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STERILIZATION ASSEMBLY DEVELOPMENT LABORATORY

"QUALITY ASSURANCE PROGRAM PLAN"

TASK 3.0
15 August 1967

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CALIFORNIA INSTITUTE OF TECHNOLOGY
PASADENA, CALIFORNIA

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15 August 1967
Task 3.0
JPL CONTRACT 951624

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-NOTE-

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PREFACE

It is the basic philosophy of the Quality Assurance Plan that quality cannot be inspected into a product, but rather it must originate with the initial Design and be continued throughout the Manufacture, Assembly, Decontamination and supporting functions. Quality requirements will be considered to have been fulfilled when the configuration verification of encapsulated spacecraft is in full conformance with all applicable Drawings, Specifications and Planetary Quarantine requirements.

In order to ensure this, the following detailed plan has been prepared to maintain a uniformly high level of quality in the Experimental Assembly Sterilization Laboratory (EASL) and Sterilization Assembly Development Laboratory (SADL) facilities.

This plan is written with the understanding that its implementation is applicable to all Flight Spacecraft, assembled, inspected and tested for acceptance in the SADL and/or EASL facilities.

The Quality Assurance Program Plan delineates the methods and procedures to assure an effective and economical system maintaining Product Quality. It is based upon complexity of Design, Microbiological burden requirements, interchangeability, Manufacturing techniques, Decontamination processes, and high reliability requirements. The procedures assure total control of conformance from product inception through control of Microbiological burden, and the entire Manufacturing process including Packaging and Shipping. The methods and procedures to be described are in conformance with NASA Publication "Quality Program Provisions For Space Systems Contractors" (NPC 200-2) as applicable.

This plan will be reviewed periodically and revised as necessary.

CONTENTS

		Page
I.	INTRODUCTION	1
	A. RELATIONSHIP TO DETAIL REQUIREMENTS	1
	B. MICROBIOLOGICAL ASPECTS	1
	C. RELATIONSHIP TO EXISTING EASL DOCUMENTATION	1
II.	MANAGEMENT	3
	A. PLANNING	3
	B. ORGANIZATION	3
	C. INTERDEPARTMENT RELATIONSHIPS	7
III.	CONTROL OF PROCURED MATERIAL	9
	A. GENERAL	9
	B. TEST PROCEDURES	9
	C. RECEIVING INSPECTION	9
	D. IDENTIFICATION, SERIALIZATION, AND AGE CONTROL	10
	E. FAILURE REPORTING	10
	F. TEST PROCEDURE REQUIREMENTS	10
IV.	CONTROL OF SPACECRAFT ASSEMBLY, INSPECTION AND TEST	12
	A. GENERAL	12
	B. PLANNING AND ENGINEERING	12
	C. IDENTIFICATION AND SERIALIZATION	12
	D. FAILURE REPORTING	12

Page

V. NON-CONFORMING MATERIAL 14

A. CONTROL OF NON-CONFORMING MATERIAL 14

B. MATERIAL REVIEW BOARD..... 14

C. CONTAMINATION VIOLATION/FAILURE REPORT 15

D. CONTAMINATION REVIEW BOARD..... 15

VI. TRAINING PERSONNEL 17

A. ORIENTATION AND TRAINING OF PERSONNEL 17

B. MICROBIOLOGICAL ASPECTS OF ENVIRONMENT..... 17

C. PROPER PROCEDURE FOR DRESSING 17

D. PERSONNEL SAFETY 17

VII. OPERATIONAL SUPPORT EQUIPMENT (TEST EQUIPMENT)..... 18

A. TEST EQUIPMENT 18

B. CALIBRATION AND CONTROL 18

VIII. CERTIFICATION REPORT 19

IX. QUALITY ASSURANCE VISUAL MONITORING LOG 20

A. QUALITY ASSURANCE PERSONNEL PROCEDURES LOG..... 20

B. QUALITY ASSURANCE PERSONNEL AND ASSEMBLY PROCEDURE LOG 20

APPENDIXES

A. SADL PROCEDURES

SADL 100.01 QUALITY ASSURANCE PLANNING & ENGINEERING PROCEDURE..... 22

SADL 101.01 RECEIVING INSPECTION 24

SADL 102.01 IN PROCESS INSPECTION 30

Page

SADL 103.01 FINAL INSPECTION AND TEST 32

SADL 104.01 CLEANING AND DRESSING PROCEDURE - SADL 34

SADL 105.01 MATERIAL REVIEW BOARD 40

SADL 106.01 CONTAMINATION REVIEW BOARD PROCEDURE 45

SADL 107.01 CALIBRATION AND CONTROL OF TOOLS, GAGES, MEASURING AND TEST EQUIPMENT 49

SADL 108.01 PRESERVATION, PACKING, MARKING AND SHIPPING PROCEDURE 53

SADL 109.01 QUALITY ASSURANCE AUDIT PROCEDURE 55

SADL 110.01 DECONTAMINATION, STERILIZATION AND CLEANING .. 57

SADL 111.01 MONITORING OF MICRO-BIOLOGICAL OPERATIONS 60

SADL 112.01 PRODUCT SERIALIZATION 64

SADL 113.01 CALIBRATION OF COLLATERAL CONTROL EQUIPMENT .. 67

B. OPERATION LOG FACSIMILES

1. QUALITY ASSURANCE DAILY SUMMARY LOG 70

2. DAILY ACTIVITY - SADL FACILITY 72

3. STEEL STRIP ASSAY SHEET 73

4. RODAC PLATE ASSAY SHEET 74

5. REYNIER SAMPLER - DATA REPORT FORM 75

REFERENCE DOCUMENTS

MIL-STD-105	Sampling Procedures and Tables for Inspection by Attributes
FED-STD-102	Packaging and Preservation
MIL-P-116	Methods Preservation
MIL-STD-129	Marking for Shipment and Storage
Fed. Std-209a	Clean Room and Work Station Requirements, Controlled Environment.
NPC 200-2	Quality Program Provisions for Space System Contractors. (NASA Quality Publications)

ILLUSTRATIONS

		Page
Figure 1 -	MILESTONE CHART - QUALITY ASSURANCE PROGRAM PLAN IMPLEMENTATION	8
Figure 2 -	TYPICAL ASSEMBLY FLOW CHART	11
Figure 3 -	HARDWARE FLOW PLAN	13
Figure 4 -	SYSTEMS QUALITY ASSURANCE CERTIFICATION REQUIREMENT FORM	28
Figure 5 -	INSPECTION REPORT	29
Figure 6 -	QUALITY ASSURANCE PERSONNEL PROCEDURE LOG FOR SADL OPERATIONS	39
Figure 7 -	MATERIAL REVIEW BOARD ACTION NOTICE	44
Figure 8 -	CONTAMINATION VIOLATION/FAILURE REPORT	47
Figure 9 -	CONTAMINATION REVIEW BOARD FORM	48
Figure 10 -	TOOL AND GAGE CALIBRATION RECORD	52

ABBREVIATIONS

AN	Army and Navy (Specifications)
CMTM	Capsule Mechanical Training Model
CRB	Contamination Review Board
EASL	Experimental Assembly Sterilization Laboratory
ETO	Ethylene Oxide (Freon 12 Mixture)
FA	Flight Acceptance
FAT	Flight Acceptance Testing
JPL	Jet Propulsion Laboratory of the California Institute of Technology - Pasadena, California
MRB	Material Review Board
MS	Military Specification
NASA	National Aeronautics and Space Administration
N.B.S.	National Bureau of Standards
OSE	Operational Support Equipment
PTM	Proof Test Model
QA	Quality Assurance
TAT	Type Approval Testing
SADL	Sterilization Assembly Development Laboratory
TOP	Test and Operations Plan
P.O.	Purchase Order

I INTRODUCTION

This Quality Assurance Program Plan shall be used for all operations conducted in the SADL and/or EASL facilities. Throughout this plan both SADL and EASL are implied when controlled assembly is mentioned.

There are many references to functional and/or Microbiological inspections in this plan. The definition, of "functional" is the ordinary Electronic Electrical, Mechanical, and Chemical testing or inspecting that would be required regardless of the burden requirements. "Microbiological" is defined as those inspection operations applicable to the controlled environment assembly process for monitoring burden level.

A. RELATIONSHIP TO DETAIL REQUIREMENTS

Assembly process specifications requiring low contamination requirements shall comply with the requirements of this plan.

B. MICROBIOLOGICAL ASPECTS

The Microbiological objective of SADL is to control the viable organism burden to such a level, before terminal sterilization, so that after the prescribed heat cycle, a sterilization confidence level of 10^{-4} will be obtained. This plan supports the objective by constant monitoring and verifying of the prescribed procedures that are aimed at minimizing the level of Microbiological burden during assembly and test of a spacecraft.

C. RELATIONSHIP TO EXISTING EASL DOCUMENTATION

1. EASL 100.00 -- Quality Assurance Control Document: The "Procedures" section of this QA Program Plan contains separate SADL Procedures, each one is numbered separately. Each of these represents either a SADL equivalent to EASL 100.00, or a SADL document adding to the scope of EASL 100.00.

2. EASL 101.00 -- Problem/Failure Reporting System: Whereas the system for EASL is separately contained in one document, the requirement for Problem/Failure reporting is contained throughout the QA Program Plan in appropriate sections.

3. EASL 200.00 -- Process Specification Decontamination of Component Parts, Tools and Equipment: In the QA Program Plan, "Procedures"for Decontamination, Sterilization and Cleaning are thereby accounted for as the equivalent SADL function. In addition the "Procedures" reference the SADL Operations Handbook which contains the tool and equipment decontamination requirements.

4. SADL 201.00 -- Personnel Procedures for Phase II EASL Operation: In the QA Program Plan, the "Procedures" contain SADL personnel procedure requirements.

5. EASL 202.00 -- Routine Cleaning and Decontamination of the EASL Facility: The QA Program Plan required that audits be performed to monitor cleaning of the SADL Facility.

6. EASL 300.00 -- Microbiological Assay and Certification of Spacecraft Hardware Sterility: Quality Assurance, Monitoring of Microbiological Operations, is part of the QA Program Plan which defines the Quality Assurance monitoring functions of biological activities.

II -MANAGEMENT

A. PLANNING

All Quality Assurance Policies and SADL Procedures in this plan, shall be adhered to in the prescribed areas. Documentation shall be available to demonstrate adherance to the requirements and Policies of the program. The Quality Assurance Milestone Chart for this program is shown in Figure 1.

Quality Assurance shall review documents produced by other disciplines that are directly related to the Capsule Mechanical Training Model (CMTM), its associated equipment and Microbiological Experiments. These documents shall be reviewed for the purpose of determining Inspection and Test requirements and to prepare Quality Assurance Inspection and/or Test documents as necessary.

Quality Assurance is responsible to determine Product Quality Status and shall therefore perform the necessary inspections, systems test and acceptance tests as required.

B. ORGANIZATION

The Quality Assurance organization shall consist of (1) a Quality Assurance Manager (2) a Quality Assurance Senior Staff Engineer (3) a Quality Assurance Senior Engineer and (4) a Quality Assurance Senior Inspector/Technician.

1. Quality Assurance Manager

The Quality Assurance Manager is responsible for all quality aspects of all operations and functions performed in the EASL and SADL Facilities and shall manage the implementation of the Quality Assurance Program Plan. The Quality Assurance Manager shall be the chairman of the Material Review Board, Contamination Review Board and shall have direct reporting access to the Quality Assurance Director. He shall also be responsible for task assignments to Quality Assurance personnel including duties, responsibilities and Quality Assurance systems implementation.

2. Quality Assurance Senior Staff Engineer

The Quality Assurance Senior Staff Engineer reports technically and administratively to the Quality Assurance Manager. He may be delegated to represent the Quality Assurance Manager at the Contamination Review Board or the Material Review Board meetings. He is responsible for the preparation of inspection and test procedures relative to items being procured or manufactured/assembled in the SADL facility.

An example of assigned duties and responsibilities are as follows:

(a) LABORATORY EXPERIMENTS

(a) 1. Participate in Microbiological experiments to develop and implement inspection and test techniques and Quality Assurance Engineering requirements.

(a) 2. Develop plans to monitor, witness and record the eventual Microbiological Certification of the Sterilization Assembly Development Laboratory (SADL). Assist in establishing contamination level standards.

(a) 3. Participate on the Contamination Review Board.

(a) 4. Review Purchase Requisitions for Microbiological equipment and establish inspection or test requirements.

(a) 5. Monitor and document the operation of determining locations on the CMTM hardware which is subjected to handling and contamination, and to develop a plan for monitoring the Bio-Coupon installation.

(a) 6. Monitor the CMTM sub-system preparation and cleaning for entry into the SADL Assembly Room.

(a) 7. Participate in the development of the "Data Encoder Sub-System Check-out Procedure" and perform the test.

(b) Quality Assurance Program Plan

(b) 1. Assist in updating and revising the Quality Assurance Program Plan.

(b) 2. Contribute Quality Assurance criteria for the SADL Operation Handbook.

(b) 3. Develop and conduct a Quality Assurance/SADL Facility Training Program.

3. Quality Assurance Senior Engineer

The Quality Assurance Senior Engineer reports technically and administratively to the Quality Assurance Manger. He may be delegated to represent the Quality Assurance Manager at the Material Review Board meetings. He shall prepare inspection procedures for procured items and for manufactured/assembled items in the SADL Facility.

An example of assigned duties and responsibilities are as follows:

(a) Capsule Mechanical Training Model (CMTM)

(a) 1. In-Process and Final Inspection of:
The Capsule Mechanical Training Model subassemblies and assemblies.

Operational Support Equipment.

Develop inspection techniques and prepare documents.

Prepare Inspection Records.

Review Purchase Requisitions for the CMTM and incorporate inspection and/or certification requirements.

Participate in the update and revision of the CMTM Assembly Procedures.

Participate in the preparation and revision of the Inspection, Test, and Optical Alignment Procedure.

Develop a procedure and perform the optical alignment of the CMTM and document the action.

Perform Final Mechanical Inspection of the CMTM.

(b) Certification of SADL Facility

(b) 1. Witness various tests of collateral and environmental equipment for the eventual certification of the SADL Facility.

(b) 2. Prepare test reports of Facilities Equipment tests.

(b) 3. Perform audits of the SADL facilities for proper maintenance of equipment and maintenance of service records.

(b) 4. Quality Assurance Senior Inpector/Technician

Quality Assurance Inspector/Technicians will be provided in sufficient number to meet the inspection requirements and schedules imposed by the assigned tasks. The Inspector/Technician shall perform detail parts inspection and also monitor and record time/action activities during the assembly of items in the EASL or SADL facilities. He shall record infractions or violations of the Microbiological barrier or Decontamination procedures and is also responsible for monitoring the personnel entering the EASL or the SADL clean room facilities.

An example of assigned duties and responsibilities are as follows:

(a) Detail Parts Inspection

(a) 1. Receiving Inspection of:

Spececraft Parts and Hardware

Spacecraft Operational Support Equipment

Raw Materials

Microbiological items

Glassware - Graduates - Petries - Rodacs, etc.

Protective clothing (Hoods - Smocks, Masks, Gloves).

Facilities items

Measuring and Test Equipment

Develop and prepare Inspection Techniques

Prepare Inspection Records.

(b) Monitoring

(b) 1. Monitor the EASL Microbiological and Assembly operations and prepare time/action logs.

(b) 2. Monitor the SADL Microbiological and Assembly operations and prepare time/action logs.

(b) 3. Monitor custodial personnel.

(c) Inspection Equipment Requirements

(c) 1. Investigate and determine the requirements for inspection tools, gages and measuring and test equipment.

(c) 2. Procure, store and maintain Inspection Equipment.

(c) 3. Develop and maintain Tool, Gage and Measuring and Test equipment Calibration Cycle and Record cards for each.

(c) 4. Maintain Facility collateral equipment instrumentation Calibration Card cycle.

C. INTERDEPARTMENT RELATIONSHIPS

The Quality Assurance Department is responsible for anticipating and preventing through the utilization of modern Quality Control techniques and experience, the occurence of any conditions detrimental to the quality of hardware or any action leading to contamination.

It is a Quality Assurance function to provide assistance to the related departments in those situations affecting quality or burden level which might arise. It is also their function to integrate and reciprocate with other departments as described below:

1. Assembly Operations Department Relationship

The development of Inspection, Systems and Acceptance test techniques and procedures for test and acceptance of spacecraft, is a Quality Assurance responsibility.

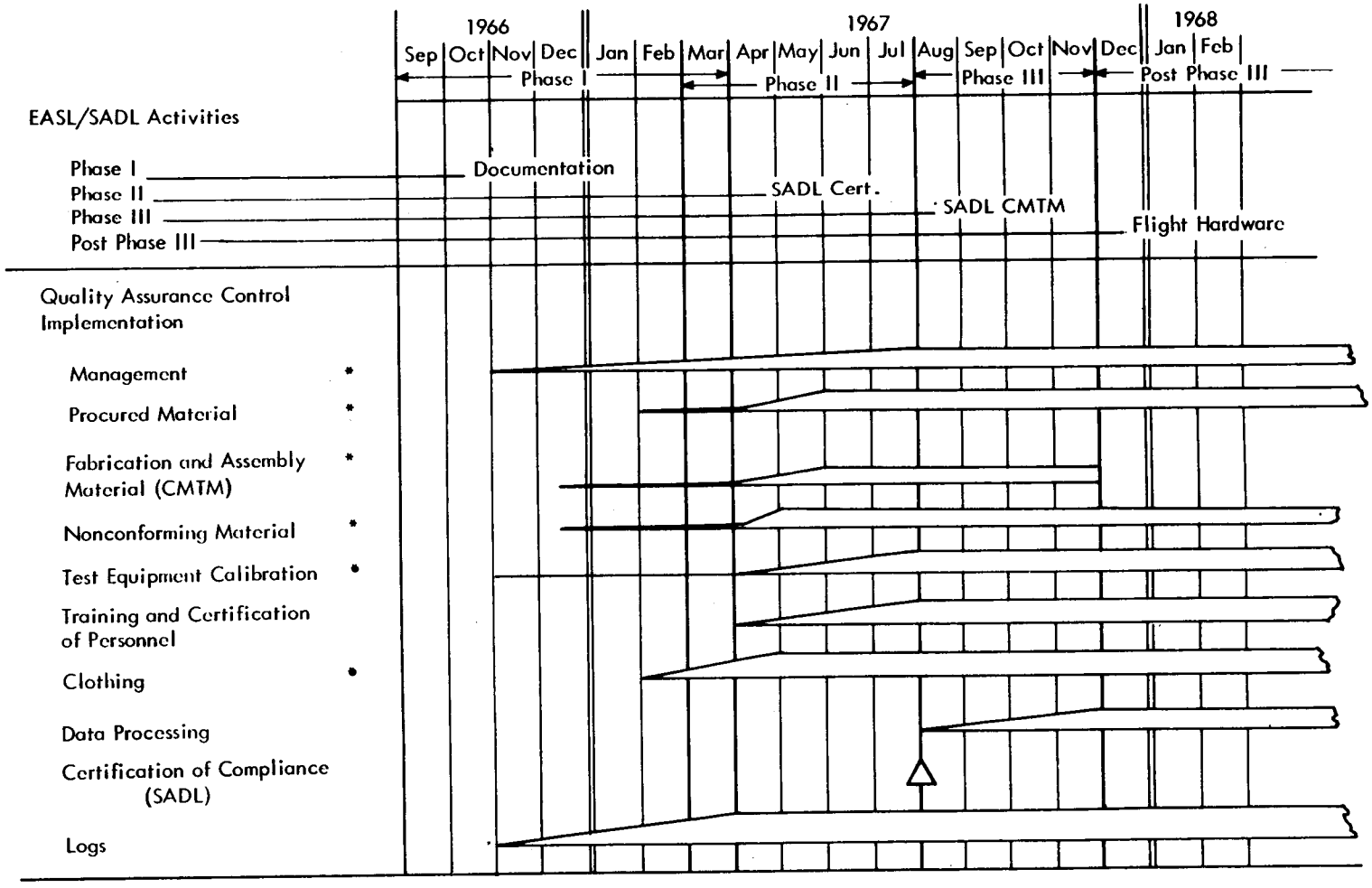
Upon review of Assembly Operations documents, the inspection and test techniques and methods will be prepared and documented for all assemblies to ensure conformance to specifications and other acceptance criteria. Quality Assurance documentation of all assembly operations will serve as a record of performance and objective evidence.

2. Facilities Department Relationship

Quality Assurance Engineering shall participate and/or verify the testing of equipment in the initial and subsequent certifications of the SADL facility. Facility maintenance activities shall be monitored and audited. Calibration schedules shall be developed with calibration dates established on all appropriate equipment.

3. Microbiology Department Relationship

Quality Assurance shall perform inspection of incoming Microbiological items and actively participate by verifying all decontamination and sterilization operations. Recording and reporting of all Microbiological violations during assembly operations and personnel violations during washing and dressing in preparation to entering the clean room shall be completed by Quality Assurance. Quality Assurance shall also monitor all Microbiological sampling of filtered air, walls, work areas, gloves and clothing performed by the Microbiological personnel to assure adherance to the prescribed methods and procedures.



* Phase I implementation as possible within Phase I scope and manpower limitations

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Figure 1 MILESTONE CHART - QUALITY ASSURANCE PROGRAM PLAN IMPLEMENTATION

III CONTROL OF PROCURED MATERIAL

A. GENERAL

The burden level on all material procured for eventual use in the Assembly Room must be controlled. To help achieve a low-level burden, procedures relative to handling, testing, and packaging must incorporate specified Microbiological practices where applicable.

B. TEST PROCEDURES

The Quality Assurance Planning and Engineering is responsible for the formulation of test procedures based upon the specification requirements. These specifications will define in detail the inspection and test requirements, both technical and Microbiological. These procedures shall include statements, of test equipment required, any special instructions to the Inspector/Technician and Microbiological barrier control information.

Each procedure shall include approriate blocks for Quality Assurance verification of inspection or test as the assembly is being performed, so that at the end of the assembly operation the assembly acceptance will be documented and ready for the next assembly operation. A typical Assembly Flow Chart is shown in Figure 2 .

C. RECEIVING INSPECTION

Material received directly into the SADL Facility from a vendor will be inspected to the Purchase Order or contractually referenced drawing and test procedure. In the event that either of these documents are missing, the Quality Assurance Inspector/ Technician shall contact the cognizant Quality Assurance engineer for inspection instruction and further direction.

The Inspector/Technician shall review the test procedure and drawing to see that the test equipment required is calibrated and he shall perform the test operations required.

If Microbiological requirements exist he will verify that they have been satisfactorily accomplished.

Upon satisfactory completion of inspection and test, except the information on the Microbiological data, the part, material, or hardware will be placed and held in Quality Assurance bonded stores until the Microbiological assay data is available. Only when the assay report is recieved and accepted will the part or material be released for the next operation.

The normal process for acceptable items will be to pass the packaged part or material into the Assembly Room via the pass-thru after decontamination.

If the part or material is not acceptable for either technical or Microbiological reasons, the part or material will be referred to the MRB or CRB as applicable for disposition.

D. IDENTIFICATION, SERIALIZATION, AND AGE CONTROL

All hardware parts or material intended for use in the Assembly Facility will bear an identifying serial number on or in the package and on all of the accompanying paper work.

Serialization shall be established by Quality Assurance and shall consist of a basic set of 5 digits preceded by a capital letter and a digit which indicate the month and the year.

Material that can be degraded by age or existance in improper storage, shall have a label prominently affixed to the unit package stating the storage conditions and expiration date of the material.

E. FAILURE REPORTING

All failures observed by the inspector in the Receiving Inspection Room shall be reported as described in Section V, Nonconforming Material.

All failures in this case include both functional and Microbiological as well as Microbiological contamination by accident of anyone in the room.

F. TEST PROCEDURE REQUIREMENTS

Quality Assurance shall prepare Q.A. Test Procedures as necessary to verify detection of factors to determine the quality of the hardware, or the facility, for acceptance purposes. The close monitoring and control of contamination level and the continual recording of environmental conditions before testing form the matrix of the test procedures. Each monitoring and acceptance procedure will be so written as to identify variation of workmanship, burden level, and monitoring methods. Section V, Nonconforming Material describes a closed-loop failure reporting system that documents the variation to the criteria of a procedure and the resultant corrective action.

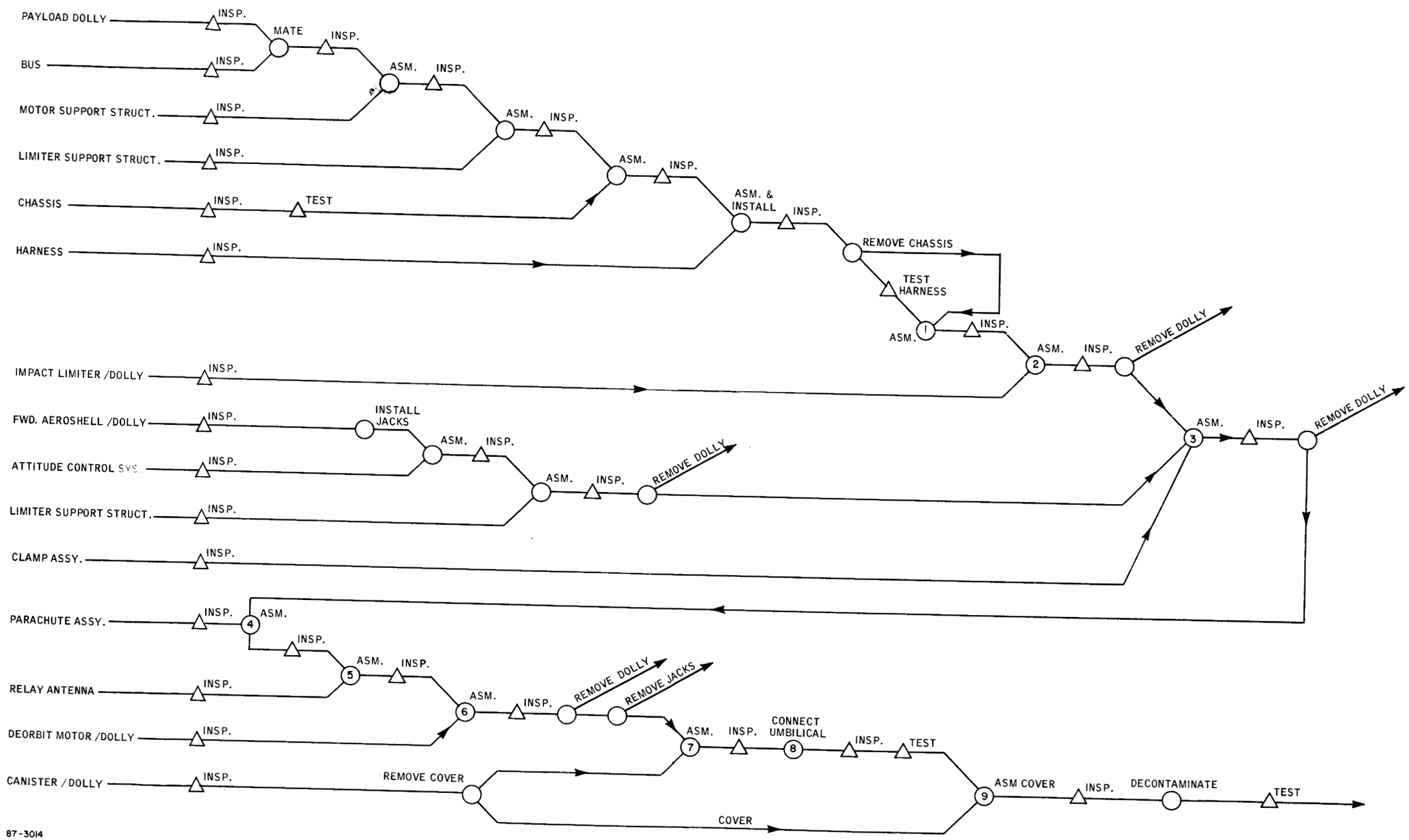


Figure 2 TYPICAL ASSEMBLY FLOW CHART

11-1

IV - CONTROL OF SPACECRAFT ASSEMBLY INSPECTION AND TEST

A. GENERAL

Assembly operations of the Spacecraft shall be performed in the Laminar Flow Assembly Room. Major rework or fabrication of the Spacecraft shall be accomplished outside of the Assembly Room. All items sent into the Assembly Room shall be clearly identified and its inspection status visible through the packaging. Items stored in the Assembly Room awaiting assembly will be monitored periodically by Quality Assurance to assure that the Microbiological barrier is still intact.

B. PLANNING AND ENGINEERING

Quality Assurance Planning and Engineering is responsible for establishing the inspection and test operations and shall participate with the Assembly Department in the preparation of an assembly flow chart including adequate Quality Assurance inspection steps (e.g., Figure 2).

1. Spacecraft assembly operation shall not be started until the prior assembly has been accepted by Quality Assurance.

2. The Hardware Flow Plan is shown in Figure 3 .

3. Sequence of Sterilization is shown in Figure . (Not yet provided)

C. IDENTIFICATION AND SERIALIZATION

Each assembly having a definite identification will be assigned a serial number by Quality Assurance. This serial number will be affixed to the assembly by the method prescribed on the drawing. All applicable inspection records will indicate this serial number.

D. FAILURE REPORTING

Discrepancies noted in the assembly of the Spacecraft will be reported as described in Section "Non Conforming Material". The assembly operation shall be suspended until the MRB or CRB (as applicable) has dispositioned the discrepancy.

In the event that the item cannot be moved to a Bonded Room, it will be considered as bonded in place if a tag is affixed to it giving the applicable MRB or CRB Number.

The actual MRB or CRB will be written and dispositioned outside of the Assembly Room, if practicable.

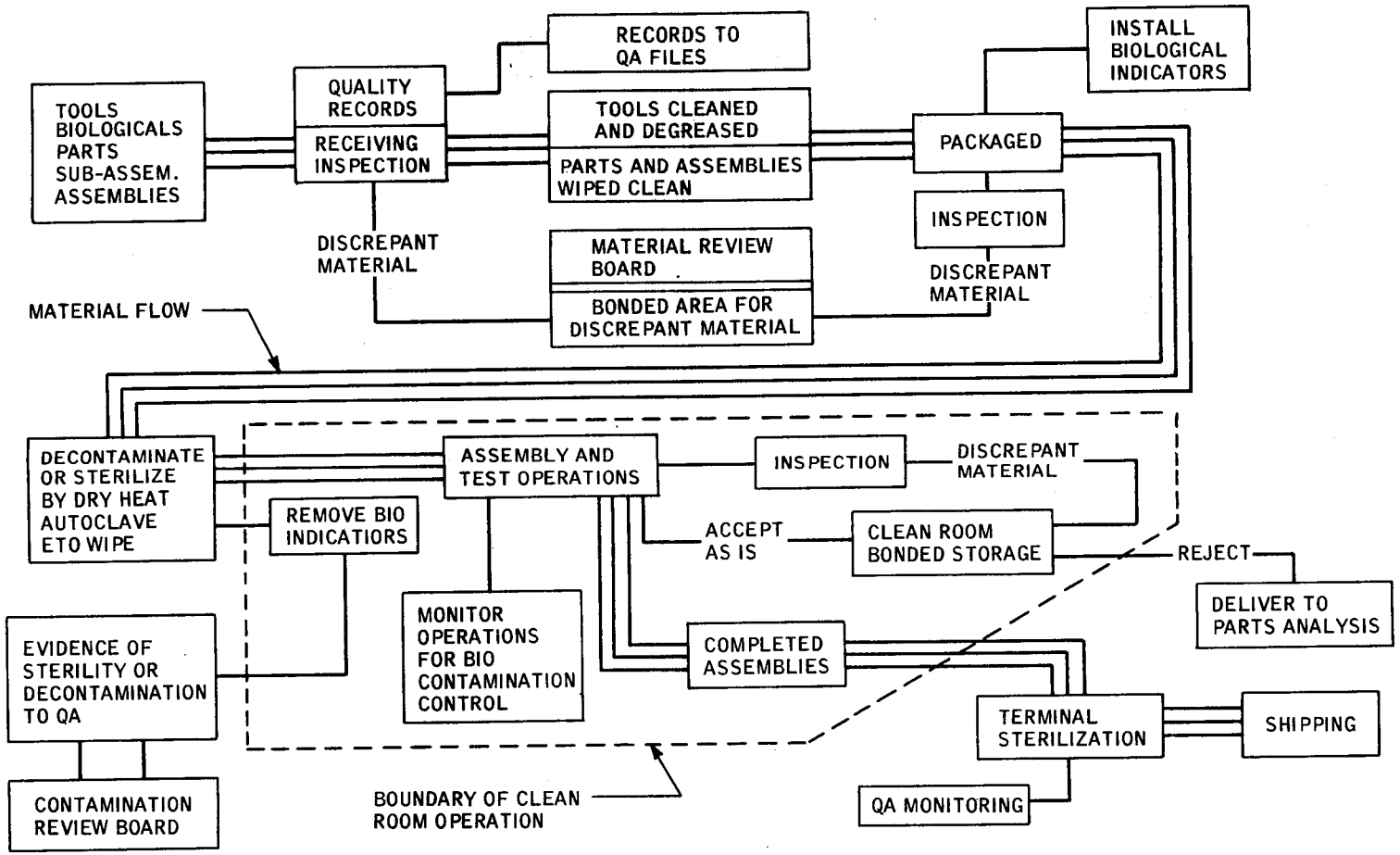


Figure 3 HARDWARE FLOW PLAN

V - NONCONFORMING MATERIAL

A. CONTROL OF NONCONFORMING MATERIAL

Hardware and material that is determined discrepant in the Receiving Inspection Room shall be identified with a copy of the Inspection Report Form JPL 1453. The item shall be reviewed by the cognizant using Engineer and the Quality Assurance Engineer. If a mutual agreement for acceptance is decided, the Inspection Report shall be so anotated. If a disagreement exists, the discrepant items shall be submitted for Material Review Board action accompanied with a Material Review Board Action Notice JPL Form 0703.

Hardware determined discrepant in the Assembly Room shall be bonded in place. An Inspection Report and a Material Review Action Notice shall be prepared and submitted to the Material Review Board for disposition.

If the disposition is to "Accept", the hardware shall be stamped with the Acceptance stamp.

If it is necessary to remove the discrepant item from the Assembly Room either for rework or repair, the item shall be decontaminated after acceptable rework is completed prior to submitting the item for assembly.

As a result of this action, members of the Board may be required to enter the Assembly Room to view the discrepancy. This shall not be allowed without the specific written approval of the Facility Manager.

B. MATERIAL REVIEW BOARD

This procedure affords a method for the evaluation and disposition of raw material, detail parts, components, and spacecraft having variations from specification requirements. This will also serve as a deterrent for the repeated manufacture of discrepant material by creating specific methods of effecting corrective action, and will establish a uniform basic policy for determining the acceptability of materials having variations from the drawings and specifications.

The Chairman of the Board shall be the Quality Assurance Manager. The members will be composed of qualified representatives of Quality Assurance, Assembly Engineering, and the cognizant Government representative. Any member of the Board may request the Board to convene in order to reach a decision concerning material submitted. When an actual meeting is not required, each member may individually examine and record his recommendation on the Material Review Form.

Records of Material Review Board action shall be maintained by the Quality Assurance Staff Engineer. These records shall be reviewed periodically by the Quality Assurance Manager who shall initiate reports suggesting action to correct any recurring discrepancies. Detailed MRB procedures are contained in the Procedure Section MRB SADL .

C. CONTAMINATION VIOLATION/FAILURE REPORT

The Contamination, Violation/Failure Report (Figure 8) has been devised to provide burden information and resultant action not available through the use of the other defect reporting systems. The additional information is needed to control and maintain the low-burden requirement. It should be stressed that this is an additional reporting system and does not replace the existing Material Review Board. If any disagreement exists between the Microbiology Engineer and the Quality Assurance Engineer this shall constitute the need for a Contamination Review Board disposition. The SADL 201.00 Procedure relative to personnel entering the SADL Assembly Room defines the Major and Minor type of violations.

It is the objective of this system to record detailed information which is a true indication of hardware, personnel, procedural deficiency, or facility failure of a contamination nature.

The report may be generated by any person observing or becoming aware of a contamination violation and be recorded and forwarded by Quality Assurance to the Microbiology Department for further action and referral to the CRB.

All forms when completed must be routed through the Quality Assurance Department to be processed and evaluated by the Contamination Review Board. Upon completing the disposition action, the form shall be returned to the Quality Assurance Department and placed into the record file.

D. CONTAMINATION REVIEW BOARD

In view of the rather specialized nature of the facility, a formal Contamination Review Board is required for the purpose of reviewing, analyzing, evaluating, and dispositioning items or materials that may have become inadvertently contaminated during the process of handling or assembly.

The Contamination Review Board will be composed of qualified representatives of Quality Assurance, Facilities, Microbiology Departments and the cognizant Government representative. Members of the Board may call upon other personnel to act in an advisory or consultant capacity. Such advisory or consultant personnel shall have no vote in decisions made by the Board.

The duties of the Contamination Review Board are to:

1. Review the reported discrepancy and to determine and verify that a contamination problem exists.

2. Determine the disposition or action to be taken regarding the contaminated facility, hardware, or personnel.

3. Assure that effective follow up ensures that corrective action is taken to remedy the cause of the contamination.

4. The Quality Assurance Manager shall be the Chairman of the Contamination Review Board, and Quality Assurance Staff Engineer shall be responsible for maintaining all Contamination Review Board forms (Figure 9) and their availability for ready reference. These records shall indicate recurring discrepancies and corrective actions taken. They shall also provide information which form the basis for Contamination Review Board decisions.

5. Each member shall individually examine the discrepancy and record his recommendations listed on the Contamination Review Board Report form. However, any member may request a formal Contamination Review Board meeting to consider disposition of an item or the facility.

6. A detailed CRB procedure is contained in the Procedures Section SADL (Appendix A).

VI TRAINING PERSONNEL

A. ORIENTATION AND TRAINING OF PERSONNEL

Prior to entering the Sterilization Assembly Room, all personnel shall be briefed by Quality Assurance on the proper scrubbing and dressing techniques employed to maintain a low level of burden. They shall be given a conducted tour of the OSE Room by one of the Facility Engineers and a procedure check list to study.

B. MICROBIOLOGICAL ASPECTS OF ENVIRONMENT

All Quality Assurance personnel assigned to the SADL Facility shall be instructed in a course on the preparation of biological samples. Upon successful completion of this course the Inspector/Technician will be qualified to monitor the sampling and assaying performed by the Microbiological group. He shall also be indoctrinated on the proper care and maintenance of Micorbiological equipment.

C. PROPER PROCEDURE FOR DRESSING

1. It is the responsibility of Quality Assurance to conduct training classes for Quality Assurance Personnel relative to the proper personal hygiene and dressing routine for persons entering the laminar air flow Assembly Room.

2. All personnel shall comply with the requirements of the check list for proper scrubbing and dressing, each time they enter the Assembly Room.

3. Quality Assurance shall record any infractions that are observed and will bring them to the attention of the person who will take remedial action immediately, e.g., replace torn gloves.

4. Evidence of carelessness in the observance of Microbiological barriers shall be cause for barring an individual from the Assembly Room.

D. PERSONNEL SAFETY

It shall be an accepted practice to have a minimum of two people in the Assembly Room whenever assembly operations are in progress. The specific approval of the Facility Manager is required for one man to work alone in the Assembly Room.

VII - OPERATIONAL SUPPORT EQUIPMENT (TEST EQUIPMENT)

A. TEST EQUIPMENT

The movement of specialized test equipment into the Assembly Room shall be kept to a minimum. Whenever possible, the test equipment will be maintained in the OSE Room and connected by wires or cables connected into bulkhead connectors in the wall. Wires or cables from the spacecraft will also be connected to the bulkhead connectors to complete the electrical circuit.

If it becomes necessary to bring test equipment into the Assembly Room, for any level of testing, permission must be obtained from the Facility Manager in accordance with SADL 200.00 and/or an applicable portion of the SADL Operation Handbook.

B.

Operational Support Test Equipment shall be subjected to the requirements of the SADL Procedure. "Calibration and Control of Tools, Gages, Measuring and Test Equipment."

VIII CERTIFICATION REPORT

A Certification Report attesting to the Environmental and Microbiological qualifications of the SADL and/or EASL facilities is prepared and submitted by Quality Assurance, which certifies to the customer that the contractual specification requirements have been successfully complied with. It also certifies that the supporting technical data attached are objective evidence of conformance to the applicable technical specification requirements.

The facility is certified once monthly in accordance with the SADL Certification Plan. Technical reports of Microbiological and Environmental tests performed in the Assembly Room, by the Microbiology and Facilities Engineering Departments, are submitted to the Quality Assurance Department as justification for preparation and formal certification of the facility. Examples of data submitted to Quality Assurance are: Laminar Air Flow Velocities Temperature, Relative Humidity, Surface and Air viables, using the Reynier Air Sampler, Rodac Plates, and Stainless Steel Strips. The format shown below shall be recognized as the formal Certificate of Compliance Document.

CERTIFICATE OF COMPLIANCE

The attached reports are the actual test results which were submitted for the Environmental and Microbiological certification of the "Sterilization Assembly Development Laboratory" (SADL).

The tests were performed in accordance with the requirements defined by the JPL Specification XOY - 50543-GEN "General Specification Certification Requirements for the Experimental Assembly and Sterilization Laboratory."

This is to certify that on _____, the Sterilization Assembly Development Laboratory is Environmentally and Microbiologically certified.

_____

Manager Quality Assurance
Spacecraft Sterilization
Operations Group.

IX QUALITY ASSURANCE VISUAL MONITORING LOGS

Quality Assurance Log Books are maintained to document actions of personnel and disseminate this information to the cognizant personnel. The logs serve as a permanent record of the visual monitoring performed by Quality Assurance and a basic purpose for each is listed below;

A. Quality Assurance Personnel Procedures Log

This log is specifically designed to monitor each person desiring to enter the Laminar Flow Assembly Room. It has a step-by-step sequence of requirements for personnel to clean, scrub and dress themselves for work in the Assembly Room. It includes a column to indicate violations, plus a column to place check marks to indicate Quality Assurance verification.

B. Quality Assurance Personnel and Assembly Procedure Log

This log is prepared to reflect the time and action of personnel performing Assembly Operations and Microbiological sampling in the Assembly Room. This is a time and action log - (not to be confused with time and motion study for production piece parts) for recording the exact time each specific operation is performed and a description of the operation. The information recorded in this log is also available to the Microbiological Department to assist them with their evaluations and corroletions with their data.

APPENDIX A

SADL Procedures

QUALITY ASSURANCE PLANNING AND ENGINEERING PROCEDURE

I. PURPOSE

To set forth the procedures governing the Quality Assurance Planning requirements relative to establishing Inspection Instructions, preparing Test Procedures and the evaluation of Test Data Packages.

II. SCOPE

This procedure is applicable to procured and "on-lab" fabricated items to be used in the assembly and test of spacecraft hardware and associated equipment.

III. DEFINITION

Inspection and Test Procedure. A Quality Assurance Inspection and Test Procedure is a formal document prepared by Q.A. Engineering describing the method that components and assemblies shall be tested for acceptance, and to assure that the applicable Specification requirements have been complied with.

IV. GENERAL

A. Quality Assurance Inspection and Test Procedures shall be prepared by Q.A. Planning and Engineering when it is necessary to:

1. Further define and supplement existing specifications.

2. Provide inspection instructions where specification and/or drawings do not exist.

3. Identify the procedure with a document title that specifically establishes the particular item or assembly it applies to, and to also establish a control number for each document.

B. The Inspection and Test Procedures shall be updated by the originator whenever Specification, drawing or assembly methods have an impact on the existing inspection or test operations.

V. INSTRUCTIONS

A. Quality Assurance Planning Engineers shall review Purchase Requisitions to determine the extent of inspection or test required for the item being procured.

B. Whenever it is a requirement for Vendor Test Data to be forwarded with the item being procured, the Planning Engineer shall include this as a requirement on the Purchase Requisition. Upon receipt of the item procured and the Test Data, the Planning Engineer shall review and evaluate same to determine acceptance in accordance with the applicable Specification requirements.

C. If the item is acceptable, the item shall be processed through Receiving Inspection for the remainder of the inspection to be performed in accordance with the Receiving Inspection Procedure.

D. Engineering Specifications and Drawings with up-to-date changes shall be reviewed by Quality Assurance Engineering. Mechanical and/or electrical inspection and functional test requirements shall be established including the proper test instructions and the appropriate documentation to be used for reporting the test results.

E. The Quality Assurance Staff Engineer shall be responsible for developing and implementing a number control for all Inspection and Test Procedures that are prepared and issued for product acceptance. These procedures shall be submitted to the Quality Assurance Manager for his approval.

F. Quality Assurance Planning Engineers shall also develop, prepare, and document Inspection and Test Procedures for subassemblies and assemblies of hardware that is manufactured and/or assembled "on-lab".

RECEIVING INSPECTION

I. PURPOSE

To set forth instructions and to establish the controls necessary to assure that purchased items are complete and in accordance with governing documents such as the Purchase Order, Specifications, Drawings, and other contractual acceptance requirements.

II. SCOPE

This procedure is applicable to those items having been purchased for spacecraft, Operational Support Equipment (OSE), Biological Materials, and Facility Hardware and Materials. It establishes the system and control governing the Inspection, Test Acceptance and reporting of discrepancies for incoming hardware.

III. GENERAL

A. Upon receipt of purchased items, the Inspector/Technician shall verify by visual inspection that no damage was incurred during transportation and that the correct item has been received.

B. The Inspector/Technician shall verify serialization as required.

C. Verification of Vendor Certification shall be completed when this is a requirement. (Certificates shall be kept on file.)

D. When applicable, Decontamination, Mechanical, Electrical and/or Functional Inspection shall be completed as specified by governing acceptance criteria.

E. Upon completion of Receiving Inspection, acceptable material and associated documents shall be stamped with the acceptance stamp and forwarded to the designated stores area.

Items that are not acceptable shall be segregated from accepted product and referred to the MRB or CRB (as applicable) for inspection.

F. The Test Data Package accompanying all functional hardware shall be reviewed by Quality Assurance Engineering and the "System QA Certification Requirements" form (JPL 0461) shall be completed and maintained in the Receiving Inspection file.

IV. INSPECTION INSTRUCTIONS

A. Incoming Spacecraft Hardware

1. Quality Assurance shall verify that the required documents, Control Tags and Inspection Reports for spacecraft hardware have been received relative to the Specifications/Drawings and Quality Assurance acceptance criteria.

2. Quality Assurance Engineering shall review the data package that accompanies the hardware received.

3. Inspection procedure shall be as follows:

   a. Perform visual inspection and proceed with the mechanical and/or electrical inspection as necessary to assure that the spacecraft hardware has not been damaged in transit and is functionally acceptable.

   b. Record the results of inspections performed on the Inspection Report form JPL 1453 and maintain these reports on file as evidence of product verification. The Inspector/Technician shall prepare an Inspection Report for each type of item (regardless of multiple quantity) received.

   c. Upon completion of Inspection functions, acceptable items shall be stamped or tagged with an acceptance stamp impression indicating acceptance of spacecraft hardware.

   d. Discrepant items, requiring MRB Action, shall be reported on the Material Review Board Action Notice form JPL 0703 and forwarded to the Material Review Board for disposition. For those instances where the wrong items have been received, QA shall forward the materials to the receiving/shipping area to be returned to the vendor.

4. Quality Assurance shall maintain files containing Inspection Reports, Test, Data Packages and Test Reports.

B. Incoming Test Equipment

1. Quality Assurance shall verify by visual inspection, the possibility of any damage that may have been incurred during transportation and that the correct type of equipment and quantity of same has been received in accordance with the Purchase Order. The Inspector/Technician shall prepare an Inspection Report for each type of item (regardless of multiple of quantity) received.

2. Each item of test equipment shall be identified with a control number issued by the Facilities Engineering Department.

3. Test equipment shall be submitted to the calibration laboratory for functional test. Upon return of the equipment to the Inspector/Technician and the equipment is acceptable, and in accordance with the manufacturer's specifications, a calibration cyclic period shall be established. A sticker indicating the next calibration date shall be affixed in accordance with the instructions defined in the "Calibration and Control of Tools, Gages, Measuring and Test Equipment Procedure"

4. Quality Assurance shall stamp the appropriate documents with an acceptance stamp and release the equipment to the requisitioner.

C. Incoming Biological Materials

1. Quality Assurance shall verify by visual inspection that the correct type and quantity of items in accordance with the Purchase Order have been received. The Inspector/Technician shall prepare an Inspection Report for each type of item (regardless of multiple of quantity) received.

2. Check the packaging for possible damage or broken seals.

3. Review the items and/or documents for previous certification by Vendor Quality Assurance or evidence of acceptance for decontamination/sterilization. Certification of decontamination/sterilization shall provide traceability to the specific items.

4. Review spore test reports or strips for negative report..

5. Stamp acceptable items with the acceptance stamp and release them to bonded clean store room.

6. Stamp all other acceptable bio-materials with an acceptance stamp and release them to the bio-material storage room.

7. If wrong items have been received submit them to receiving/shipping for return to the vendor.

8. If items received are unacceptable due to damaged or broken seals, QA shall prepare an Inspection Report pending Contamination Review action and forward the items to the material hold room and the Report to the Contamination Review Board for disposition.

9. QA shall file Inspection Reports and other acceptance documents in the Receiving Inspection file.

D. Incoming Facility Hardware and Materials

1. Facilities hardware and materials shall be inspected upon receipt at Receiving Inspection for any possible damage that may have occurred during transportation, and for correct type and quantity in accordance with the P. O. The Inspector/Technician shall prepare an Inspection Report for each type of item (regardless of multiple quantity) received.

2. When applicable, Mechanical, and/or Electrical inspection shall be performed in accordance with the appropriate acceptance criteria.

3. Upon completion of inspection, acceptable materials and Inspection documents shall be stamped with the acceptance stamp and the Facilities Engineering Department shall be notified that their equipment is acceptable. The inspection documents shall be maintained on file in the Receiving Inspection area.

4. Items that are unacceptable shall be returned to the vendor for replacement.

SYSTEMS Q. A. CERTIFICATION REQUIREMENTS

Q.C.R. 1374

DIV.					
PROGRAM	S/C	SUBSYSTEM	SUPPLIER	COGNIZANT ENGINEER	EXTENSION

ENTER N/A IN THE APPLICABLE AREAS

UNIT NO.	SERIAL NUMBER	NOMENCLATURE	DWG. NO. – REV.	ECR NO.	OPERATING TIME/CYCLES	POWER CONSUMPTION	WEIGHT	MRB NO.

ITEM	HAVE THE FOLLOWING REQUIREMENTS BEEN COMPLIED WITH:	SPECS.	YES	NO	N/A	DATE
1	HAS A LIKE UNIT PASSED THE TYPE APPROVAL TEST?					
2	PASSED FLIGHT ACCEPTANCE TEST?					
3	WAS A LIKE UNIT SUBJECTED TO LIFE TEST?					
4	WAS THE UNIT CHECKED FOR MAGNETIC CONSIDERATION?					
5	IS THE UNIT WITHIN THE WEIGHT LIMITS?					
6	ARE THERE OPEN PROBLEM/FAILURE REPORTS? (LIST IN REMARKS)					
7	IS THE UNIT COMPLETED. FINAL PRINTS AND SPECS. SUBMITTED? TOP ASSEMBLY DWG.					
8	HAS THE UNIT PASSED ALL INSPECTION REQUIREMENTS?					
9	HAVE THE ECR'S BEEN INCORPORATED? LIST ALL ABOVE.					
10	WAS THE UNIT SUBJECTED TO MRB? LIST ABOVE IF ANY.		FLT	PTM	TA	PROTO
11	INDICATE TYPE OF UNIT.	COPY CHK				
12	DO WAIVERS EXIST? SUBMIT PROJECT APPROVAL COPY.					

REMARKS:

DEVIATIONS WAIVED

SIGNED _____ DATE _____

COG. ENG _____ DATE _____

VEND. COG. ENG. _____ DATE _____

Q.A. ENG. _____ DATE _____

INSPECTOR _____ DEL. DATE _____

Q. A. DOCUMENTATION CONTROL CENTER

Figure 4 SYSTEMS QUALITY ASSURANCE CERTIFICATION REQUIREMENTS FORM

I. R. NO.

INSPECTION REPORT

MO.	DAY	YR.

SHEET OF

PROGRAM	REF. DESIG.	S/N	NOMENCLATURE	P.O.	REQ. NO.

ASSY	SUB ASSY	ACCT. CODE NO.	REG. NO.	CONTRACT NO.

OPERATION AFFECTED	QTY. REC.	CERTS	MAT'L	HEAT TREAT	STRESS R.	FLUR. PEN	X-RAY	ULTRA SON.	OTHER	SUPPLIER
DWG/PART NO.	MRB NO.	REQ.								
WHERE INSP. PERFORMED	MRB ITEM NO.	FURN.								
SOURCE										

COG. ENG.	EXT.	LEVEL OF INSP.				TYPE HARDWARE				TRAVELER NO.
		REC.	IN-PROC.	TEST	FINAL	FLT.	PROTO	TA	OSE	

STATUS	SPEC. NO.	TYPE	LOT NO.	INSP. LEVEL CHK.

ITEM	ZONE	DISCREPANCIES	DISP.	REMARKS	STAMP

INSP.	DATE

ITEM	CORRECTIVE ACTION

.. ACCP'T.	QTY. REJ.	PARTS REC. BY

COG. ENG.	DATE	Q. A. ENG.	DATE

Figure 5 · INSPECTION REPORT

IN-PROCESS INSPECTION

I. PURPOSE

To set forth instructions governing the In-Process Inspection of spacecraft parts, components and sub-assemblies, manufactured to Engineering Design requirements, for use on projects conducted in the "Sterilization Assembly Development Laboratory" (SADL) and/or the "Experimental Assembly Sterilization Laboratory" (EASL) facilities.

II. SCOPE

This procedure is applicable to those items being assembled in the Laminar Downflow Rooms or the Receiving Area.

III. GENERAL

A. Quality Assurance shall verify and document the assembly of all spacecraft sub-assemblies by performing the necessary visual, dimensional and/or electrical inspections in accordance with the appropriate acceptance criteria.

B. The Quality Assurance Inspector/Technician shall record all inspections and verifications completed and maintain a file for objective evidence.

C. All discrepancies shall be recorded and reported to either the Contamination Review Board or the Material Review Board (as applicable for evaluation and disposition.

IV. INSTRUCTIONS

A. The Quality Assurance Inspector/Technician shall visually verify that the detail parts and components used to assemble the spacecraft subassemblies shall have evidene of Receiving Inspection and Acceptance.

B. Each item shall be examined for evidence of a serial number (exclude fastener type hardware, connectors, brackets, diodes, resistors, etc.). If a serial number does not exist, one shall be applied prior to assembly.

C. The Inspector/Technician shall verify that the items to be used in this assembly shall be identified in accordance with the appropriate drawing numbers as specified on the assembly drawing/bill of materials.

D. Inspection records for all items incorporated into each sub-assembly shall be placed together in a folder which shall be identified to the respective assembly drawing number and serial number. This envelope shall be placed into a file maintained for future objective evidence.

E. The Inspector/Technician shall witness by observing the assembly of major interfaces of sub-assemblies and recording the inspection of such functions upon completion of each inspection.

F. The mating of surfaces for each sub-assembly item shall be witnessed by Quality Assurance.

G. All items which are assembled with fastener type hardware shall be inspected for proper torque values and records shall be maintained by the Inspector/Technician.

H. In-Process Electrical and Functional tests shall be performed by Quality Assurance and a record of each test shall be recorded on the Inspection Report. (See Figure 5).

I. Mechanical Inspection shall be conducted by Quality Assurance personnel and the results recorded on the Inspection Report.

FINAL INSPECTION AND TEST

I. PURPOSE

To set forth instructions governing the Final Inspection and Testing of assembled spacecraft, to assure proper performance and conformance to design acceptance criteria.

II. SCOPE

This procedure is applicable to spacecraft (and their assemblies where applicable) being assembled in the SADL facility. The instructions define the systems and controls necessary to govern the inspection and test hardware presented for Final Acceptance.

III. GENERAL

A. Quality Assurance shall monitor and verify the assembly of the Capsule Mechanical Training Model (CMTM) by performing the necessary visual dimensional and/or electrical inspections in accordance with acceptance criteria.

B. Functional or systems test of the (CMTM) Data Encoder, when required, shall be performed by Quality Assurance to the extent necessary to assure the test objective has been complied with. The basic document to be used for testing the Data Encoder is the "Simulated Sub-System Test Procedure for Data Encoder" which is prepared in accordance with the JPL Engineering Planning Document No. 85 Rev. 1 titled, "Testing and Calibration Instructions for Data Encoder Ranger Block III" -- 16 December 1963.

C. Quality Assurance Inspector/Technicians shall record all inspections and verifications completed and maintain a record file for objective evidence (Figure 6).

D. Discrepancies shall be recorded and reported on the Material Review Board Action Notice form JPL 0703 and forwarded to the MRB for evaluation and disposition.

E. Quality Assurance is responsible for performing the Optical Alignment and Functional Test of spacecraft hardware and for documentation of all test data.

IV. INSTRUCTIONS

A. The Quality Assurance Inspector/Technician shall verify that there are inspection records available for all hardware installed in a spacecraft.

B. Each item shall be inspected for serial number integrity (excluding fastener-type hardware, electrical connectors, brackets diodes, resistors, etc.). If a serial number does not exist, one shall be applied prior to assembly.

C. The Spacecraft shall be examined by the Quality Assurnace Technician for proper identification in accordance with the specific drawing numbers.

D. Quality Assurance shall ascertain that all inspection tools, test equipment, and other measuring and testing devices have been calibrated and are within the respective cyclic frequency prior to performing inspection.

E. Upon completion of final acceptance, Quality Assurance shall record the test results of tests completed on the appropriate Inspection Record.

F. All items which are assembled with fastener-type hardware shall be witnessed by the Quality Assurance Technician for proper torque values.

G. The functional systems tests on the CMTM data encoder shall be performed by Quality Assurance to ascertain that the tests performed are in accordance with the Simulated Sub-System Procedure For Data Encoder which is in accordance Testing and Calibration Instructions for "The Data Encoder Ranger Block III" document No. 85 Rev. 1.

H. The Quality Assurance "Inspection, Test and Optical Alignment Procedure" will be used to record all the Final Assembly inspections, tests and optical alignment functions. This document, when stamped with the Acceptance Stamp for all actions performed, shall be the official "Acceptance Document" for the spacecraft at time of delivery to the customer.

CLEANING AND DRESSING PROCEDURE
STERILIZATION ASSEMBLY DEVELOPMENT LABORATORY (SADL)

I. PURPOSE

To provide instructions to personnel for the correct method of personnel cleaning and dressing (prior to entering the Laminar Flow Assembly Room or the Sterile Transfer Room compatible to the SADL JPL Procedure 201.00, Personnel Procedures for SADL Operations) requirements.

II. SCOPE

This procedure is applicable to all persons having a specific need to enter either of these two rooms of the "Sterilization Assembly Development Laboratory" facility.

III. GENERAL

A. Personnel having a need to enter the Laminar Down Flow Assembly Room or the Sterile Transfer Room shall register their name, the time of entry, and the date in the Personnel Register Log maintained by Facilities Control.

B. Personnel entering either of these two rooms shall do so in accordance with the requirements established on the SADL "Personnel Procedures for SADL Operations", SADL JPL Procedure 201.00, check list (See Figure 6). In addition, the procedure contains a specific list of violations which are factors which have the potential of affecting the contamination level of the hardware being worked on in SADL.

C. Quality Assurance shall verify by monitoring all personnel entering the SADL Assembly Room or the Sterile Transfer Room, for compliance to the cleaning, washing, and dressing procedures as defined on the check list.

D. Quality Assurance shall verify by monitoring the personnel in the Assembly Room and record personnel violations or equipment failures that may have occurred.

IV. INSTRUCTIONS

A. Facility Control Room (116)

1. All personnel having justification to enter the Laminar Down Flow Assembly Room (140), or the Sterile Transfer Room shall register their name, the time of entry and the date in the Log maintained by the Facility Control personnel in Room (116).

2. The type of work to be conducted or performed by the personnel desiring to enter the Assembly Room or the Sterile Transfer Room, shall also be recorded in the Log. Example: (a) Bio-Assay, (b) Mechanical Assembly, etc.

B. Shoe Cleaning Room (114)

1. Personnel shall proceed from the Facility Control Room to the Shoe Cleaning Room where they shall:

a. Remove a clean wiping cloth from its container.

b. Thoroughly wipe the top, sides, and bottom of each shoe.

c. Discard the used cloth into its appropriate container.

d. Brush clean each shoe in the shoe cleaner for a minimum of twenty (20) seconds.

C. Locker Room (133)

1. Personnel shall proceed from the Shoe Cleaning Room to the Locker Room.

2. Personnel shall remove outer garments such as jackets, suit coats, top coats, or sweaters, wrist watches, and place them in the locker.

D. Washroom (134)

1. Personnel shall proceed from the Locker Room to the Wash Room.

2. Upon entering the Wash Room, the personnel shall:

a. Remove a sterile brush and fingernail file from the container.

b. Clean fingernails.

c. Set the timing device for two (2) minutes operating time.

d. Scrub hands to six (6) inches (approximately) above the wrists with Phisohex soap and the sterile brush for a minimum of two (2) minutes.

e. Rinse hands and arms in clean warm water after two (2) minute scrub.

f. Thoroughly dry both arms and hands, using the hot air dryer. Starting and recycling the hot air dryer shall be accomplished by striking the start switch with the elbow and not by hand.

NOTE: It is of utmost importance to remember that as of this time, and until the time each person exits the Assembly Room, there shall be no body or clothing contact (except sterile clothing) with the hands.

E. Air Shower

1. Each person shall individually depart the Wash Room and enter the Air Shower Room 136.

2. Personnel shall place both hands above their head with arms stretched and turn around slowly.

3. After the air shower stops, open the door and enter the Sterile Suite pick-up Room and obtain garments from the locker.

F. Dressing Room (138)

1. Upon exiting the Sterile Suite pickup room, each person shall with their sterile hood, smock, mask, gloves and wiping cloth proceed through the air lock into the Dressing Room.

NOTE: Caution shall be exercised by all personnel entering the Dressing Room. Personnel shall not cross over the "Z" line until fully gowned and examined by a Quality Assurance Representative.

2. Personnel shall don the sterile clothing in the following sequence:

a. hood

b. smock

c. mask (breath deflector)

d. rubber gloves

3. The wiping cloth shall be used to remove the powder from the gloves.

4. Personnel clothing shall be examined at this time by Quality Assurance prior to crossing "Z" line and proceeding into the Air Lock Room (139).

G. Entering Assembly Room (140)

1. Personnel shall procedd through the Air Lock Room (139) and continue on through to the Assembly Room (140) or the Sterile Transfer Room (141).

2. Upon entering the Assembly Room or the Sterile Transfer Room, personnel shall begin their assigned functions.

3. Quality Assurance shall monitor those functions being conducted in the Assembly Room and record the violations or failures that may occur.

H. Exiting Assembly Room

1. Personnel shall exit the Assembly Room by entering the Operational Support Equipment Room (122) OSE and remove spacial clothing.

2. Personnel shall exit the Sterile transfer Room by the Bio-Lab Utility Room (127) and remove spacial clothing.

3. Personnel shall continue to the Suit Handling Room (115) where the special clothing shall be placed into appropriate containers.

4. They shall proceed to the Facility Control Room (116) and record the time they exited the Assembly Room in the log maintained by the Facility personnel.

5. Personnel desiring to re-enter the Assembly Room (140) shall comply with these instructions as described commencing with paragraph IV-A.

NOTE: For Custodial Services and/or work to be performed in the Laminar Down Flow Assembly Room or the Sterile Transfer Room, the above instructions shall be complied with.

V. QUALITY ASSURANCE

A. Monitoring

1. Quality Assurance shall witness the washing, cleaning and dressing of personnel preparing to enter the Assembly Room or Sterile Transfer Room.

2. Work functions and operations being conducted in the Assembly Room shall be continuously monitored by Quality Assurance.

3. Custodians entering either of the two (2) rooms shall be monitored on a surveillance basis by Quality Assurance.

4. Deviations, violations, or equipment failures shall be recorded by Quality Assurance, and a report requiring corrective action shall be submitted to the appropriate source.

QA DATA SHEET NO. _____

QUALITY ASSURANCE

PERSONNEL PROCEDURES LOG FOR SADL OPERATIONS

Date _____

PERSONNEL ENTERING

Step No.	Operation Description	VIOL.*	QVE
1.	Enter door outside locker room and remove clean cloth from stack.		
2.	Thoroughly wipe top and sides of each shoe with this clean cloth.		
3.	Discard cloth in designated container.		
4.	Clean each shoe in shoe cleaner for a minimum of 20 seconds.		
5.	Enter locker room.		
6.	Remove sterile brush and fingernail file from container.		
7.	Clean fingernails.		
8.	Set timing device for 2 minutes operating time.		
9.	Scrub hands to 6 inches (approximately) above wrist with Phisohex soap and sterile brush for a minimum period of two minutes.		
10.	Dry arms and hands with hot air dryer.		
11.	Clean shoes on vibrating shoe cleaner.		
12.	Enter and turn on air shower.		
13.	Place hands over head and turn around slowly in air shower for a minimum air wash of 20 seconds.		
14.	Enter dressing room.		
15.	Obtain clean room clothing from pass through.		
16.	Don fresh, clean room laundered hood and smock.		
17.	Don breath deflector and obtain package of sterile cotton gloves (sterile rubber gloves for maintenance services).		
18.	Don gloves		
19.	Enter air lock and proceed through to hardware assembly area.		
20.	After entering Hardware assembly area begin work.		
21.	Upon completion of work period exit through Bioassay station.		
22.	For re-entry to hardware assembly area, repeat steps 1 through 19.		
Steps 1 through 21 above to be witnessed by QA. Any deviation will be noted and corrected. QA shall witness custodians operations steps 1 through 19 on a surveillance basis. NOTE: For custodial services and/or work in the laminar downflow room, these procedures shall be followed. Custodians are required to follow the above procedures and shall don sterile rubber gloves in lieu of cotton gloves.			

*Indicates Violation

QA Signature

Figure 6 PERSONNEL PROCEDURES LOG FOR SADL OPERATIONS

MATERIAL REVIEW BOARD

I. PURPOSE

To set forth instructions governing the review, disposition and control of discrepant materials, and to establish the functions and responsibilities of the Material Review Board.

II. SCOPE

A. This procedure is applicable to all materials, components, modules, subassemblies, and assemblies, necessary to assemble a spacecraft. Discrepant items shall be processed through the Material Review Board as set forth in this procedure.

B. This procedure is not applicable to discrepant items i.e., Inspection and Test Equipment, Support Equipment, Special Tooling, or contaminated Microbiological material and equipment.

III. DEFINITIONS

A. Material Review Board (MRB) -- A formal Contractor-Government Board established for the purpose of reviewing, dispositioning, and obtaining corrective action for nonconforming supplies.

B. Deviation (Class I) -- Any departure that could, in itself or in its relation to other components, result in failure or malfunction, adversely affect the safety of personnel, performance, durability, interchangeability, reliability, materially affect weight, or otherwise result in failure to perform properly its intended function.

C. Variation (Class II) -- Any departure from established standards of workmanship, or similar standards to a degree which has no significant bearing on the effective use or operation of the item or related components and which does not involve any of the factors regarded as a Class I departure.

D. Nonconforming Materials -- Any item or part in which one or more characteristics do not conform to the Drawings, Specifications, or other applicable product description.

E. Accept-As-Is -- A disposition approved by the Material Review Board to denote that a departure has been determined consistent with the criteria of an acceptable variation.

F. Rework -- A disposition approved by the Material Review Board to denote that standard corrections shall be adequate to bring the departure within the criteria of the Drawing or Specification.

NOTE: "Rework - Repair" -- a non-standard correction which shall bring the item within the criteria of an acceptable variation, but not identical to the drawing or specification. Non-standard corrections shall be implemented upon formal customer approval.

G. Reject or Scrap -- A disposition approved by the Material Review Board to denote that the item is unfit for use or cannot be economically repaired.

H. Waiver -- A formal customer approval of a contractor's request to deviate from a customer requirement for an identifiable item.

IV. GENERAL

The primary purpose of the MRB is to disposition discrepant hardware, eliminate the causes of and prevent recurring discrepancies. This MRB procedure applies to material which, due to improper or faulty processing, treatment, handling or work operations, fails to conform to the requirements, specification, or other applicable product acceptance criteria.

A. The Material Review Board shall be chaired by the Quality Assurance Manger. In addition, members from the cognizant Engineering Department and the cognizant Government representative shall constitute the active participating members of the MRB.

B. Each proposed Engineering and Quality Assurance MRB Member shall upon request, submit to the Chairman, evidence of technical competence and a thorough knowledge of product quality and functional requirements for his assigned program. This evidence shall be maintained on file by the MRB Chairman. The Chairman shall publish and distribute this list to all members.

C. Representatives of any department familiar with the technical details of the discrepant item or lot of material may participate as non-voting members of the MRB at the request of any board member.

V. INSTRUCTIONS

A. Discrepant items submitted for MRB action shall be forwarded to the Material Review Crib. The items shall be accompanied by the Quality Assurance Material Review Board Action Notice, form JPL 0703 and a copy of the Inspection Record Form JPL 1543 prepared by the Inspection Technician.

The Inspection Report document number shall be referenced on the Material Review Board Action Notice and the MRB Action Notice document number shall be referenced on the Inspection Report. Any item or material that cannot be submitted to the MR Crib due to size, safety or possibility of contamination, shall be identified by attaching the "Equipment" copy of the MRB Action Notice to the specific item and the remainder of the Action Notice shall be submitted to the Material Review Board for disposition.

B. Upon receipt of the discrepant items, the MR Crib technician shall notify the cognizant members of the Material Review Board to initiate action.

C. The Material Review Board shall disposition material submitted for review as follows:

1. Accept-As-Is -- When the departure is of a type identical to that which the Material Review Board has determined to be consistent with the criteria of an acceptable variation. Acceptance of non-conforming material shall be determined by unanimous decision by the MRB.

NOTE: If the discrepancy is a Deviation, the cognizant Engineer shall submit a formal Request for Waiver to the customer whenever the disposition could be other than Reject.

2. Rework -- A disposition that the item shall be reworked to conform to the specified requirements. This requires the signature of the cognizant Engineer and Quality Assurance members.

3. Reject or Scrap -- To denote that the supplies are unfit for use, or are found to be uneconomically repairable. If the item is procured, it shall be rejected and returned to the vendor. This requires one signature of any member of the MRB.

D. After obtaining the MRB disposition, the Inspector/Technician shall process the item in accordance with the disposition action.

E. The copies of the Material Review Board Action Notice shall be distributed as follows:

1. Q.A. REPRESENTATIVE Copy - Forwarded to the Quality Assurance Government Representative.

2. COGNIZANT ENGINEER Copy - Forwarded to the cognizant JPL Design Engineer assigned to the specific project.

3. Q.A. DOCUMENTATION CONTROL Center Copy - Forwarded to the AVCO Quality Assurance Senior Staff Engineer.

4. The remaining copies are retained on file by the Senior Inspector/Technician.

F. The Material Review Board shall assure that immediate action is, or has been taken to prevent recurrence of the discrepancy.

G. It is not necessary for members of the Board to meet concurrently; however, any member of the Board may request the Board to convene to review material submitted.

H. The Quality Assurance Staff Engineer shall maintain records pertaining to all Material Review Board actions. These records will supplement any records prepared in the initial review process and shall provide information which formed the basis for Material Review Board decisions as well as information concerning recurring discrepancies and corrective actions taken. Each discrepant item shall be dispositioned on its own condition relative to the discrepancy involved.

I. Records or summary data of all actions pertaining to nonconforming material shall be reviewed periodically by responsible Quality Assurance management personnel for the purpose of checking on the progress in correcting conditions causing defective items.

QUALITY ASSURANCE
MATERIAL REVIEW BOARD
ACTION NOTICE

MRB NO.

MO.	DAY	YR.

REF. DESIG./ITEM	SERIAL NO.	NOMENCLATURE ☐ OLD ☐ NEW	SYSTEM/SUBSYSTEM
DWG. PART NO.	CONTRACT/ P.O.	SUPPLIER	MANUFACTURER

TYPE OF INSPECTION	EQUIPMENT TYPE	SPECIFICATION	MODEL NO.	PLACE OF INSPECTION
☐REC. ☐IN-PROC. ☐FINAL ☐REWORK ☐OTHER	☐FLT ☐OSE ☐DSIF ☐MSFN ☐PROTO			
	COG. ENG./BUYER ENG.	INSPECTOR	I.R. NO.	ECI/ECR # MODIF.

ITEM	DESCRIPTION

ITEM	MRB DISPOSITION/REMARKS

ITEMS		ITEMS			
	NOT ACCEPTABLE		REWORK AT SITE		RETURN TO SUPPLIER
	REWORK		ACCEPT AS IS		

CORRECTIVE ACTION:

EFFECTIVITY:

Q.A. NONCONCURRENCE REMARKS		COGNIZANT ENGINEER	DATE
		Q.A. ENGINEER	DATE
Q.A. REPRESENTATIVE	DATE	SECTION MANAGER	DATE

Figure 7 MATERIAL REVIEW BOARD ACTION NOTICE

CONTAMINATION REVIEW BOARD PROCEDURE

I. PURPOSE

To set forth the instructions governing the review, disposition and control of Microbiologically discrepant (contaminated) items or materials and to establish the functions and responsibilities of the Contamination Review Board.

II. SCOPE

The Contamination Review Board shall be composed of qualified Engineering Representatives of Microbiology, Facilities Engineering, and the Quality Assurance Departments and the cognizant Government Representative.

III. GENERAL

It may be requested by any member of the CRB that other personnel may be called upon to act in an advisory or consultant capacity. Such advisory or consultant personnel shall have no vote in decisions arrived at by the CRB.

IV. INSTRUCTIONS

A. The Contamination Review Board shall review the discrepancy reported on the Contamination Violation/Failure Report (Figure 8) to determine if a contamination violation exists.

B. If it is determined that a contamination violation or failure exists, the CRB shall prepare a Contamination Review Board form (Figure 9), determine the disposition of the discrepancy, furnish the necessary corrective action, obtain the appropriate member signatures.

C. The original CRB form shall be maintained on file by the Quality Assurance Staff Engineer. One (1) copy shall be submitted to the originator of the Contamination Violation Failure Report so that corrective action may be implemented. One (1) copy shall also be submitted to the cognizant Government Representative.

D. The CRB shall also provide followup action to assure that corrective action has been implemented and to ensure that the incorporation of this corrective action is adequate to remedy the cause of the contamination or failure.

E. The Quality Assurance Manager shall be the chairman of the CRB and Quality Assurance Staff Engineer will be responsible for maintaining adequate records of the CRB actions, and assure the availability of the records for future reference.

F. Each member of the CRB may individually (without a formal meeting) review the discrepancy and record his recommendations for the discrepant item reported on the CRB Report. Any member of the CRB may request a formal CRB meeting to render a disposition for the item in question.

G. Possible displsitions for the Configuration Review Board are:

1. Accept-As-Is -- The violation is of a type that the CRB has determined to be without detriment to the item or operation and will not increase Microbial burden.

2. Rework -- The violation is of a type that the CRB has determined detrimental and has affect on Microbial burden, therefore establishing the requirement for a decontamination or sterilization operation (as applicable).

3. Reject -- The violation is of a type that the CRB has determined to be detrimental and that recovery of the item for use could not be obtained by decontamination or sterilization. As an adjunct, a damaged/contaminated item shall be rejected by the CRB and submitted for MRB Action.

CONTAMINATION VIOLATION/FAILURE REPORT
Originated By: _____ Date: _____
Effected Hardware, Personnel or Facility:
Description of Violation/Failure:
Forwarded by Quality Assurance to Microbiology Department for Further Action on Date: _____. Q.A. FILE # _____
Referred to Contamination Review Board on date: _____.
ATTACH BIO-ASSAY REPORT IF APPLICABLE

Figure 8 CONTAMINATION VIOLATION/FAILURE REPORT

Number 00000

CONTAMINATION REVIEW BOARD

Part Number _____ and Name _____ Date _____

Assembly Number _____ and Name _____

Facility designation _____

File Number of (attached) Bio-Assay Report: #_____

DESCRIPTION OF DISCREPANCY:

CRB DISPOSITION:

RECOMMENDED CORRECTIVE ACTION: (to prevent recurrence)

CORRECTIVE ACTION TAKEN:

CONTAMINATION REVIEW BOARD SIGNATURES:

Quality Assurance: _____

Facility Engineering: _____

Microbiology: _____

Govt. Rep. _____

Figure 9 CONTAMINATION REVIEW BOARD FORM

CALIBRATION, AND CONTROL OF TOOLS, GAGES, MEASURING AND TEST EQUIPMENT

I. PURPOSE

To set forth instructions governing the control of the intial and cyclic calibration of tools, gages and other measuring and testing devices.

II. SCOPE

This procedure applies to all tools, gages, meters, measuring and recording devices used for inspection and/or acceptance purposes by Quality Assurance, Assembly and Facilities personnel in the EASL and/or SADL Facility.

This does not include instruments, gages, meters etc., of Collateral Support Equipment, such as Facilities Environmental Controls which are inspected and controlled in accordance with procedure No. "Calibration of Collateral Control Equipment."

III. GENERAL

A. The Quality Assurance Receiving Inspection personnel shall be responsible for maintaining and controlling the cyclic calibration of all high accuracy measuring devices. This calibration may be accomplished by either on site facilities or by JPL approved off site facilities. All calibrations must be performed using nothing less than secondary standards having certified accuracy traceable to the National Bureau of Standards (NBS) approved primary standards.

B. Employee-owned tools and gages may be used, but are subject to the same cyclic calibration controls as defined by this procedure.

C. Instruments, gages and meters that are standards used by the Facilities Dept. personnel for verifying the accuracy of Collateral Facilities equipment shall be included in the Quality Assurance cyclic calibration list.

D. All tools, gages, meters, instruments and all other measuring devices which are subject to cyclic control and have been re-worked or repaired in any way must be calibrated before being returned to use.

E. Quality Assurance shall, on a monthly basis, issue a tabulated list of tools, gages, meters and other measuring devices (including personally owned) which require cyclic calibration.

IV. INSTRUCTIONS

A. Calibration of New Tools and Gages

1. Upon receipt of a new tool, gage, meter or other measuring device, Q.A. Receiving Inspection shall (by Electro-Etch or other method if necessary) apply the assigned identification number to it and forward the item to the calibration laboratory.

2. The calibration laboratory shall inspect the item to the purchase requirements and the appropriate Manufacturer's Specifications. Upon completion of the inspection and calibration, they shall return the item together with a certificate of calibration (and test data where applicable), to Quality Assurance Receiving Inspecting.

3. Upon receipt of the item and data from the calibration laboratory, Quality Assurance Receiving Inspection shall, if the item is acceptable:

a. Add the item to the inventory list of tools, gages, etc., requiring cyclic calibration.

b. Prepare a "Cyclic and Calibration Record" for the item. (Figure 10).

c. Establish a cyclic calibration recall period for the item.

d. Apply a Serviceable Tool Sticker, showing the next cyclic due date and the Inspector's stamp. The item is then ready for issuance.

4. If the inspection or calibration data show that the item is not acceptable, the requisitioner of the new item shall be notified, and the item will be either returned to the vendor for correction or held for local corrective action.

B. 1. Quality Assurance Receiving Inspection shall establish and maintain a control system to assure that, on a monthly basis, tools, gages, etc., are recalled for cyclic calibration no later than their due date. This shall be accomplished via a master card system.

2. Each Dept. Manager shall be notified, on a monthly basis, by means of a memorandum listing the specific items due for calibration.

3. Upon receipt of a recalled item, Receiving Inspection shall remove the Cyclic and Calibration Record for the item from the file, enter date received and the date the item is forwarded (with the request for calibration) to the Calibration Laboratory and place the item record in the outstanding suspense file.

4. Upon return of the item, with its certification and/or calibration data, from the calibration laboratory, the Receiving Inspector shall, if the item is acceptable:

a. Attach a Serviceable Tool Sticker to the item showing the next cyclic due date and the inspector's stamp.

b. Complete the item Cyclic and Calibration Record card including the new calibration due date and return it to the master file.

c. Forward the item to the using personnel.

5. If the item is unacceptable, Receiving Inspection shall:

a. Enter the existing discrepancy on the item Cyclic and Calibration Record card.

b. Tag the item as "Unuseable" and notify the appropriate Dept. Manager so that he may arrange for repair or replacement.

c. Maintain the item Cyclic and Calibration Record card in suspense file.

6. If an unacceptable item is submitted for repair, upon completion of the repair or rework it must be presented to the Q.A. Receiving Inspector to be forwarded to the calibration laboratory and processed in accordance with the established controls of this procedure.

7. If an unacceptable item is dispositioned for replacement Receiving Inspection shall:

a. Retire the item cyclic record card.

TOOL AND GAGE CALIBRATION RECORD

NAME	MFG.	MODEL	ITEM I.D.#
DATE RECEIVED	CALIBRATION FACILITY		RECALL CYCLE

DATE REC'D	TO CALIB. LAB.	DATE RETURNED	NEXT CALIB. DUE DATE	DISCREPANCIES	ASSIGNED USER

FIGURE NO. 10

PRESERVATION, PACKING, MARKING, AND SHIPPING PROCEDURE

I. PURPOSE

To set forth instructions governing the inspection of Preservation, Packing, Marking, and Shipping of items in order to assure and maintain adequate performance and compliance to applicable Specifications and Contractual requirements.

II. SCOPE

The provisions of this procedure are applicable to items such as spares, sub-assemblies, assemblies, and spacecraft where specific requirements shall be complied with. It does not include plant equipment, laboratory test equipment and instrumentation, or rejected material being returned to the vendor.

Referenced Documents

MIL-P-116

MIL-STD-129

MIL-STD-105

FED. STD. 102

III. DEFINITIONS

A. Preservation and Packaging

Application or use of adequate protective measures to prevent deterioration, including as applicable: use of appropriate preservatives, protective wrappings, cushioning, and interior containers; in addition complete identification marking up to, but not including, the exterior shipping container.

B. Packing

Application or use of exterior shipping containers and assembling of items or packages therein, together with the necessary blocking, bracing or cushioning, weather proofing, exterior strapping and marking of shipping containers.

C. Marking

Numbers, nomenclature, or symbols stamped, painted on, or otherwise affixed to items or containers for identification.

D. Level of Preservation, Packaging, and Packing

As defined by Federal Standard No. 102, there are three (3) levels of preservation and packaging and three (3) levels of packing. These levels define the various environments that can be required for the military needs.

E. Methods and Sub-Methods of Preservation, Packaging, Packing

As defined by Military Specification MIL-P-116, there are three (3) basic methods of preservation and packaging and various sub-methods. The methods and sub-methods define the specific materials to be used; such as, preservatives, moisture-vapor type barriers, cushioning materials, etc.

IV. GENERAL

A. The cognizant Design Engineer shall provide the necessary information for preservation, packaging, and packing of all items being prepared to contract requirements.

B. Quality Assurance Planning Engineer shall review the requirements and establish inspection criteria for the method of preservation and packaging to be used.

V. PROCEDURE

A. Upon receipt of the Shipping notification, the Quality Assurance Inspector/Technician shall verify that the unit has received Final Inspection and bears the Acceptance Stamp. The Part Numbers of the units shall be compared to the Shipping Notification to assure that parts and paperwork are in agreement and that the quantity of parts is correct.

B. The package unit shall be inspected for layout and packaging in accordance with the packaging instructions prepared by the cognizant Design Engineer.

C. When Level A or B of MIL-P-116 is specified on the Shipping Notification, the Heat Seal and Quick Leak Tests shall be performed as defined in MIL-P-116. These tests are to be performed by the Quality Assurance Inspector/Technician on a random sample basis taken in accordance with MIL-STD-105D, Inspection Level L-2, and AQL of 4.0 percent.

D. Upon acceptance of package layout, packaging and testing, the Shipping Notification will be stamped with the Acceptance Stamp. Units determined unacceptable in regard to layout or packaging shall be returned to the originator of the Shipping Notification.

E. Accepted items shall be released by Quality Assurance for shipment to destination.

QUALITY ASSURANCE AUDIT PROCEDURE

I. PURPOSE

To set forth the instructions governing the performance of Quality Assurance Audits and to assure the status of product quality with respect to inspections performed during all phases of manufacture.

II. SCOPE

This procedure is applicable to all functions in the SADL facilities which affect end-item product quality.

III. GENERAL

A. The Quality Assurance Manager shall initiate and implement the Quality Assurance Audit Plan.

B. The inspection functions affecting end-item quality shall be audited on an unannounced basis.

C. The auditor may request the services of an Inspector/Technician, or he may perform the audit inspection himself. In all cases, setups of equipment, tools, etc., shall be performed by the Inspector/Technician.

D. An Audit Report shall be issued to the Supervisor of the area audited no later than three (3) working days after the audit is completed. All deficiencies noted shall be answered in an Audit Reply Memo no later than one (1) week which shall after the Audit Report is received, include the immediate action to correct the deficiencies and corrective measures implemented to prevent them from recurring.

IV. INSTRUCTION

A. A schedule of audits to be performed shall be prepared by the Quality Assurance Manager. The schedule shall be maintained by the Quality Assurance Department, and no distribution will be made. The schedule shall also identify the particular Department and area to be audited. The audit maybe performed on a product and/or records.

B. The Quality Assurance Engineer performing the audit shall, upon arrival in an area, notify the Supervisor that his area is being audited. The Supervisor, or his designated alternate, shall accompany the auditor through the area. The auditor shall randomly select an item and/or records and perform a complete evaluation. This shall encompass final inspected items, items in-process, items inspected in conjunction with other assemblies or systems and associated records.

C. Upon selection of an audit item, the auditor shall inform the Inspector/Technician and the Supervisor of the specific item, and that it is not to be forwarded to the next fabrication, decontamination, or inspection function until completion of audit re-inspection. The Quality Assurance Audit shall be performed by the auditor and assisted by the Inspector/Technician when deemed necessary.

D. The auditor shall select characteristics and/or parameters of the item under audit and retest or re-inspect as required. The Inspector/Technician shall assist the auditor by providing the necessary tools, equipment, and setups required to inspect the item. The auditor shall review all tools, documents, stamps, and other controls necessary to assure adherence to Quality Procedures. Upon completion of the audit the auditor shall briefly review all deficiencies with the responsible Supervisor.

E. Within three (3) days of the audit, the auditor shall issue to the responsible Supervisor a written summary of the findings indicating deficiencies, if any, and including recommendations for corrective action to prevent recurrence.

F. Within one (1) week of the receipt of the audit report, the responsible Supervisor shall issue a written corrective action reply to the Quality Assurance Manager for all discrepancies noted in the Auditor's report. The Quality Assurance Manager shall review each of the replies and determine if the corrective action indicated is adequate.

G. If the corrective action is determined to be inadequate, the Quality Assurance Manager shall so advise the respective Department Manager and follow-up for adequate corrective action.

H. The Quality Assurance auditor shall review and evaluate the accuracy of records such as; the

Daily Activity Log - SADL Facility
Bio-Assay and Assembly Room Personnel Entries
Sterile Strip Assay Sheets
Reynier Sampler - Data Report Form
Inspection Records
Cyclic Calibration Records, etc.

I. Records

The auditor shall maintain a file by area audited and activity of each audit report and its corresponding corrective action reply.

DECONTAMINATION, STERILIZATION, AND CLEANING

I. PURPOSE

To set forth Quality Assurance instructions governing the monitoring of methods and procedures used for decontamination, sterilization, and cleaning in compliance with the requirements of EASL 200.00 and the SADL Operations Handbook.

II. SCOPE

This procedure is applicable to all items used in the SADL Facility which require decontamination, sterilization, or cleaning in compliance with EASL 200.00 and/or the SADL Operations Handbook.

III. PROCEDURE

A. Packaging

1. Quality Assurance will verify that all items prior to decontamination, sterilization, or cleaning have been prepared in the following manner:

   a. All items, where practicable, shall be individually packaged in plastic bags and separated.

   b. A spore strip chemical, or thermal indicator is to be included in each lot of items being decontaminated.

2. Quality Assurance shall inspect for damage to seals, tears, or holes.

3. Quality Assurance shall inspect/verify that all equipment being used is calibrated within its appropriate cycle.

4. Decontamination Methods

   a. Dry Heat (Class 1)

   Oven Setting -- Quality Assurance will verify that the following dial settings are maintained (per SADL 200.00):

Temperature	135°C ± 5°C
Time	24 hours

b. ETO (Class 2)

ETO Settings -- Quality Assurance will verify that the following dial settings are maintained (per EASL 200.00):

Temperature	40°C ± 3°C
Vacuum	25 inches
Pressure	8-10 psig
Time	8 to 10 hours
Relative Humidity	35% + 15% or -5% R.H.

c. Steam (Class 3)

Steam Autoclave Settings -- Quality Assurance will verify that the following dial settings are maintained (per SADL 200.00):

Temperature	121°C + 5°C
Time	15 minutes

d. Chemical Wipedown (Classes 4 and 5)

Quality Assurance will verify that the sealed containers are wiped down, prior to insertion into the laminar downflow room with amphyl or alcohol (per EASL 200.00).

5. Post Decontamination -- Quality Assurance, after completion of decontamination, will:

a. Inspect seals for damage.

b. Stamp Decontamination Record Sheet indicating acceptance of decontamination cycle.

c. Document any discrepancies using the IR disposition in accordance with SADL 106.00 Contamination Review Board.

d. Release accepted material for use.

IV. LOT SYSTEM IN USE

Each decontamination cycle whether conducted either in SADL or elsewhere is identified by a three-symbol lot identification. The first lot will be identified with the first letter of the alphabet and subsequently with B, C, etc., for the following daily lots. The remaining two symbols are for the calendar day of the month - 02, 14, 27. No month identification is used.

V. SPORE STRIPS

If spore strips are used on any lots, Quality Assurance will verify the spore strips are in separate but similar packages. Items will not be released to stores until the spore strip assays are complete and accepted.

VI. STERILOMETER STRIPS

Heat cycles also contain sterilometers in each package. These are examined at the time the item is used. Thus, although the lot may be satisfactory , an item in the lot may be unsterile according to the strip.

MONITORING OF MICRO-BIOLOGICAL OPERATION

I. PURPOSE

To set forth instructions to define the areas and items that will be monitored by Quality Assurance Personnel whenever Microbiological Personnel conduct operations in the EASL or SADL Facilities.

II. SCOPE

This procedure applies to all Microbiological assays conducted in the EASL or SADL Facilities and the frequency of implementation shall be established by the Quality Assurance Manager based upon the amount of Microbiological operations.

III. GENERAL

Quality Assurance Personnel shall:

A. Verify that all environmental conditions are as specified.

B. Verify that the locations to be sampled by means of Rodac and Reynier Plates are properly identified and that the identity is accurately transferred to the Plate Cover.

C. Verify that the specified media is used and was properly processed.

D. Verify that all Rodac and Reynier dishes are sterile at the time the media is poured into them.

E. Verify that the Reyniers are properly placed and that operating conditions are as specified.

F. Verify that the stainless steel coupons used for fallout assay were properly sterilized; placed in the proper locations and the sample coupons taken in the proper sequence.

G. Monitor the processing of the stainless steel coupons through the Microbiological laboratory on a spot check basis.

H. Verify that incubation conditions for the various samples (Rodac, Reynier, etc.) are as specified.

I. Record all information on the proper forms and verify that the proper logs are kept as to personnel activities such as entry into controlled areas, placement of assaying media and other assaying activities.

J. Monitor Microbiological records of the various samples and verify the results on a spot check basis.

IV. INSTRUCTIONS

A. Verify initial sterility of Rodac and Reynier dishes by:

1. Indicator strip in the individually packaged stacks.

2. Random sample tests run by the Bio-lab. Record results on form.

B. Verify type of media by checking Bio-lab logs and compare against the assay specifications.

C. Verify Rodac and Reynier sample locations and transfer of the location identity to the plates by:

1. Observing the locations and location identity against the location identifications as called out in the assay plan.

2. Observing the identity on the plates against the location call out in the plan and compare them with the actual location identification.

D. Verify operating conditions of the Reynier Sampler by:

1. Observing the following Reynier characteristics:

a.) Speed of rotation

b.) Airflow in cubic feet per minute (cfm)

c.) Slit width

d.) Slit cleanliness

E. Verify that the actual environmental conditions meet the specified requirements by:

1. Observing the following conditions and comparing them against the Microbiological plan requirements.

a.) Air temperature

b.) Relative humidity

c.) Air particulate count

d.) Rate of Airflow

F. Verify that the incubation conditions are as specified in the assay plan by:

1. Observing the following conditions and comparing them against the specification requirements.

a.) Incubator temperature

b.) Incubator relative humidity

c.) Length of incubation cycle

G. Monitor Microbiological records of the various samples on a spot observation basis by:

1. Randomly reviewing approximately 10% of the "Steel Strip Assay Sheets" (JPL 2761-1) and signing the data sheets checked to show Q.A. Verification. Review the data sheets for completeness of information and note any incorrect or omitted entries.

2. Randomly review approximately 10% of the "Rodac Plate Assay Sheet(s)" (JPL 2761) and signing the data sheets reviewed to show Q. A. Verification. Review the data sheet for completeness of information and note any incorrect or omitted entries.

3. Randomly checking approximately 10% of the "Reynier Sampler Data Report Form"(s) and initialing or stamping the sheets checked to show Q.A. Verification. Check these data sheets for completeness of information and note any incorrect or omitted entries.

H. 1. Verify that the proper logs are key and for each area by checking the logs for proper entries.

2. Monitor all personnel entering controlled areas using the procedural check off sheet for each area. Record any violations in procedure.

3. Record personnel activities relevant to the assigned task and report any violations of either dressing procedure or task on the "Contamination/Failure Report".

J. Verify that all stainless steel coupons used were properly sterilized and placed by:

1. Checking the temperature and time of the sterilizing cycle as shown on the Sterilizer Recorder charts.

2. Checking the Sterile indicator strip ncluded with the strips during the sterilizing cycle.

3. Verify proper placement and location of strips by comparing against the task plan layouts.

K. Quality Assurance personnel shall maintain a complete file of activities by:

1. Filing copies of all written reports on monitored activities.

2. Filing copies of all reports received from other departments participating in the task.

PRODUCT SERIALIZATION

I. PURPOSE

To set forth instructions governing the issuance and control of serialization identification of parts, components, subassemblies and assemblies.

II. SCOPE

A. This instruction is applicable to all items fabricated in house or procured from vendors and intended for end item use.

B. This instruction does not apply to:

1. Items procured for development purposes which will not be used in flight items.

2. Inspection tools, measuring and testing equipment.

3. MS and AN fastener hardware, standard electrical components, such as resistors and capacitors, and commercial hardware such as screws, washers, nuts and bolts.

III. GENERAL

A. All items within the scope of this instruction shall be controlled by Individual or Lot Serialization. Both Individual and Lot Serialization numbers will be issued and controlled by the Quality Assurance Department.

1. Individual Item serialization numbers shall be assigned and a separate Quality Assurance Serialization Log listing each number and part when any of the following conditions exist.

(a) Actual data must be recorded by the Quality Assurance personnel.

(b) Certification of special processes or material is required in lieu of Quality Assurance inspection and/or test.

(c) Engineering or Procurement requirements exist for the item that requires item control for traceability purposes.

A four digit basic serial number prefixed by a letter and a number will be used to identify each part under Individual Item Serialization.

2. Lot Serialization shall be assigned to items not identified by Individual Serialization. All parts in the lot will be marked with the Lot Serialization number suffixed with the letter "L" to denote that the item is controlled by Lot Serialization.

IV. INSTRUCTION

A. Quality Assurance shall maintain a current master list of item and lot serial numbers issued and the item each number is issued against. The master list information shall include item name, part number, vendor and receiving IR number.

B. A serial number shall consist of a basic set of digits preceded by a capital letter and a digit. The capital letter shall designate the month of the year; the first digit shall indicate the year; and the remaining digits shall be the basic serial number. The following letters have been allocated for the months:

A-January	D-April	G-July	K-October
B-February	E-May	H-August	M-November
C-March	F-June	J-September	N-December

EXAMPLE:

Item Serial Number

Serial Number F 7 4736

a. Month (June)

b. Year (1967)

c. Sequential Serial Number

Lot Serial Number

Serial Number F 7 4736 L

a. Month (June)

b. Year (1967)

c. Sequential Serial Number

d. Lot Designation

C. The assigned serial number shall be applied to each part by Q.A. personnel under or adjacent to the part number and shall be legible and conspicuous. Light and dark items shall have serial numbers of a contrasting color applied per drawing requirements as applicable. Items that cannot be physically marked because of size, configuration, material or functional reasons shall be identified by means of a tag or envelope.

D. Serial numbers shall be assigned sequentially, starting with the number 1000 at the beginning of each month.

E. Items or assemblies that require re-identification shall be checked against the latest B/P changes and requirements to assure that the configuration is current prior to re-identification. A new serial number shall be required only in the case of a drawing number change.

CALIBRATION OF COLLATERAL CONTROL EQUIPMENT

I. PURPOSE

To set forth instructions governing the control of the initial and cyclic calibration of collateral control equipment such as instruments, gages, meters, etc., used by the Facilities Department for environmental control.

II. SCOPE

This procedure applies to all collateral control type equipment, instruments, meters, gages, etc., which because of type or method of mounting or other unique circumstances, make it inadvisable to remove the item for calibration on a cyclic basis.

III. GENERAL

A. The Quality Assurance Receiving Inspection personnel shall be responsible for maintaining the records of and controlling the cyclic calibration of all items controlled by this procedure. The calibration of these items shall be accomplished by either an on-site or off-site agency with the item remaining in its normal place of operation during the calibration. All calibrations shall be performed using standards having certified accuracy traceable to the N.B.S. approved standards.

B. The cyclic calibration record for each item shall be maintained by Quality Assurance Receiving Inspection by means of a card system.

C. Approval of calibration, certifying facilities and methods shall be the function and responsibility of the Quality Assurance department. Approval of off-site facilities shall be coordinated with JPL.

D. All items which are subject to cyclic control and which have been re-worked or repaired in any way must be calibrated before being returned to use.

E. Quality Assurance shall on a monthly basis issue a tabulated list of items which require cyclic calibration.

IV. PROCEDURE

A. Inspection of New Items

1. Upon receipt of a new item Quality Assurance Receiving Inspection shall apply the assigned identification number to it and notify the appropriate Department Manager that the item has been received and will require initial calibration prior to final acceptance.

2. The item shall be calibrated to the purchase requirements and the appropriate manufacturer's specifications. A certificate of calibration and test data, where applicable, shall be submitted to the Quality Assurance Receiving Inspection.

3. Upon receipt of the certification and data, Quality Assurance Receiving Inspection shall, if the item is acceptable:

   (a) Add the item to the inventory list of items requiring cyclic calibration.

   (b) Prepare a "Cyclic and Calibration Record" for the item.

   (c) Establish a cyclic calibration recall period for the item.

   (d) Apply a Serviceable Tool Sticker showing the next cyclic due date and the Inspector's Stamp. The item is then ready for use.

4. If the calibration data show that the item is not acceptable, the Facilities Manager and the requestor of the item shall be notified. The item shall be tagged as discrepant and held for appropriate corrective action.

B. Cyclic Inspection

1. Quality Assurance Receiving Inspection shall notify the Manager of each affected Department by means of a memo on the first working day of each month of the items of collateral equipment in his department which will require cyclic calibration during the month and the date on which the current cyclic calibration expires. On the basis of this information, the Department Manager shall arrange for the required calibration of the equipment on or prior to the expiration date. Upon completion of the cyclic calibration, all of the data shall be presented to the Receiving Inspection personnel.

2. Upon receipt of the cyclic calibration data, Receiving Inspection shall evaluate the data and determine if the equipment meets specified requirements, a Serviceable Tool Sticker showing the next cyclic due date and the Inspector's Stamp shall be applied to the equipment. If the data shows that the item is not acceptable, the affected Department Manager shall be notified, the item shall be tagged as discrepant and held for appropriate corrective action.

APPENDIX B

SADL OPERATIONS LOG FACSIMILES

QUALITY ASSURANCE
DAILY SUMMARY LOG

Date_____

Facility Log Entries verified_____
Tool Decontamination verified for lot number_____
Clothing Decontamination verified_____
Component Decontamination verified_____
Bio-assay verification_____

Total dressing violations_____
Total personnel violations_____
Facility Operation violations_____

Personnel Operations Violation descriptions:

Comments:

_____
Quality Assurance Engineer

DAILY ACTIVITY - SADL FACILITY

Date_____

1. ENVIRONMENTAL DATA

a. Assembly Area

Max. Temp_____°F, Time_____

Min. Temp_____°F, Time_____

b. O.S.E. Area

Max. Temp_____°F, Time_____

Min. Temp_____°F, Time_____

Static Pressure

0800_____in water

1200_____in water

1600_____in water

c. Dressing Room

Static Pressure

0800_____in water

1200_____in water

1600_____in water

2. ROUTINE FACILITY CONTAMINATION CONTROL

a. Morning Wipeoff of Working Surfaces, O.S.E. Area, and Pass Thrus_____

b. Evening Cleaning

Daily Routine on:

Bio-Assay Room_____

Assembly Room_____

Dressing Room_____

O.S.E. Area _____

Locker/A/S _____

Shoe Cleaner _____

O.S.E. Entrance_____

Weekly Routine on:

Bio-Assay Room_____

Assembly Room_____

Dressing Room_____

O.S.E. Area _____

Locker/A/S _____

Shoe Cleaner _____

O.S.E. Entrance_____

3. BIO-ASSAY AND ASSEMBLY ROOM PERSONNEL ENTRIES

Name	Period	Purpose

4. DECONTAMINATION PROCESSING/LOCATION

Garments _____

Tools _____

Parts/Assemblies _____

Equipment _____

5. PROBLEMS:

6. VISITORS

NAME	ORGANIZATION	PERIOD

7. DATE OF LAST CERTIFICATION _____

NEXT CERTIFICATION DATE _____

8. REMARKS

TASK NO. _____

STEEL STRIP ASSAY SHEET

Site _____ Strip _____ Date Sampled _____ Incubation Temperature _____ QA Verification _____

Sample taken by _____ Assayed by _____ Culture Medium _____

Total organisms _____ Total aerobes _____ Total anaerobes _____

Total fungi _____ Total aerobic spores _____ Total anaerobic spores _____

Aerobic bacteria	24 hours	48 hours	72 hours
A			
B			

Anaerobic bacteria	72
C	
D	

Aerobic bacteria Heat shocked (Spores)			
E			
F			

Anerobic bacteria Heat shocked (Spores)	
G	
H	

Aerobic Fungi			
A			
B			

Anaerobic Fungi	
C	
D	

Aerobic Bacteria Strip 24 hours ____ 48 hours ____ 72 hours ____

Aerobic Fungi Strip 24 hours ____ 48 hours ____ 72 hours ____

REMARKS _____

_____

JPL 2761-1 NOV 66

Task No. _____

RODAC PLATE ASSAY SHEET

Site _____

Sample taken by _____

Total organisms _____

Date _____

Assay by _____

Total aerobic bacteria _____

Q A Verification _____

Culture medium _____

Total aerobic fungi _____

Aerobic bacteria	24 hours	72 hours
1.		
2.		
3.		
4.		

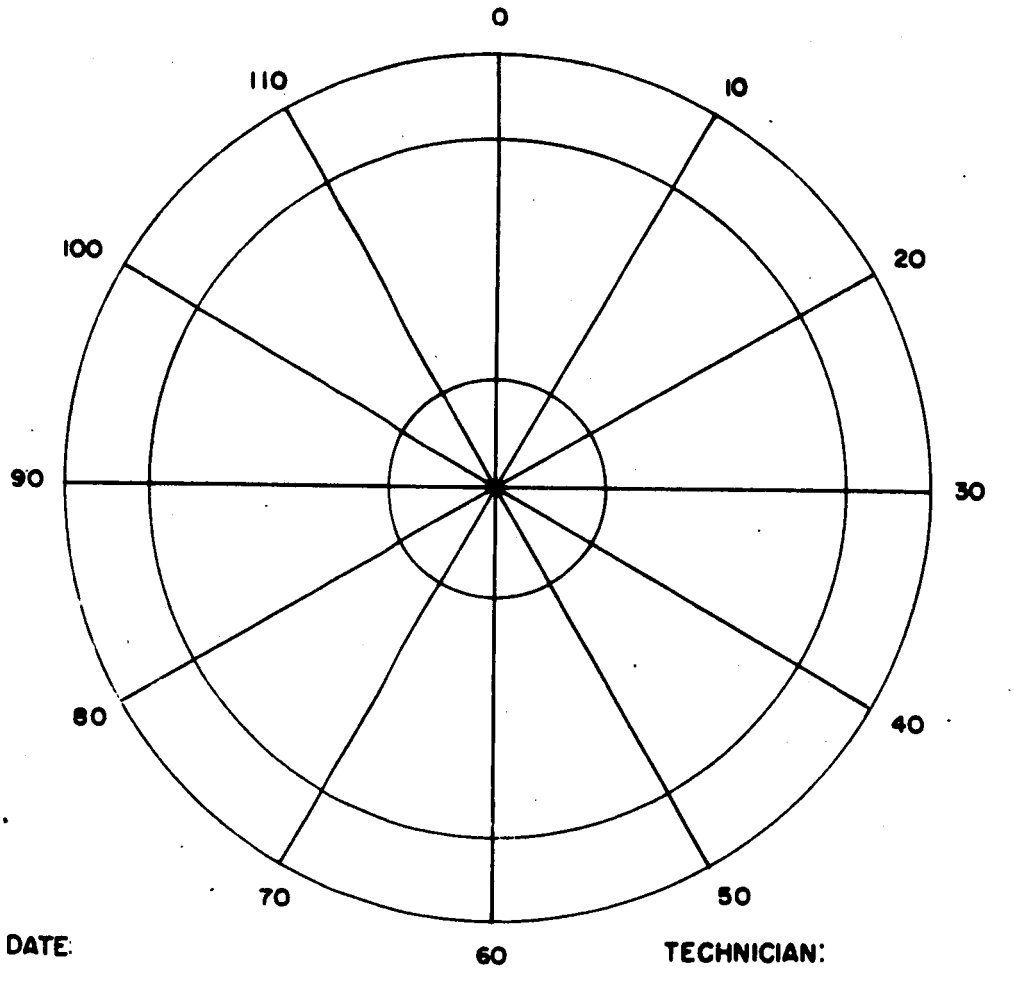
Aerobic fungi	24 hours	72 hours
1.		
2.		
3.		
4.		

REMARKS _____

_____

JPL 2761 NOV 66

REYNIER SAMPLER - DATA REPORT FORM



DATE: TECHNICIAN:

(1) Sampler Location:

(2) Time of Operation: ON: OFF: TOTAL TIME:

(3) Bacteriological Medium:

(4) Incubation of sample: TEMP: TOTAL TIME:

REMARKS----------