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LIFE SCIENCES FLIGHT EXPERIMENTS PROGRAM
LIFE SCIENCES PROJECT DIVISION
PROCUREMENT QUALITY PROVISIONS

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PREFACE

This plan provides the basis for developing Quality Assurance provisions to be incorporated in Life Science Project Division procurements.

This plan consists of Life Science Project Division/Quality Assurance Division interfaces, hardware categorization methods, general quality assurance provisions, and hardware to quality provisions matrices.

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LIFE SCIENCES PROJECT DIVISION
PROCUREMENT QUALITY PROVISIONS

1.0 INTRODUCTION

1.1 PURPOSE

This document defines the methods to be used by the JSC Level III Life Sciences Project Division for implementing Level II Quality Assurance Policy and Requirements.

1.2 SCOPE

The requirements and policies specified herein apply to all Life Sciences Experiments Program flight and ground hardware either developed, handled, or integrated by the JSC Level III Project Office; i.e., Life Sciences Project Division. The Life Sciences Project Division shall assure implementation and compliance by all project participants, including contractors, investigators and inhouse support elements.

2.0 APPLICABLE DOCUMENTS

SW-E-0002, Space Shuttle Ground Support Equipment Design Requirements

SN-C-0005, Contamination Control Requirements for the Space Shuttle Program

3.0 POLICY

3.1 GENERAL

It is the policy of the Life Sciences Project Division to implement a quality assurance effort tailored to the needs of the Life Sciences Experiments Program. Quality requirements for LSLE (Life Sciences Laboratory Equipment), experiment hardware, miscellaneous support equipment, integration and test support equipment, and integrated payloads shall be established and implemented to reasonably assure flight hardware and payloads will perform to the level required to successfully conduct scientific investigations aboard the STS.

3.2 LOW COST APPROACHES

The JSC quality assurance approach is to establish a cost effective quality program which will include the following:

- a. Use of contractor plans.
- b. Inhouse evaluation of off-the-shelf hardware proposed for flight.

c. Optimum tailoring of quality requirements prior to inclusion in acquisition documentation.

d. Minimum documentation requirements.

4.0 IMPLEMENTATION

4.1 QUALITY ASSURANCE/PROJECT ENGINEER

The project engineer is responsible for the definition, development and acquisition of the end item or experiment and is the prime interface with the end item supplier.

The Quality Assurance Division will designate a representative to provide support to the project engineer on all matters pertaining to quality.

4.2 SELECTION OF QUALITY REQUIREMENTS

4.2.1 The HDP (Hardware Development Plan) for LSLE shall identify the category in which the hardware has been placed. All LSLE hardware will be categorized using the criteria in paragraph 4.3.

4.2.2 The PAP (Product Assurance Plan) for experiments will be developed during the definition phase of the experiment. Specific quality requirements in this document will depend on inhouse capabilities of the principal investigator, degree of hardware development, resources available and PI (principal investigator) commitments. These factors used in conjunction with the criteria in paragraph 4.3 will form the basis for categorizing the experiments in the PAP.

4.2.3 Change Control - Once approved, a change in hardware category can be made only with the approval of the Level III Life Sciences CCB (Configuration Control Board).

4.3 CATEGORIES OF HARDWARE

4.3.1 FLIGHT HARDWARE

a. Class A - High Development. Hardware in this category requires considerable development and is generally complex. Total contract costs for items in this category usually exceed one million 1978 dollars.

b. Class B - Moderate Development. Total contract costs of items in this category range from \$250 thousand to \$1 million. The equipment is generally modified commercial off-the-shelf hardware, or modified flightworthy equipment and only moderate development is required.

c. Class C - Low Development. Class C hardware is generally commercial off-the-shelf with possible minor modifications. Total contract costs for Class C hardware is generally less than \$250 thousand.

4.3.2 GROUND SUPPORT EQUIPMENT

GSE (ground support equipment) consists of two classes:

a. Class 1 - Class 1 GSE interfaces with STS elements such as the Spacelab, payload bay, pallet or Orbiter. Class 1 GSE shall meet testing requirements given in paragraph 4.2 of SW-E-0002.

b. Class 2 - Class 2 GSE interfaces with experiment related equipment only, such as LSLE or experiment unique equipment. Class 2 GSE shall adhere to good commercial practice. Testing shall include interface checks.

4.4 TAILORING OF REQUIREMENTS

Based upon the hardware categorization, quality requirements will be developed and specified in end item specifications and statements of work.

Tables 1 through 4 list the applicable quality requirements for each hardware category. A description of each requirement is given in paragraph 5 below.

Guidelines for tailoring are as follows:

- a. Review each requirement under the appropriate category for applicability.
- b. Delete all procedural inference from each applicable requirement.
- c. When possible, replace general requirements with known inspection requirements.
- d. Use contractor specifications when available.

5.0 GENERAL QUALITY ASSURANCE REQUIREMENTS

Tailoring of quality assurance requirements shall be based on the following general requirements:

5.1 MANAGEMENT AND PLANNING

The contractor shall maintain an effective inspection system which shall include provisions for defining and verifying article and material quality throughout all operations including procurement, fabrication, test and delivery. The system shall ensure the maintenance of objective evidence of quality in the form of records of inspections and test results. The system shall also ensure that any unsatisfactory conditions are discovered and documented, and that remedial and preventive actions are taken at the earliest possible time.

- a. Certification of personnel for selected processes shall be controlled by both a written examination and a performance demonstration. Recertification shall be based on quality of work or services, changes in techniques or interruption of work for extended periods.

b. Quality activities shall include participation in design reviews to ensure that designs permit and facilitate productivity, repeatability, inspectability and maintainability, and that related quality considerations are well defined.

c. Change Control. A change control system shall be maintained providing for document distribution to the proper points at the proper times and removal of obsolete documents from operating areas. The control system shall provide for initiation of document change requests. Changes which involve interface relationships or which affect articles and materials controlled by others shall be coordinated with the affected parties. These requirements shall be effectively integrated with other document control requirements of the contract.

d. Change Effectivity. The effectivity point (e.g., date, serial number, lot numbers) of documents and changes which affect article and material procurements, fabrication, inspection and test operations shall be clearly specified. Changes accomplished on the affected articles or materials shall be appropriately and clearly marked or identified; and associated documents shall be revised accordingly.

5.2 IDENTIFICATION AND DATA RETRIEVAL

a. The contractor shall develop and maintain an identification and data retrieval system for articles and materials to provide:

(1) Identification to which design, procurement, fabrication, processing, inspection and operating records can be related to, and

(2) Means for locating articles and materials.

5.3 PROCUREMENT CONTROLS

a. The contractor is responsible for the adequacy and quality of all purchased articles and materials.

b. Articles shall be inspected upon receipt.

c. Raw materials shall be inspected and tested (e.g., chemical and/or physical testing conducted) to determine conformance to applicable drawings and specifications; drawings and specifications shall include chemical and/or physical test criteria, as appropriate. Reports of actual test results shall be identified with the particular materials. Raw materials shall be segregated and controlled to prevent use of materials which do not conform to drawings and specifications or which are awaiting completion and receipt of satisfactory test results.

d. Procurement documents shall be controlled to ensure incorporation of applicable quality and technical requirements.

(1) Changes. Suppliers shall notify the contractor of any proposed changes in design, fabrication methods, or processes previously approved by the contractor.

(2) Purchased Raw Materials. Purchased raw materials shall be accompanied with chemical and/or physical test results.

(3) Raw Materials Used in Purchased Articles. Acceptance test results on all raw materials that are required to satisfy specification requirements and which are employed in the fabrication of articles purchased on a sub-contract or purchase agreement shall be made available to the contractor upon request.

(4) Preservation, Packaging, Packing and Shipping. Requirements for preservation, packaging, packing and shipping of articles and materials shall be specified or referenced.

(5) Age Control and Life Limited Products. Records for articles and materials having definite characteristics of quality degradation or drift with age and/or use shall indicate the date and test time or cycle at which useful life was initiated, the life or cycles used, and the date and test time or cycle at which useful life will be expended. When appropriate, specify that the articles and materials exhibit similar information. Suppliers shall ensure removal or rework of such articles and materials as required.

(6) Identification and Data Retrieval. Identification and data retrieval requirements shall be specified.

(7) Inspection and Test Characteristics. Characteristics to be subject to inspection or tests by the supplier shall be specified.

(8) Inspection and Test Records. Inspection and test records to be maintained by the supplier shall be clearly specified. Records to be provided to the contractor or his quality assurance personnel shall be specified.

(9) Resubmission of Nonconforming Articles or Materials. Nonconforming articles and materials returned by the contractor and subsequently resubmitted by the supplier shall bear adequate identification of such nonconformance, either on the articles, materials, or applicable supplier records.

(10) GSI (Government Source Inspection). When the Government elects to perform inspection at a supplier's plant, the following statement shall be included in the procurement document:

"All work on this order is subject to inspection and test by the Government at any time and place. The Government quality representative who has been delegated NASA quality assurance functions on this procurement shall be notified immediately upon receipt of this order. The Government representative shall also be notified 48 hours in advance of the time articles or materials are ready for inspection or test."

(11) Procurements Other Than Those Requiring GSI. Procurements which do not require GSI shall include the following statement:

"The Government has the right to inspect any or all of the work included in this order at the supplier's plant."

(12) Records Retention. Detailed requirements for retention of records shall be specified by the contractor.

5.4 FABRICATION CONTROLS

a. Contamination Control. Contamination control requirements for flight hardware shall be clearly identified and controls developed from specification SN-C-0005, "Contamination Control Requirements for the Space Shuttle Program," as applicable.

b. Process Controls. Controls, including written procedures, shall be established over processes for which the uniform quality of articles or materials cannot be assured solely by inspections or tests. These processes include, for example, plating, anodizing, radiography, ultrasonics, magnetic particle and liquid penetrant inspection, heat treating, welding, and soldering. When approval or certification of processes, personnel, equipment, or procedures is required by contract, drawings or specifications, such approvals or certification of processes shall be obtained prior to processing articles and materials. Records shall be maintained of approvals and certifications of processes, personnel, equipment and procedures, and results of inspections associated with processes. These records shall be maintained to evidence continuous control over the processes involved.

5.5 TESTING, INSPECTION AND EVALUATION

a. Planning. The contractor shall provide the necessary planning function for the accomplishment of inspections and tests. The planning function will provide for:

(1) Inspection and Test Controls. Procured and fabricated articles and materials shall be inspected and tested to ensure conformance to contract requirements including applicable drawings, specifications, and changes thereto. These inspections shall occur during receiving, processing, fabrication, assembly, and shipping phases. Written specification and test procedures shall be prepared, supplementing contract requirements, to clarify details of the inspection and measuring equipment required, the detailed operations to be performed, the criteria for determining quality conformance or rejection of articles and materials and the results to be documented.

(2) Inspection and Test Records. Records of all inspection and test performed shall be maintained. The records shall provide evidence that the required inspections and tests for individual articles and materials have been performed.

(3) Inspection Status Controls. Control shall be maintained for continuously indicating the inspection status of articles and materials by using identifications distinctly different from Government inspection identification.

5.6 NONCONFORMING MATERIAL CONTROL

When an article or material does not conform to applicable drawings, specifications or other requirements, it shall be identified as nonconforming, segregated from work operations to the extent practicable, held for further action, and the nonconformance documented.

When a Material Review Board is authorized, the following decision on nonconforming material may be made:

- Return for Rework or Completion of Operations. Nonconformances may be corrected by rework or completion of operations using the established drawings, specifications or procedures. Such articles or materials shall be resubmitted to normal inspection and/or test operations.
- Scrap. Articles or materials obviously unfit for use shall be scrapped in accordance with Government approved contractor procedures for identifying, controlling, and disposing of scrap.
- Repair. Nonconformances which the contractor considers correctable by additional, documented repair procedures shall be submitted to the Material Review Board.
- Use As Is. Nonconformances which the contractor considers do not adversely affect safety, reliability, durability, performance, interchangeability, weight or basic objectives of the contract shall be submitted to the Material Review Board.

5.7 METROLOGY CONTROLS

A documented metrology system shall be established and utilized to control measurement processes in order to provide objective evidence of quality conformance. Measurement standards and equipment shall be selected and controlled to the degree necessary to meet contract requirements. Measurement processes shall be performed in accordance with established written procedures.

5.8 GOVERNMENT PROPERTY CONTROLS

The contractor shall be responsible for all Government property supplied by the Government in accordance with provisions of the contract. Contractor responsibilities towards Government property shall include, but not be limited to, the following:

- Examination upon receipt to detect damage in transit.
- Inspection for quantity, completeness, proper type, size and grade as specified in shipping documents.
- Provision for the protection, maintenance, calibration, periodic inspection, segregation and controls necessary to prevent unauthorized use, damage, or deterioration during handling, storage, installation, or shipment.

6.0 PROBLEM REPORTING AND CORRECTIVE ACTION

The contractor shall provide a system for the reporting of all problems (failures and unsatisfactory condition reports) and the establishment of corrective action for all problems concerning flight and certification hardware, GFE for which the contractor is cognizant, and spare hardware. The contractor shall be responsible for ensuring that problem reporting and corrective action system of suppliers will meet the requirements of this section. Formal failure reporting shall commence at the start of acceptance testing of production hardware (including certification hardware).

a. Problem Reporting - Reporting of problems shall be as directed in the contract and task order.

b. Problem Analysis - An analysis of each problem reported to NASA shall be performed to determine the cause of the problem and to implement adequate measures to prevent its recurrence.

c. Problem Resolution - The contractor shall resolve each problem by one of two methods: closeout or explanation. The contractor shall direct all efforts toward closing a problem in lieu of an explanation, and in no case shall the contractor attempt to explain a problem until it becomes impracticable to close the problem.

d. Problem Status - The contractor shall maintain a status on all open problems. The methods employed by the contractor in maintaining the status of problems shall be compatible with those of NASA in responding to requests for information.

7.0 SOURCE SELECTION

Quality Assurance will assist in the source selection by performing the following tasks, as applicable to each procurement:

a. Conduct pre-award surveys to determine the capability of the supplier's quality system to satisfy procurement specification and quality requirements. The survey will consist of a review of the quality, organization, calibration system control of manufacturing, inspection and measuring system and packaging and shipping.

b. Evaluation of supplier responses to RFP's (request for proposal). Basic quality assurance considerations will be responsiveness to quality provisions, past performance, and quality costs.

c. Post award survey/conferences. Resolve open problems regarding requirement interpretations and conduct DCAS delegation conference, if applicable.

d. Arrange for GSI and provide quality delegation instructions.

PROCUREMENT DESCRIPTION	QA LEVELS
<p><u>CLASS A</u></p> <p>Supplier Designed</p> <p>Complex Design or Manufacture</p> <p>State of the Art Advancement</p> <p>Mission Success Critical</p> <p>Cost in Excess of One Million Dollars</p>	<p>5.1 Management and Planning</p> <p>5.2 Identification and Data Retrieval</p> <p>5.3 Procurement Controls</p> <p>5.4 Fabrication Controls</p> <p>5.5 Testing, Inspection and Evaluation</p> <p>5.6 Nonconforming Material Control</p> <p>5.7 Metrology Control</p> <p>5.8 Government Property Controls</p> <p>6.0 Problem Reporting and Corrective Action</p> <p>NOTE: Numbers refer to paragraphs in text.</p>

TABLE 1

PROCUREMENT DESCRIPTION	QA LEVELS
<p><u>CLASS B</u></p> <p>Modified Off-the-Shelf</p> <p>Moderately Complex Design or Manufacture</p> <p>Nonmission Success Critical</p> <p>Some Flight History</p> <p>Cost - 250 Thousand to 1 Million</p>	<p>5.1 (a) and (c) - Certification Change Control</p> <p>5.3 (a), (b) and (c) - Procurement Controls</p> <p>5.4 (b) - Process Controls</p> <p>5.5 (1) - Inspection and Test Controls</p> <p>5.6 - Nonconforming Material Control</p> <p>5.7 - Metrology</p> <p>5.8 - Government Property Controls</p> <p>6.0 Problem Reporting and Corrective Action</p> <p>NOTE: Numbers refer to paragraphs in text.</p>

TABLE 2

PROCUREMENT DESCRIPTION

QA LEVELS

CLASS C

Commercial Off-the-Shelf

Supplier Designed or Manufacture

No Flight History

Nonmission Success Critical

Cost Less Than 250 Thousand

Engineering Drawings

Test Data

Certificate of Compliance/Conformance

NOTE: Engineering drawings and test data may be developed by LSPD or provided by the supplier. Certificate of compliance/conformance will be provided by the supplier.

PROCUREMENT DESCRIPTION

QA LEVELS

GROUND SUPPORT EQUIPMENT

Class 1

Spacelab/STS Interface

Class 2

Experiment Interface Only

Paragraph 4.2 of SM-E-0002

Certificate of Compliance/Conformance

Test Data

Engineering Drawings

NOTE: Certificate of compliance/conformance will be provided by the supplier. Test data and engineering drawings may be provided by LSPD or the supplier.