Good Manufacturing Practices Performance Assurance Plan

Mo/Yr

Revisions		Rev:
Letter	E.O. Number - Description	Date

Used On	Contract#:		**Your Co**
Prepared By:			
Your Dept:			
Your Dept:			**GOOD MANUFACTURING PRACTICES**
Your Dept:			Your Procedure #
Your Dept:			Size: **A** CAGE: Your Form # (mo/yr)

Your Logo

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1.0 GENERAL

1.1 BASIC REQUIREMENTS

This Performance Assurance Plan (PAP) applies to hardware-software and ensures that Good Manufacturing Practices (GMP) and Quality Assurance requirements are satisfied throughout all phases of the project.

1.2 SCOPE OF REQUIREMENTS

This PAP describes the methods and controls to be implemented by (Your Co) for its GMP and QA program. The PAP shall be invoked and maintained throughout the project. The deliverable hardware being built by (Your Supplier) for the project falls within the definition of Quality Assurance Level ?? of the Supplier Quality Assurance Plan.

The requirements of this PAP shall be flowed down to subcontractors and/or suppliers via (Your #). Conformance to (Your #) and/or approved internal procedures shall allow subcontractors and suppliers to maintain compliance with the requirements of the project.

The following list provides a summary of the developed hardware-software requirements for the project:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

e) [redacted]

f) [redacted]

g) [redacted]

h) [redacted]

i) [redacted]

j) [redacted]

k) The disposition of nonconforming parts and materials shall be in accordance with t[redacted]

l) [redacted]

m) [redacted]

n) [redacted]

o) This table summarizes the configuration requirements for the project:

[redacted]

1.2.1 REFERENCES

(Your Co)

1.3 ORDER OF PRECEDENCE

Once approved by (Your Customer), this plan becomes the primary controlling document for all activities in the project, and other documents are only applicable to the extent specified herein. In the event of conflict between this document and any referenced document, this document shall govern. Document revisions in effect at the time of the PAP approval shall apply. The original signatories shall [redacted]

The quality representative shall [redacted]

1.4 MANAGEMENT OF THE ASSURANCE PROJECT

The (Your Customer) Project Office and (Your Co) Program Manager have been given oversight responsibility for reliability, quality assurance, and design issues. The Program Manager of (Your Co) reports directly to (Your Customer) Project Office and is responsible for [redacted] A Responsible Engineering Authority (REA) must be assigned to the project. The REA shall [redacted] The REA is the single point of contact between (Your Co) and the (Your Customer) Project Office for R&QA issues.

Figure 1. (Your Co) Organization

Figure 2. (Your Co) Quality Assurance Group Organization

The (Your Co) Department shall employ drafting, package design, fabrication, assembly, and Quality Control (QC) inspection services of the (Your Co) Department to build deliverable hardware. Figure 3 shows the (Your Co) organization, which supports hardware fabrication. Quality Control (QC) inspectors from (Your Co) work with (Your Customer) personnel to provide the workmanship and configuration control inspections necessary to ensure a reliable and adequately configured end product. (Your Co) Quality Assurance has the following functions:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]

Figure 3. (Your Co) Department Organization

1.5 STATUS REPORTS

The REA shall report the status of QA activities, problems, and deficiencies, (both in-house and from outside subcontractors) to the Program Manager and the (Your Customer) Project Office monthly, via the Contracts Group. The REA shall include the following quality assurance information as part of the QA report:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]

1.6 PROCUREMENT

1.6.1 General

All purchased hardware specifications shall have quality requirements included in the procurement documents. (Your Co) shall perform the following tasks as appropriate to verify the quality and reliability of hardware purchased from subcontractors and vendors for the project:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]

1.6.2 Supplier Controls

1.6.2.1 General

(Your Co) shall review the reliability and quality requirements of purchased materials, articles, and services for the hardware as necessary.

1.6.2.2 Selection of Qualified Procurement Sources

When requested, (Your Co) shall recommend procurement sources, which are capable of [redacted]

1.6.2.3 Preferred EEE Parts Supplier

(Your Customer) may have identified certain preferred manufacturers of parts and components, based on [redacted]

1.6.2.4 Procurement Documents

The requirements of this plan shall be imposed upon subcontractors and/or suppliers to the extent necessary to assure compliance with the requirements of the project. Provisions shall be included for:

a) [redacted]
b) [redacted]
c) [redacted]

1.6.2.5 Specifications Review

All procurement specifications shall be reviewed by (Your Co) prior to release. This review shall determine, as a minimum, that:

a) [redacted]

b) [redacted]

1.7 SURVEYS AND AUDITS

The Quality Assurance Group shall perform surveys and audits, as necessary, to evaluate the adequacy of and conformance to these QA requirements. Audits of (Your Co) shall be performed in accordance with (Your #) Audit Procedure. Subcontractor and supplier surveys shall be performed in accordance with (Your #), Procedure for Supplier Quality Surveys. These surveys and audits shall provide [redacted] The frequency of a particular survey/audit in a given area shall be based upon [redacted]

2.0 PRODUCT ASSURANCE REVIEWS

2.1 DESIGN DRAWINGS

The Project shall use a Level ?? drawing system. Level ?? drawing and change control signature responsibilities shall be documented by (Your Co). All drawing changes shall [redacted]

2.2 DESIGN REVIEWS

2.2.1 Design Reviews

(Your Co), under the direction of the REA, shall conduct formal and documented design reviews of the hardware designs. These reviews shall include [redacted]

Design data packages shall be available as agreed by the (Your Customer) Project Office. Application level reviews include all activities associated with the project. The Principle Investigator (PI) shall [redacted]

[redacted]

2.2.2 Subsystem Design Reviews

Acceptance reviews shall be held for instruments, components, and hardware/software. The REA shall schedule in-house reviews of subsystem electronic circuit and packaging design, manufacturability, test readiness, and integration readiness in accordance with (Your #). Minutes of these reviews shall be distributed internally. Electronic packaging design and manufacturability reviews [redacted]

2.2.3 Design Review Support

(Your Co) shall participate in design reviews. The REA shall attend or arrange for representatives to participate in design reviews to ensure [redacted]

2.2.4 Review of Existing/Modified Designs

Certain components, either procured or designed and fabricated by (Your Co), that have heritage in previously accepted hardware, shall [redacted]

2.3 ACCEPTANCE DATA PACKAGE

An Acceptance Data Package shall be available ten days prior to the Final Acceptance Review as a part of the data package for that review. The Acceptance Data Package shall include [redacted]

3.0 PERFORMANCE VERIFICATION REQUIREMENTS

3.1 GENERAL

All components of the hardware (including instruments) shall be tested to levels necessary to ensure the capability of the design to perform its intended function, in accordance with the Environmental Specification, (Your #). Test plans shall identify [redacted] The test plan shall be in accordance with, and shall satisfy, the applicable portions of the performance verification requirements for the deliverable hardware, including [redacted]

3.2 ACCEPTANCE TEST DOCUMENTATION

Acceptance tests shall be performed on all components and instruments. Acceptance tests shall [redacted]

3.2.1 Acceptance Test Report

A brief test report summarizing test results and their implications shall be available within 10 days after test completion. A final test report shall be prepared within 30 days after test completion.

3.2.2 Documents and Records of All Acceptance Tests and Inspections

The disposition of acceptance test documents and records shall be as specified in the Acceptance Test Plans and Procedures. The scope, duration, and number of inspections and tests to be conducted on the completed equipment shall [redacted] After acceptance tests and inspection have been completed, the REA and Program Manager shall [redacted] The Test Review Board shall determine the extent of any re-inspection or retest. The Quality Assurance inspectors shall [redacted]

3.3 GROUND SUPPORT EQUIPMENT (GSE)

Prior to use for testing hardware, all GSE (if applicable) shall [redacted]

3.4 TEST REVIEW BOARD (TRB)

A Test Review Board shall be established. The TRB members shall include (or represent) the cognizant Design Engineer, REA, QA Engineer, and Program Manager. The TRB shall:

a) [redacted]

b) [redacted]

c) [redacted]

3.5 PROJECT DOCUMENTATION RECORDS

Records that provide evidence of inspections, tests, configuration and material review actions during the fabrication and assembly process shall be maintained. These records shall become a part of the end unit data package. The documentation listed below shall be used to provide a complete record of the hardware, including traceability, configuration control, and application history:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]
f) [redacted]
g) [redacted]
h) [redacted]
i) [redacted]

3.6 PROBLEM/FAILURE REPORTS AND CORRECTIVE ACTION

Problem/failure reporting is initiated with acceptance testing of a component or instrument and continues throughout integration and test of the final assembly. Problem/failures occurring at subcontractor or other team organizations shall [redacted] After the start of integration, any problem/failures on subcontracted items or instruments shall [redacted] Any subsequent failure analyses and/or corrective actions [redacted] The closeout of all P/FRs shall [redacted]

3.7 FAILURE-FREE OPERATION

Hardware shall demonstrate a minimum of xx hours cumulative failure-free operation immediately prior to delivery.

4.0 SAFETY ASSURANCE

The Program Manager is responsible for [redacted] This responsibility includes [redacted]

4.1 PERSONNEL SAFETY

All appropriate precautions shall be taken to provide for maximum protection of personnel. Where necessary, special provisions shall be made and/or procedures prepared to [redacted]

4.2 HARDWARE SAFETY

Provisions shall be made to protect hardware from damage. Accepted safety practices include but are not limited to the following:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

e) [redacted]

5.0 EEE PARTS REQUIREMENTS AND DEFINITIONS

(Your Co) shall: (1) [redacted] (2) [redacted] (3) [redacted] (4) [redacted] (5) [redacted] (6) [redacted]

5.1 PARTS, MATERIALS, & PROCESS SELECTION and SPECIFICATION

Approved EEE parts for hardware include [redacted]

[redacted]

5.2 EEE PARTS SCREENING

5.2.1 EEE Parts Screening and Test

EEE screening shall be in accordance with (Your Co) requirements as defined in (Your #). Optional additional testing may be specified by (Your Co) based on [redacted]

Parts which are not selected from a valid QPL or PPL and that cannot meet the above criteria shall [redacted] Additionally, any other screening deemed necessary shall be imposed by (Your Co) depending on the criticality of the parts.

5.2.2 Data Evaluation

All manufacturer test data purchased with EEE parts, and test data generated by (Your Co) shall [redacted] Deficiencies shall be reviewed with the REA to determine the impact on part performance. If serious deficiencies exist, which cannot be resolved with the manufacturer and the REA, the lot shall [redacted]

5.2.3 Destructive Physical Analysis

When recommended by (Your Co), Destructive Physical Analysis (DPA) shall be performed in accordance with (Your #), Destructive Physical Analysis Procedure. DPA shall be imposed with the concurrence of the Program Manager. Pre-cap inspection by (Your Customer) or its designated representative may [redacted]

5.2.4 Re-testing of EEE Parts in Stock

Parts intended to be issued from existing stock shall be reviewed for storage life considerations prior to issuance to systems. If at the time of review, the parts have not been electrically tested and visually inspected within 10 years, they shall [redacted]

5.3 (Your Customer) MANUFACTURED EEE PARTS

Parts manufactured at (Your Customer) for assembly shall be evaluated as above. The REA shall [redacted]

[redacted]

6.0 MATERIALS AND PROCESS CONTROLS

6.1 MATERIALS AND PROCESSES

Materials and processes used to fabricate hardware shall be reviewed for acceptability, compatibility, and conformance to applicable design documentation and quality assurance requirements. Controls are initiated from [redacted] Production tooling, jigs, fixtures, and other equipment affecting critical dimensions, contours, or location of machine operations shall [redacted]
Nonmetallic materials selected for use shall be reviewed for previous experience and for conformance to properties using (Your Co) Publication, (Your #). Potential outgassing materials that are not within a hermetic enclosure shall [redacted]

6.2 METALLIC MATERIAL SELECTION

Materials selected for use as structural elements, housings, brackets, etc. shall be subject to the criteria of (Your #) for controlling [redacted] When recommended, the nondestructive test inspection methods of (Your #) shall be used. The test results shall be maintained by (Your Co).

6.3 PARTS AND MATERIALS LIST

Materials shall be identified in fabrication drawing bills of materials for hardware. An as-built parts and materials list shall be prepared for hardware, and shall include the following:

a) [redacted]
b) [redacted]

6.4 CRITICAL FASTENERS

For the project, any fastener whose failure could contribute to a single point failure of the system shall be designated a "Critical Fastener." "Critical Fasteners" shall be identified during the design phase of the project. The list of identified "Critical Fasteners" shall [redacted]

6.5 CORROSION PROTECTION

Metals shall be of the corrosion-resistant type or suitably protected to resist corrosion.

The hardware shall be designed so as to avoid [redacted]

6.6 FINISHES AND COATINGS

The use of cadmium, zinc and pure tin is prohibited.

6.7 PRINTED WIRING BOARDS

Printed wiring boards (PWBs) shall meet the requirements of (Your #). Design requirements governing printed wiring boards, printed wiring assemblies, and design considerations for the mounting of parts and assemblies shall be in accordance with (Your #).

7.0 DESIGN ASSURANCE AND RELIABILITY REQUIREMENTS

7.1 RESPONSIBILITIES AND ORGANIZATION

The reliability tasks shall be undertaken and achieved principally by (Your Co), using (Your #) as a guide.

7.2 WORST-CASE ANALYSIS

Electronic circuits and electromechanical and mechanical items shall be designed using a worst-case design philosophy, in which the engineer considers [redacted]

7.3 TREND ANALYSIS

Trend analyses shall identify performance parameters for critical components, subsystems, and systems, which may require [redacted]

7.4 MAINTAINABILITY

To the extent possible, design features shall allow component access and facilitate performance of all [redacted]

7.5 EEE PARTS STRESS DERATING

EEE parts derating shall be in accordance with (Your #). Each electronic/electrical design engineer shall be responsible for [redacted]

[redacted] Parts that do not meet the derating criteria must [redacted]

7.6 LIMITED-LIFE ITEMS

Limited-life items shall be identified on a Limited-Life Items List and included as part of the deliverable data package.

8.0 QUALITY ASSURANCE

8.1 TRAINING AND CERTIFICATION OF PERSONNEL

Supervisors shall ensure that all persons working on high-reliability hardware have received the proper training to produce high quality workmanship. Training is comprised of specific instruction in several basic areas as follows:

a) [redacted]

b) [redacted]

c) [redacted]

d) [redacted]

8.2 ELECTROSTATIC DISCHARGE (ESD) CONTROL

Hardware shall be protected from ESD damage according to (Your #).

8.3 NON-CONFORMANCE CONTROL

Nonconforming articles or materials (defined as those not satisfying fabrication, processing, assembly, or configuration requirements) shall be reviewed initially by Quality Assurance personnel and shall be subjected to one of the following dispositions:

a) [redacted]

b) [redacted]

c) [redacted]

8.4 MATERIAL REVIEW BOARD (MRB)

All referred non-conformances shall be evaluated by a MRB, as a minimum consisting of:

(1) [redacted] (2) [redacted] (3) [redacted] (4) [redacted]

The MRB shall draw upon the various skill centers as required. A report of the MRB action shall be prepared on a Material Report Form (MRF) and shall include [redacted]

Unanimous agreement must be obtained from the four MRB members, and for all articles and materials submitted to the MRB one of the following dispositions shall be directed. When there is not unanimous agreement, one of the steps below shall be followed at the option of the Program Manager.

a) [redacted]

b) [redacted]

c) [redacted]

8.5 SUBCONTRACTOR QUALITY REQUIREMENTS

8.5.1 Source Selection

Source selection shall be based upon the supplier's past performance history. Where no previous quality records are available, [redacted] For (Your Customer) suppliers, surveys shall be performed in accordance with (Your #) Quality Survey.

8.5.2 Supplier Product Assurance Requirements

A Supplier Quality Requirements document shall be generated by (Your Co) to delineate the QA requirements.

8.5.3 Quality Assurance Inspection at Subcontractor Facilities

Source inspection at the supplier's facility may be required by purchase order or contract upon the recommendation of the QA authority and approved by the PM. The appropriate QA authority or a designated alternate shall [redacted]

8.5.4 Supplier MRB

When suppliers of components, subsystems, or systems are delegated MRB authority, they shall [redacted]

In all delegations, (Your Customer) reserves the right to disapprove the supplier's MRB decisions.

The supplier shall prepare a deviation or waiver for project approval to accept any discrepant hardware only when [redacted]

8.5.5 Hardware Buy-Offs

For subcontracted equipment, the buy-off meeting serves the purpose of the Integration Readiness Review for subsystems. The supplier's QA documentation package is reviewed, and

the lead engineer reviews and approves the unit's test results, and confirms readiness to ship and integrate.

8.6 INSPECTION AND CONTROLS

QA personnel shall work closely with the REA to jointly determine the most cost effective, practical approach to ensure QA requirements are met. Inspections, evaluations, and/or audits shall be performed at the level necessary to assure compliance with the following:

a) [redacted]
b) [redacted]
c) [redacted]
d) [redacted]
e) [redacted]

Inspection of support equipment shall be limited to [redacted] Ground support equipment that interfaces with hardware shall [redacted]

8.7 STAMP CONTROL SYSTEM

8.7.1 Stamp Log

An inspection stamp log shall be used to maintain traceability to the individual responsible for the use of each specific stamp. Issuance of the stamp and maintenance of the log are controlled by the Quality Group.

8.7.2 Stamp Use

Inspection stamps shall be used to [redacted] The presence of the inspection stamp on the traveler shall [redacted]

8.8 SOFTWARE QUALITY ASSURANCE

The Software Group shall develop a Software Management Plan applicable to the project and shall implement software assurance controls and reviews in accordance with the plan.
The Software Management Plan shall be based on (Your Co) Guidelines. Key personnel shall [redacted]

8.9 INSPECTION, MEASURING, AND TEST EQUIPMENT CALIBRATION

Hardware acceptance testing requires the use of Class 1 test equipment as defined in (Your Co) Test and Measurement Equipment Calibration Practices and Procedures. Calibrations shall be performed using [redacted]

8.10 PRESERVATION, PACKAGING, HANDLING, STORAGE, AND SHIPPING

8.10.1 General

(Your Co) shall maintain procedures for preserving, packaging, handling, storing, and shipping to prevent damage, loss, deterioration, tampering, degradation, and substitution.
These procedures shall take into consideration [redacted]

8.10.2 Preservation

Preservation procedures shall be designed to protect items that are subject to deterioration from [redacted]

8.10.3 Handling

Any article subject to damage due to normal handling during fabrication or testing shall [redacted]

8.10.4 Storage

(Your Co) shall provide protected and controlled storage for all assembled articles as required. Special attention shall be given to [redacted]

8.10.5 Packaging and Shipping

Packaging procedures shall be maintained for protection from damage or deterioration of the articles being shipped. These procedures shall take into consideration [redacted]

9.0 CONTAMINATION CONTROL REQUIREMENTS

9.1 PROTECTION

Gloves, protective covers, and other appropriate measures shall be used as required.
The hardware shall be covered when being moved from one location to another and when [redacted]

9.2 FACILITIES

All fabrication of electronic hardware shall be performed in class [redacted] areas.

In addition, assembly and testing at the system level and for critical components shall be performed in controlled access class [redacted] areas. Class [redacted] or better work areas shall be available should such a need be identified by the instrument teams.

9.3 MONITORING

During periods of activity, Quality Assurance personnel shall monitor [redacted]

10.0 ACRONYMS AND ABBREVIATIONS

CDR Critical Design Review
CVCM Collected Volatile Condensable Mass
DCN Drawing Change Notice
DF Discrepancy Form
DESC Defense Electronic Supply Center
DPA Destructive Physical Analysis
DRR Drawing Release Review
EDR Engineering Design Review
EEE Electrical, Electronic, and Electromechanical
EMC Electromagnetic Compatibility
EMI Electromagnetic Interference
EO Engineering Order
ESD Electrostatic Discharge
[redacted]
GIDEP Government Industry Data Exchange Program
GSE Ground Support Equipment
GSI Government Source Inspection
ICD Interface Control Document
DMR Discrepant Material Report
IRR Integration Readiness Review
Mil-Spec Military Specification
MRB Material Review Board
MRF Material Report Form
NIST National Institute of Standards and Technology
QA Quality Assurance
PAP Performance Assurance Plan
PDR Preliminary Design Review
PER Pre-Environmental Review
P/FR Problem/Failure Reports
PI Purchase Instruction (or Principle Investigator)
PM Project Manager

PPL Preferred Parts List
PPP&M Preservation, Packaging, Packing, and Marking
PSR Pre-Ship Review
PWB Printed Wiring Boards
QA Quality Assurance
QC Quality Control
QML Qualified Manufacturers List
QPL Qualified Product List
REA Responsible Engineering Authority
RR Readiness Review
TML Total Mass Loss
TRB Test Review Board
TRR Test Readiness Review

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