was noted. Weight, power, and volume penalties for given missions could possibly be reduced if the heat transfer requirements of each mission could be treated separately. A modular radiator design would permit addition to, or reduction of, cooling capacity as required and might allow more flexibility in mission planning. A feasibility study is recommended.

9.2.10 DEVELOPMENT OF A WASHING MACHINE FOR USE IN SPACE VEHICLES

A description of a washing machine concept is given in Section 6. As mission length increases, personal hygiene poses more of a problem. Aside from the possibilities of doing mineral balance studies, an on-board clothes washing capability may also result in a weight reduction since less extra clothing would have to be carried. It has been determined that such a washer is feasible; the next step should be design and fabrication of a prototype.

9.2.11 CENTRIFUGE DEVELOPMENT

Whether biochemical analyses are performed on-board, post-flight, or both, a centrifuge will be needed for the preparation of plasma and serum. A description of the centrifuge which is feasible is contained in Section 6. Design and fabrication of a prototype should be started promptly.

9.2.12 TRASH HANDLING

In the normal course of clinical laboratory operation a large amount of trash is generated. Dirty disposable syringes, needles, tubes, used agar plates replete with bacteria, bloody sponges, and the like all furnish excellent breeding grounds for more bacteria and fungi. In a space vehicle, sterilization and storage of compressed plastic appears to be a likely means of coping with this problem. A concept described in Section 6, and probably alternates, should be subjected to a design study in the near future because a trash handling system will be required in an orbiting laboratory.

9.2.13 EXPERIMENTAL DESIGN

The successful performance of contracting tasks depends in part upon the contractors' knowledge of the detailed rationale and experimental design of each experiment as further work related to experiments is initiated. Such information should, therefore, be made available to contractors.

9.2.14 EXPERIMENTER'S HANDBOOK

Most of the experiments have been proposed by principle investigators who have a good deal of scientific competence but little or no knowledge of the process by which hardware for these experiments is fabricated and qualified for flight. We urge NASA to fully exercise its management prerogatives and set forth a carefully defined method of handling experiment hardware (hardware is emphasized here because sample collection and handling analytical and preservation equipment are intimately associated with the experiments) design inputs. Our past experience indicates that the following criteria should be met by such a method:

- a. Experimenter identity is recognized and retained throughout the program.
- b. Experiment integrity is not compromised in the integration process.
- c. NASA liaison will provide opportunity for experimenter-engineer crosstalk at both the contractor's facility and the experimenter's laboratory.
- d. Contractor biomedical personnel should participate in experimenter-engineer meetings.
- e. Established deadlines for experimenter design inputs.
- f. Design inputs to be signed off by NASA and contractor personnel before prototype or flight design freeze.

- g. Prototype hardware to be laboratory tested by both experimenters and contractor.
- h. Design changes in flight hardware to be specified by experimenters within 90 days after receipt of prototype hardware.
- i. Direct contact between contractor personnel and individual experimenters for resolution of problem areas.

Each of the criteria listed is based on GE's experience as an experiment (and experimenter) integrator. Very often the basic conflict between the hardware engineer and the academic research scientist is due simply to lack of understanding of the problems each must solve in order to perform an experiment within the constraints imposed by a space vehicle.

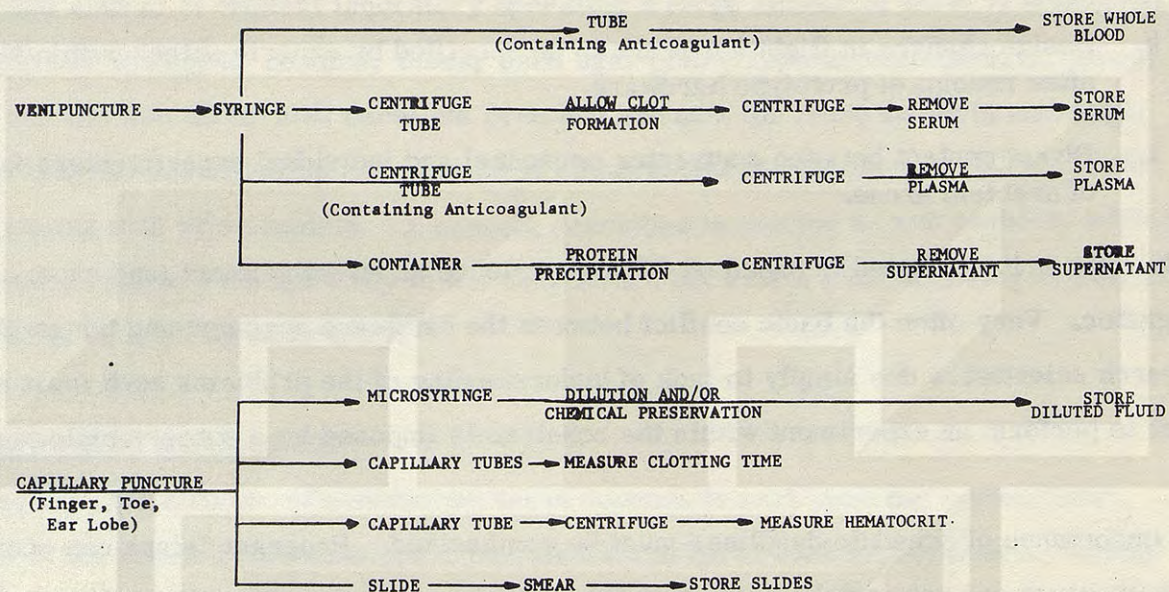
The importance of schedule deadlines must be emphasized. Program delays can occur if experimenters are not acutely aware that this is their program. Some items have a long lead time. Flight schedules can not be met if experimenter inputs are not made in a timely fashion. Design inputs should be signed off by both NASA and the contractor and engineering personnel so that the attainment of experimental objectives will be ensured and the contractor and NASA not faced with time-consuming, costly changes. Prototype testing should be performed in both the experimenter's laboratory and the contractor's laboratory so that design changes recommended for the flight articles will reflect desires tempered by reality.

The orientation of experimenters has, in the past, been hit or miss. That participation in such a costly venture, at no risk to the participant, is the case, has never fully been explained to the members of the scientific community who should be made aware, in detail, of the responsibilities of the experimenter.

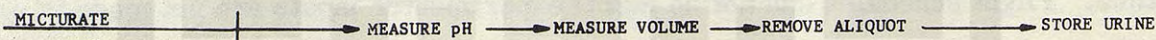
To this end, we strongly recommend that an Experimenter's Handbook be prepared, including inputs from experimenters, engineers, and biologists with prior experience on experiment programs. Such a Handbook would explain, for example, why design changes increase in cost as the program moves along.

D.4 SELECTED CHARTS AND DIAGRAMS

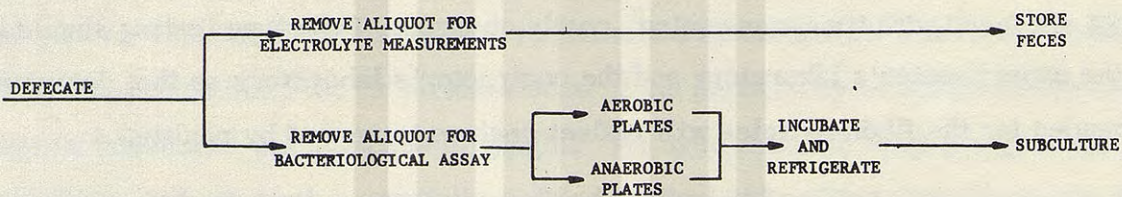
BLOOD



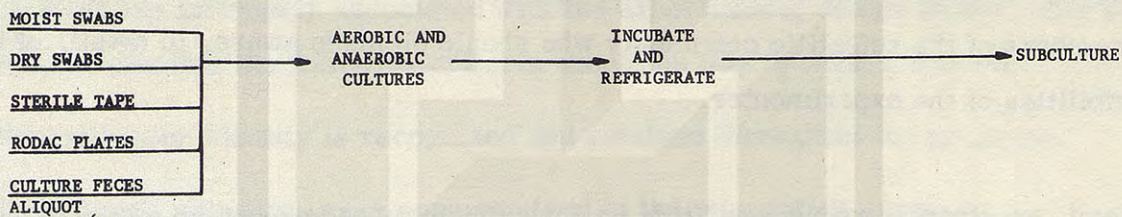
URINE



FECES



BACTERIA (on skin, clothes, cabin)



SWEAT

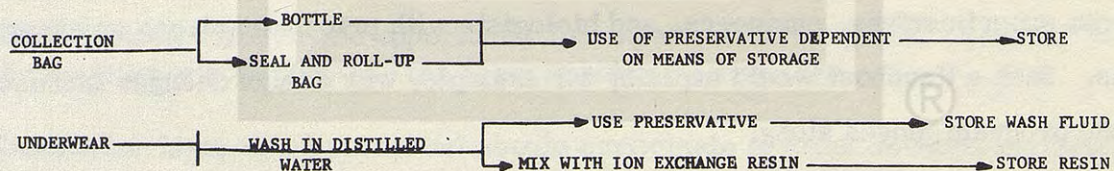


Figure 2-1. Collection to Storage Sequence

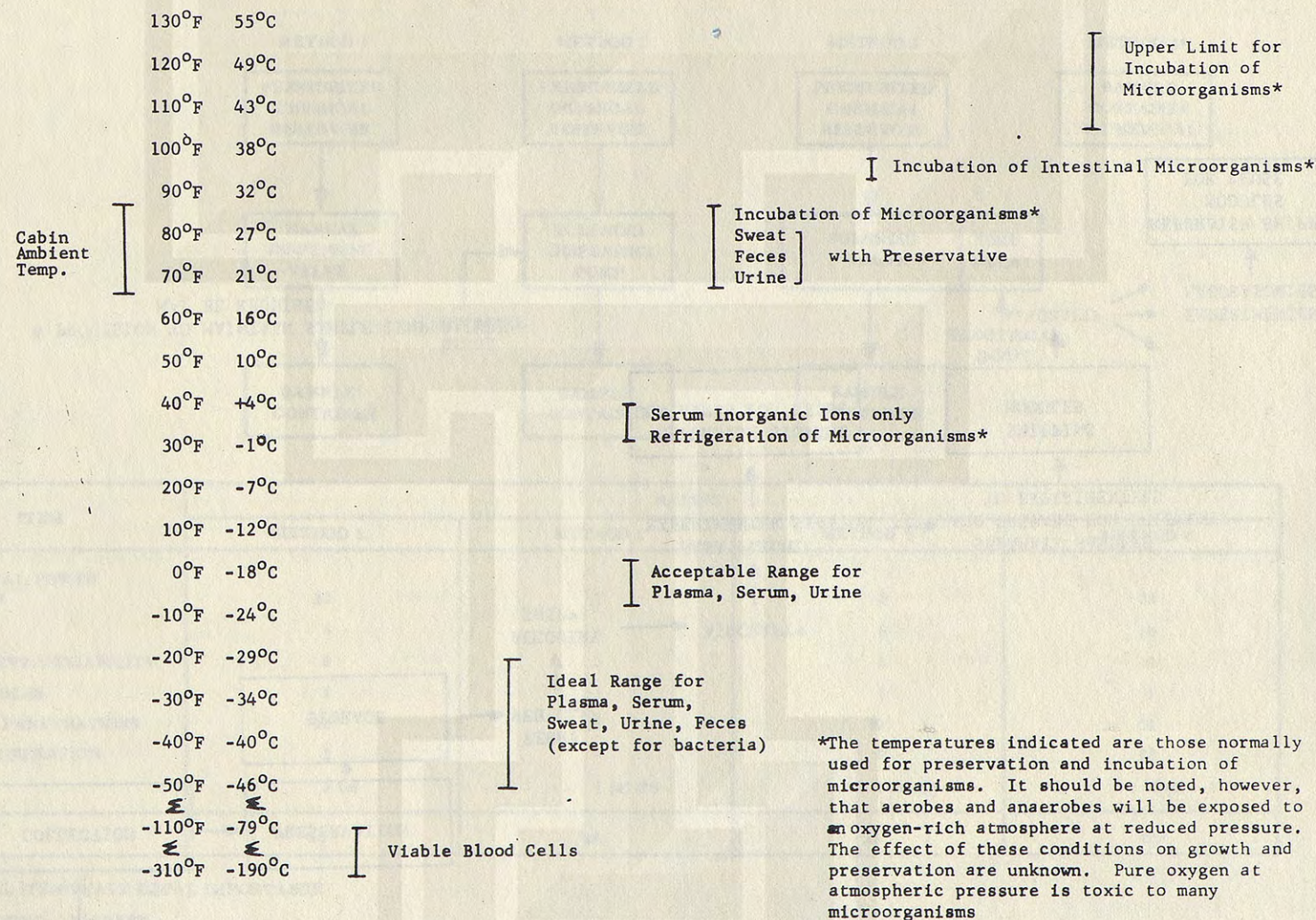


Figure 5-35. Temperature for Sample Preservation

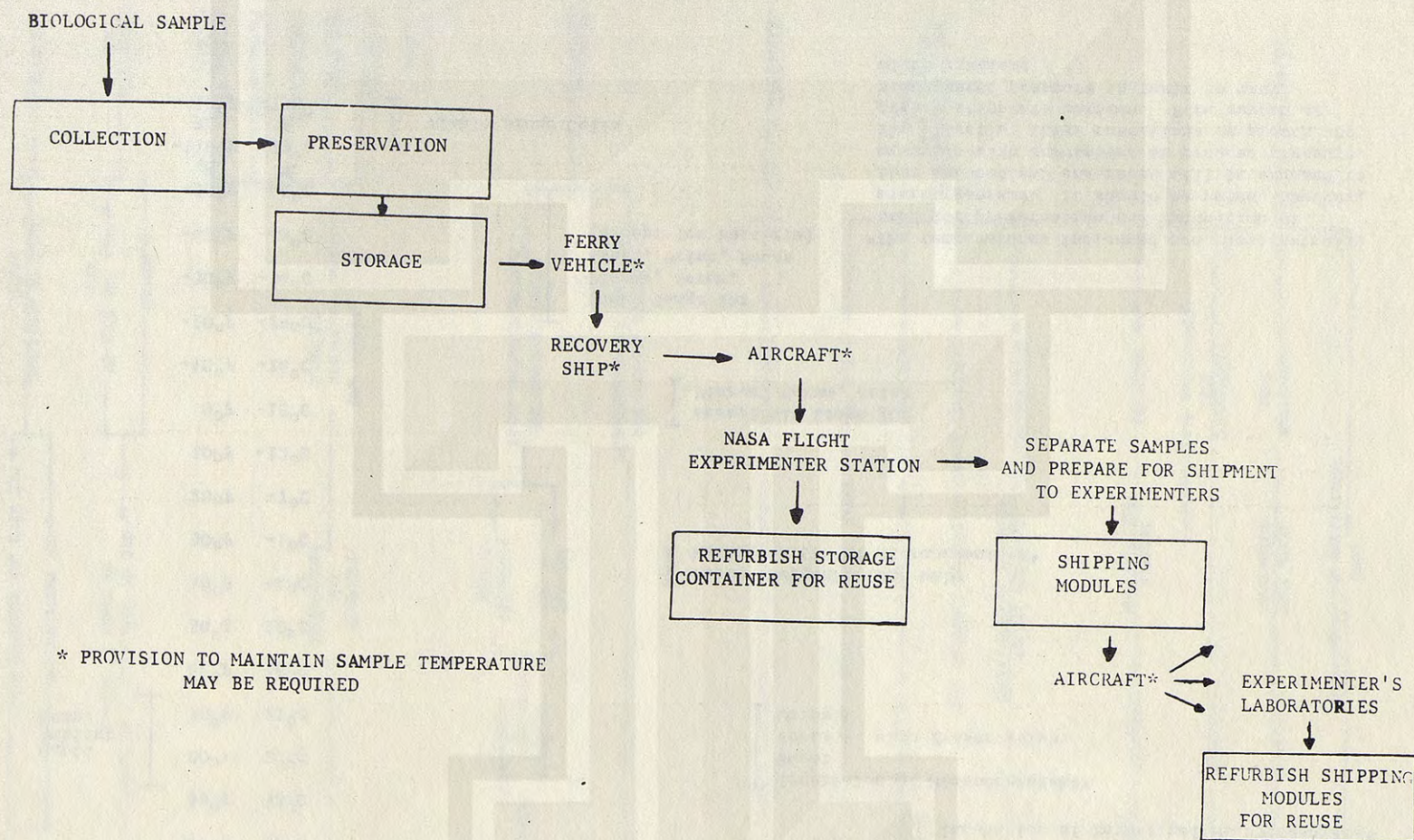
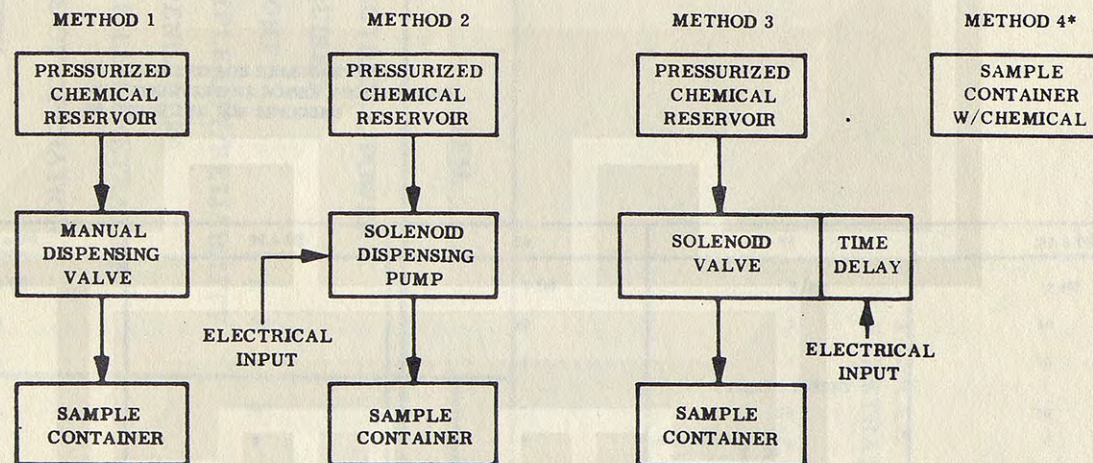


Figure 6-22. Biological Sample Handling Requirements

Table 5-2. Preservation by Chemical Methods



ITEM	RATING			
	METHOD 1	METHOD 2	METHOD 3	METHOD 4
ELECTRICAL POWER REQUIRED	10	1	5	10
WEIGHT	5	1	8	10
COMPLEXITY/RELIABILITY	8	5	5	10
EXPENDABLES	1	1	1	1
VEHICLE PENETRATIONS	10	10	10	10
EASE OF OPERATION	1	5	5	10
SAFETY	5 (a)	1 (a) (b)	1 (a) (b)	10 (c)
TOTAL	40	24	35	61*

NOTE: ALL ITEMS HAVE EQUAL IMPORTANCE

RATING: 10= BEST
1= WORST

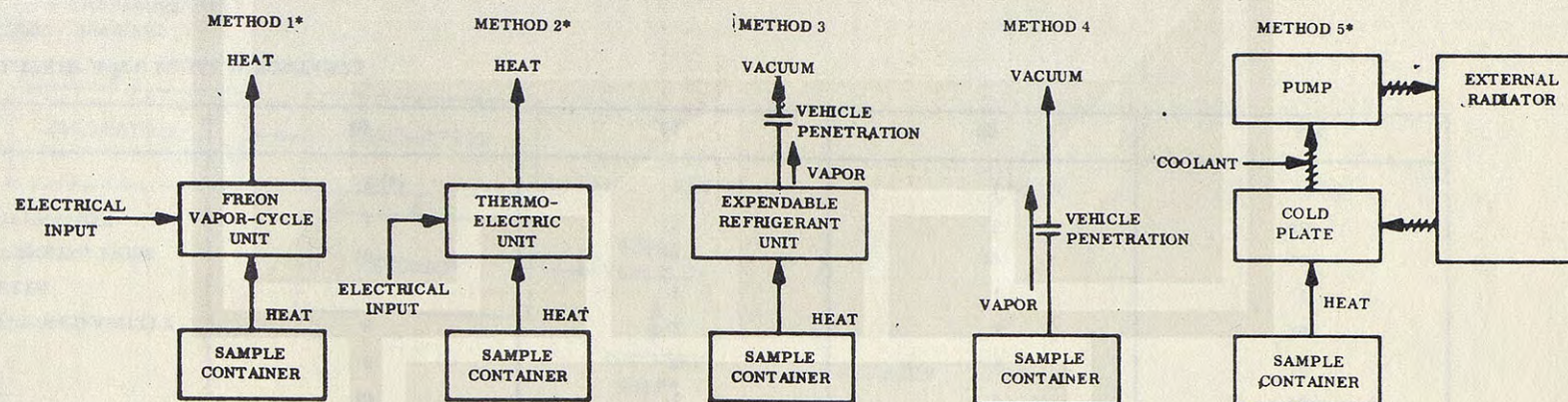
*SELECTED

(a) PRESSURE VESSEL HAZARD

(b) SOLENOID JAMMING HAZARD

(c) PRESERVATIVE LEAKAGE HAZARD

Table 5-3. Preservation by Refrigeration or Freezing



ITEM	RATING				
	METHOD 1	METHOD 2	METHOD 3	METHOD 4	METHOD 5
ELECTRICAL					
POWER REQUIRED	5	1	10	10	9
WEIGHT	5	5	1	10	7
COMPLEXITY/RELIABILITY	3	8	5	7	4
EXPENDABLES	10	10	1	10	10
VEHICLE PENETRATIONS	10	10	1	1	10
EASE OF OPERATION	10	10	10	1	10
SAFETY	1 (a)	10	1 (a)	5 (b)	5 (a)
TOTAL	44 * (c)	54 * (d)	29	44	55 * (e)

NOTE: ALL ITEMS HAVE EQUAL IMPORTANCE.
 RATING: 10 = BEST
 1 = WORST

*SELECTED

(a) GAS OR LIQUID LEAKAGE HAZARD

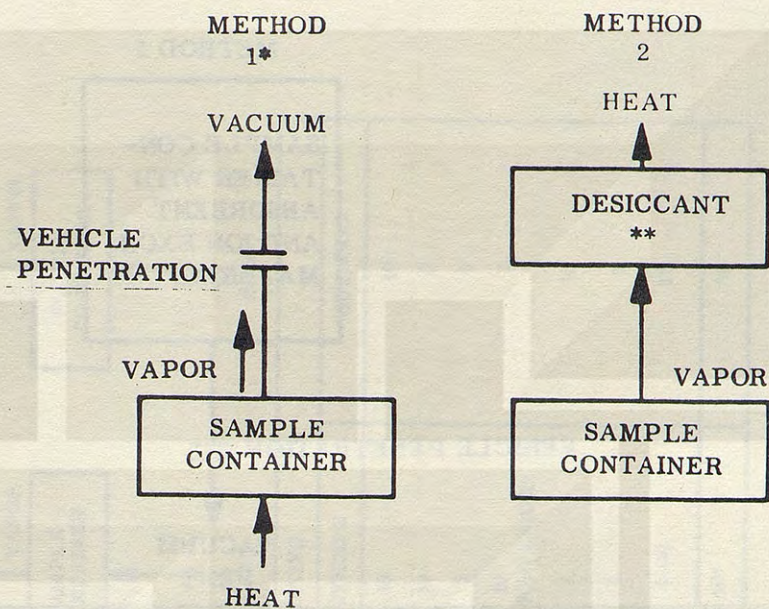
(b) VACUUM SEAL HAZARD

(c) SELECTED FOR FREEZING

(d) ELIMINATED BY POWER REQUIREMENT

(e) SELECTED FOR REFRIGERATION

Table 5-5. Preservation by Vacuum Distillation



ITEM	RATING	
	METHOD 1	METHOD 2
ELECTRICAL POWER REQUIRED	10	10
WEIGHT	10	3
COMPLEXITY/RELIABILITY	7	7
EXPENDABLES	10 SAMPLE LIQUID	1
VEHICLE PENETRATION	1	10
EASE OF OPERATION	5	5
SAFETY	5 (a)	10
TOTAL	48*	46

NOTE: ALL ITEMS HAVE EQUAL IMPORTANCE.

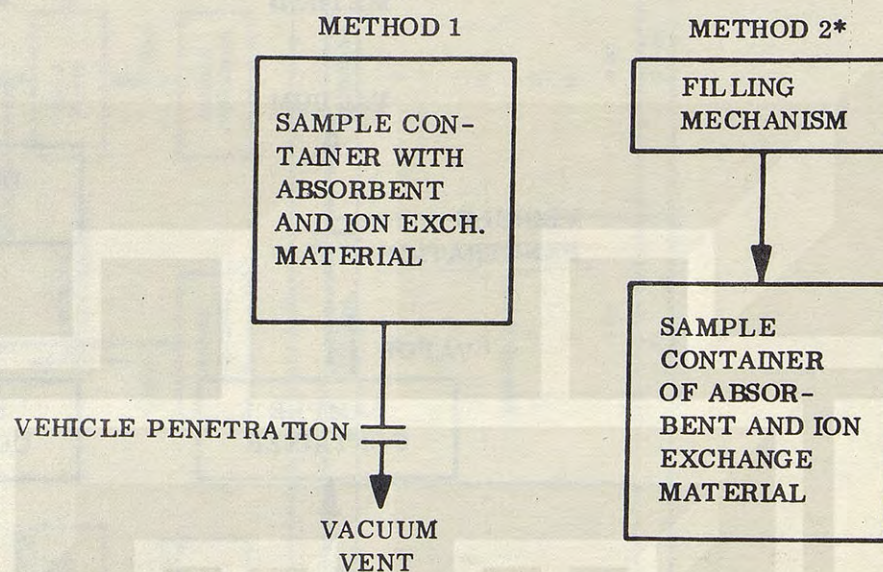
RATING: 10 = BEST
1 = WORST

*SELECTED

**IN THIS CASE THE DESICCANT ACTS AS A WATER VAPOR PUMP AND CANNOT BE ACCURATELY CALLED VACUUM DISTILLATION.

(a) VACUUM SEAL HAZARD

Table 5-6. Preservation by Adsorption and Ion Exchange



ITEM	RATING	
	METHOD 1	METHOD 2
ELECTRICAL POWER REQ'D	10	10
WEIGHT	3	1
COMPLEXITY/RELIABILITY	5	4
EXPENDABLES	1	1
VEHICLE PENETRATIONS	1	10
EASE OF OPERATION	5	1
SAFETY	5 (a)	10
TOTAL	30	37*

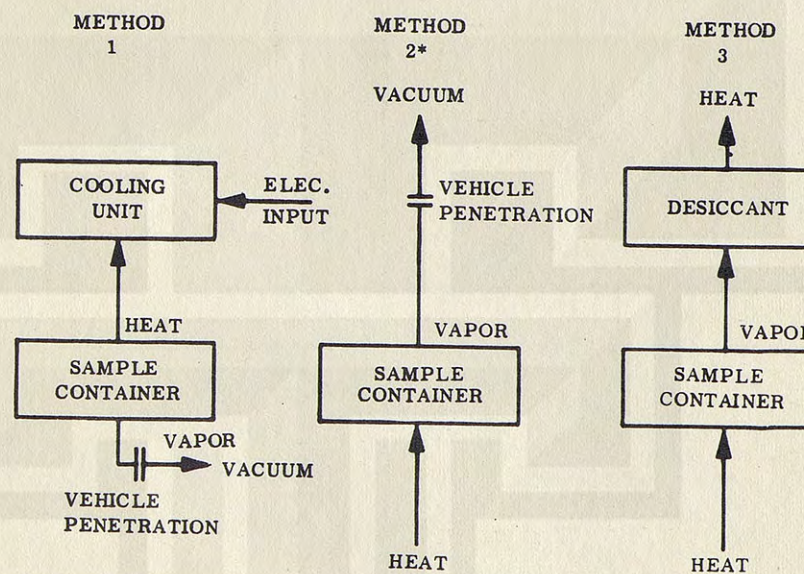
NOTE: ALL ITEMS HAVE EQUAL IMPORTANCE

RATING: 10 = BEST
1 = WORST

*SELECTED

(a) VACUUM SEAL HAZARD

Table 5-7. Preservation by Lyophilization



ITEM	RATING		
	METHOD 1	METHOD 2	METHOD 3
ELECTRICAL POWER REQ'D	5	10	10
WEIGHT	5	10	3
COMPLEXITY/RELIABILITY	3	5	5
EXPENDABLES	10	10	1
	SAMPLE LIQUID	SAMPLE LIQUID	
VEHICLE PENETRATIONS	1	1	10
EASE OF OPERATION	5	5	5
SAFETY	5 (a)	5 (a)	10
TOTAL	34	46*	44

NOTE: ALL ITEMS HAVE EQUAL IMPORTANCE.

RATING: 10 = BEST
1 = WORST

*SELECTED

(a) VACUUM SEAL HAZARD



**GENERAL
ELECTRIC**

MISSILE AND SPACE DIVISION
Valley Forge Space Technology Center
P.O. Box 8555 • Phila. Penna., 19101

