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MARPA's Guidance Material for a PMA Continued Operational Safety (COS) System

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Aviation companies use their quality systems to help them meet business goals like satisfying customer demands and promoting industry safety. A properly implemented continued operational safety program is a tool to be integrated into a business' quality system in order to help that company achieve long-term safety goals through oversight of the life-cycle of their aircraft parts. This document was produced to aid PMA companies in establishing and managing a continued operational safety program. It represents one way but not the only way to implement such a program. A continued operational safety program should be tailored to the specific needs of the implementing company. Implementing a robust continued operational safety program should help encourage aviation safety, but it cannot eliminate all possible risk, and its effectiveness may depend on the specifics of implementation and oversight; MARPA makes no representations about the results of implementing continued operational safety program in accordance with this standard. A continued operational safety program is not required by the regulations of the Federal Aviation Administration. This document is not meant to reflect a minimum standard for safety. Compliance with this document is voluntary and not mandatory.

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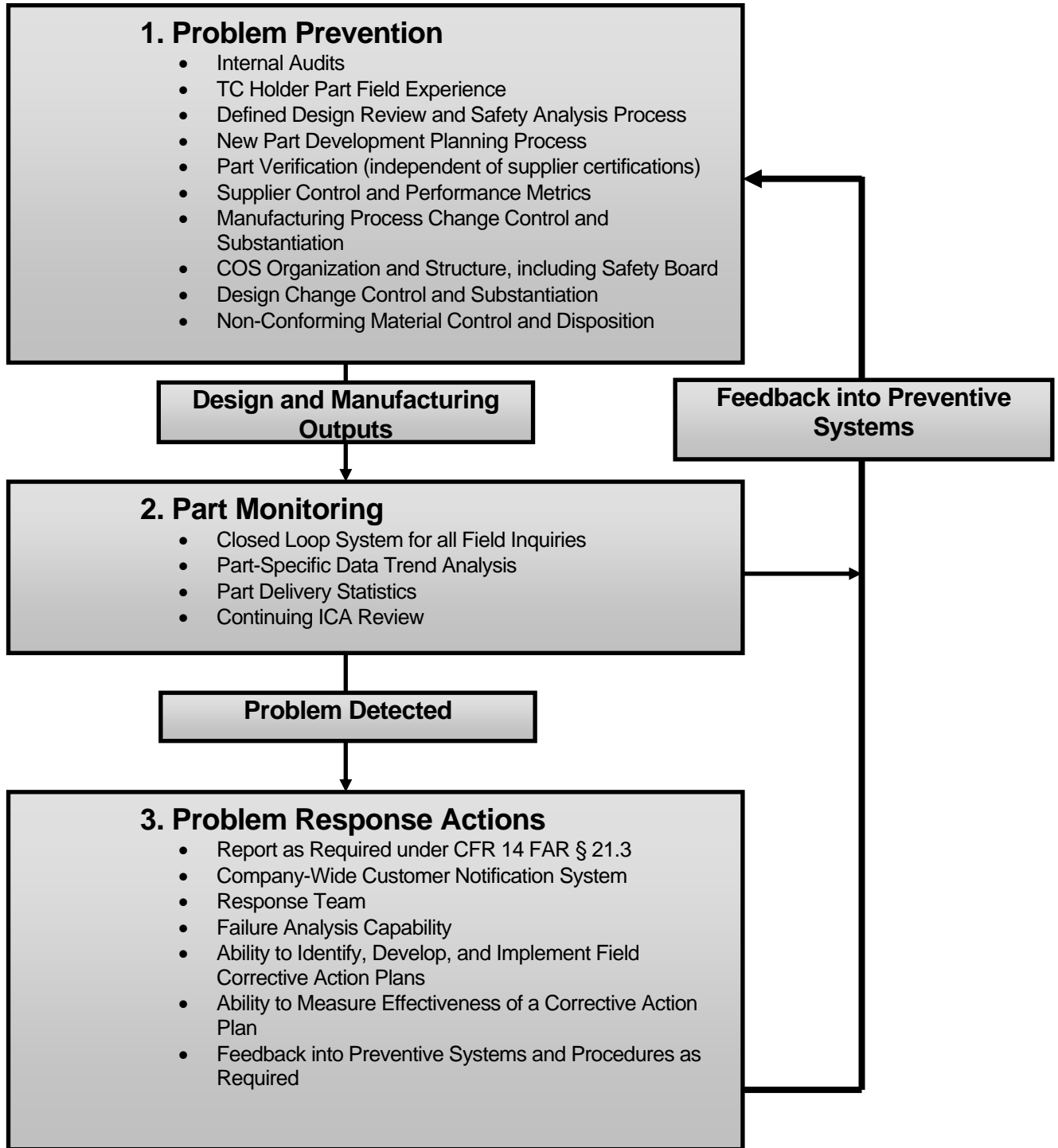
1.0 MARPA's Definition of COS

Continued Operational Safety is a closed-loop technical and logistical support system that ensures lifetime part safety and addresses applicable fleet requirements. This support system includes the following three fundamental elements addressed both before and after FAA part approval:

1. Problem Prevention
2. Part Monitoring
3. Problem Response

Figure 1 shows the MARPA PMA COS system overview.

Figure 1-Overview of MARPA's PMA COS System



Section 2

2.0 Fundamental Elements of MARPA's COS System

2.1 Preventive Systems/Procedures

The PMAH shall establish procedures within their quality system that includes the following:

2.1.1 Internal Audits-The PMAH shall perform internal audits at least annually in order to monitor compliance with required airworthiness standards and adequacy of the procedures to ensure that such procedures produce airworthy components. The internal audit part of the quality system may be contracted to another organization or a person with appropriate technical knowledge and proven satisfactory audit experience. The audit shall include a detailed review of all ACSEP audit results and any reporting under 14 CFR §21.3. The procedures shall have a quality feedback reporting system to the accountable manager that ensures proper and timely corrective action is taken in response to reports resulting from the independent audits performed.

2.1.2 TC Holder Part Field Experience-Prior to the candidate PMA induction the PMAH shall perform a comprehensive review of all available SDR/ASB/SB/AD and operator and maintenance provider inputs.

Service Difficulty Reports (<http://av-info.faa.gov/iSDR/>) and pertinent Airworthiness Bulletins shall be studied to understand the nature and extent of field issues connected to the PMA candidate part and any efforts toward corrective action on the part of the Type Design Holder. All available ICA (including Overhaul Instructions, Illustrated Parts Catalogs and Service Bulletins) shall also be reviewed. Operators and maintenance providers should be surveyed to assess their service experience with the PMA candidate; the scope of the survey should, at a minimum, enable confirmation of the findings of the SDR/ASB/SB/AD review.

The PMAH should review all available documentation related to the part throughout the part life cycle at regular intervals.

2.1.3 Defined Design Review and Safety Analysis Process-The PMAH shall have a Design Review process in place. The purpose is to systematically review the PMA candidate design at appropriate stages to establish appropriate requirements and then evaluate the ability of the results of the design activity to meet these requirements. The NHA, interface features and consequences of failure should be understood, thereby enabling identification of critical/major characteristics, feature and

manufacturing controls, and inspection plans. Follow-on reviews are intended to identify any problems and propose necessary actions, and authorize progression to the next stage. Participants in such reviews shall include representatives of functions concerned with the design being reviewed. Records of review and any actions shall be maintained. Elements of the review shall also include:

- A review of the available ICA and service history evaluation.
- A safety assessment of the PMA candidate. AC 33-75-1 can be used as guidance for engine products.

The part classification should be determined during this review to establish the extent of quality and manufacturing controls required.

2.1.4 New Part Development Planning Process-For complex parts Engineering should give consideration to structuring the design effort into significant elements to ensure part safety and reliability. The structure shall include:

- the design and development plan.
- the review, verification and validation that is appropriate to each design and development stage.
- the responsibilities and authorities for design and development, and project communication.
- design and development inputs related to part requirements shall be determined and records maintained. These inputs shall include:
 - functional and performance requirements.
 - applicable statutory and regulatory requirements.
 - information derived from previous similar designs.

2.1.5 Part Verification (Independent of Supplier Certifications)-The PMAH shall have a system in place to determine the conformity of incoming parts independent of supplier certifications. The extent of the evaluation shall include geometric, material and special process characteristics. The PMAH may contract the required services from appropriately qualified agencies, preferably those that hold ISO9001 or similar approvals.

2.1.6 Supplier Control and Performance Metrics-The PMAH shall evaluate and select suppliers based on supplier capabilities, performance and part criticality. Criteria for selection, evaluation, and re-evaluation of suppliers shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

The type and extent of control imposed onto the supplier for the purchased part or service is dependent upon the criticality of the part and the effect of the purchased part or service on downstream part realization. The control systems put in place shall meet the intent of AC 21-1B (Production Certificates) Para 9.d (7) and AC 21-20B

(Supplier Surveillance Procedures). When appropriate, the part shall be controlled through Engineering oversight of the manufacturing process, source inspection, and/or receiving inspection (see next Paragraph).

Suppliers shall be formally advised that that their facilities, personnel and articles being supplied are subject to evaluation and inspection by the PMAH and the FAA, as they constitute an extension of the facilities of the PMAH.

Supplier performance metrics should also comply with the intent of AC 21-1B paragraph 9.d (7).

2.1.7 Manufacturing Process Change Control and Substantiation-To ensure part safety and reliability, a system to control manufacturing processes and services should be considered. Such a system requires that each process be performed by qualified personnel and in accordance with approved specifications containing definitive standards of quality. Certain part categories may dictate the needs for Engineering Source Approval (fixed or frozen manufacturing processes) of changes to the manufacturing process and/or inspection system. Substantiation for a proposed process change may include functional and/or destructive testing.

2.1.8 COS Organization and Structure, including Safety Board-The PMAH shall have a defined COS Program Manager who is responsible for ensuring that the elements of the PMA Holder's COS systems and procedures are consistent with all regulatory and guidance material. In addition, the COS Program Manager shall be responsible for the creation and maintenance of PMA Holder's Safety Board. This Safety Board shall address any safety issues that may arise with the PMA Holder's parts. The Safety Board shall be responsible for communication with the FAA on any safety or airworthiness issues that may arise.

2.1.9 Design Change Control and Substantiation-The design change control process shall consist of a Review Board responsible for the evaluation and disposition of engineering change requests as well as the approval of initial releases of design data. Proposed changes will be reviewed with substantiating data, verified, and validated, as appropriate. Changes include evaluation of the effect of the changes on constituent parts verified and validated as appropriate, and approved prior to implementation (Ref 14 CFR §21.303h (7)). The PMA Holder's Safety Board shall review design changes as required by the approved COS system.

2.1.10 Non-Conforming Material Control and Disposition-The non-conforming material control and disposition process shall consist of a Review Board responsible for the evaluation and disposition of non-conforming material in accordance with the FAA approved Quality System. The PMA Holder's Safety Board shall review material dispositions as required by the approved COS system.

2.2. Part Monitoring

The PMAH shall establish procedures within their quality system that includes the following:

2.2.1 Closed Loop System for All Field Inquiries-The PMAH shall have a system and procedures in place to review, evaluate and respond to any inquiries or notifications of potential service problems from aircraft operators, maintenance service providers or the FAA. This procedure shall include a list of individuals or organizations within the company with defined responsibilities for responding to all inquiries/notifications. The procedure should require the PMAH to have appropriate methods and resources available to them to be able to identify the cause of any service difficulties, develop corrective actions and implement those actions in a timely manner. It should also define how the resolution and corrective action (if necessary) would be transmitted to the notifying entity, other entities potentially impacted (if necessary) and the FAA (per 14 CFR §21.3).

2.2.2 Part-Specific Performance Data Trend Analysis-A part-specific performance tracking system should be implemented for a PMA part that was determined during the design phase to have potential adverse effects on the operational safety of the NHA and/or product if it does not perform as intended. This system should include at a minimum, inspection and qualitative feedback from the part user after removal for any reason (including routine maintenance). The return of used parts to the PMAH for evaluation is preferred. When possible, the PMAH should develop an in-service plan with the product operator to assess part performance relative to the design assumptions.

2.2.3 Part Delivery Statistics-For all PMA parts delivered, the PMAH shall maintain records of the quantity shipped, ship date and customer. The records shall contain sufficient information to allow the PMAH to positively link each part shipped to the lot number or manufacturing order under which the parts were produced.

2.2.4 Continuing ICA Review-Each PMAH shall have a system and procedure in place to review all available new and revised TC Holder maintenance instructions, Service Bulletins, etc as well as Airworthiness Directives that pertain to the TCH part replaced by each of their PMAs. This system may utilize periodic searches of new or revised TC holder ICAs for referencing the TCH PN replaced by the PMA PN.

This procedure shall include a list of individuals or organizations within the company with defined responsibilities for determining if any new or updated ICAs potentially affect the performance of their PMA part and procedures for resolving any such issues. The procedure should define steps to be taken when it is determined that the PMA part is affected by new or revised ICA.

2.3. Problem Response Actions

The PMAH shall establish procedures within their Quality System that includes the following:

2.3.1 Report as Required under 14 CFR § 21.3-The FAA requires a means for reporting failures, malfunctions, defects and service difficulties. PMA Holders already have this requirement within the FAA approved Fabrication Inspection System (FIS). In addition to the PAH PMA approval letter requirements, AC 21-9A and AC 21-1B (Para 9.d. (12)) provides requirements for reporting under 14 CFR § 21.3.)

2.3.2 Company-Wide Customer Notification System-This system shall include a procedure for the release and control of technical information that is issued to ensure all necessary parties are aware of the field problem. The notification system may include FAA review. The notification system should include detailed technical instructions, which the end user can use to complete the necessary corrective action.

2.3.3 Response Team-A Response Team shall be developed to utilize expertise in resolving manufacturing, technical or in-service issues. The expertise may vary depending on the issue at hand and the particular part or system involved. Response teams shall be able to provide expertise and evaluate field issues, such that they not only facilitate the investigation but also provide resolution to the customer and the FAA.

2.3.4 Failure Analysis Capability-The PMAH shall be capable of providing a failure analysis of any in service or manufacturing difficulty. Failure analysis capability demonstrates that the PMAH has developed an understanding of the part, its interaction with mating parts, the NHA, and its manufacturing processes. A policy should be in place so the company as a whole understands where the responsibility lies in completing the failure analysis and how that information is disseminated and presented to the FAA if required. Although laboratory equipment does not have to be located at the facility, the PMAH must have the means to facilitate the analysis.

2.3.5 Ability to Identify, Develop, and Implement Field Corrective Action Plans-The PMA Holder's Safety Board directs the development and implementation of the field corrective action plan if it is required based on input from the Response Team. The PMAH should have a means of communicating with the supply chain and customers such that issues can be tracked and corrective actions implemented. The FIS should already include a corrective action procedure; however this procedure should be extended to include field corrective action plans.

The PAH Safety Board should conduct risk analysis of the PMA parts field reports that might involve a part reliability or safety issue for the product on which the part is installed. A good reference for creating a rational plan is AC 39-8: Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes. While there is not a parallel document at this time for airplanes, the process is outlined in AC 39-8 can be applied to assess the hazard severity and likelihood.

The risk analysis and PMAH proposed recommendations (Service Bulletin, Alert Service Bulletin, or AD) shall be reviewed and coordinated with FAA CMACO as early in the process as feasible.

The PMAH shall have the ability to source and manufacture replacement parts to ensure reliability and safety issues as required to satisfactorily manage FAA and customer expectations.

2.3.6 Ability to Measure Effectiveness of a Corrective Action Plan-Measurement of the effectiveness of the corrective action plan is a means to verify proper communication between customers, suppliers, and PMAH. When corrective action is implemented it should be monitored and compared analytically to the original data, which initiated the corrective action.

2.3.7 Feedback into Preventative Systems and Procedures as Required-The final closure to resolving service difficulties is providing feedback into the existing engineering, quality, manufacturing and safety systems. The aim is to prevent recurrence of these and similar problems, and at the very least minimize them before safety-critical action is required. Feedback can occur through various means such as a Lessons Learned library, training activities, and continuous monitoring. The PMA Holder's Management, Engineering, Manufacturing and Quality should be in the loop for service information leading to necessary changes regardless of the level of safety impacted. The key rationale is to develop and implement solutions for problem root cause so that they do not become field issues in the future.

3.0 Application of MARPA's COS System

General and Part-Specific COS Plans

The PMA COS system uses two levels, depending on the results of the safety analysis that is performed during the design phase.

3.1 General COS Plan-The General COS plan requirements would be the default requirements for all parts that do not require a part-specific COS plan. A reference to the FAA Approved PMA Holder's General COS requirements shall be included in the applicant's PMA data package.

3.2 Part-Specific COS Plan-A part should have a part-specific COS plan defined if it was determined during the design phase to have potential adverse effects on the operational safety of the NHA and/or product if the PMA candidate part does not perform as intended. This part-specific COS plan could add additional items that goes beyond the PMA Applicant's General COS plan, such as part reliability reporting, a life management system, or destructive testing of used parts. The part-specific COS plan would be defined or referenced in the PMA Applicant's data package and approved by the ACO prior to PMA approval.

4.0 Implementation and Verification of the COS System

Implementation

The PMAH or Applicant shall have a Quality System that is in compliance with the recommendations of this document.

Verification

Each PMAH shall develop an audit procedure to demonstrate initial and continued compliance of their Quality System to the general COS system requirements.

The PMAH may use the checklist in the Appendix A6.3 to ensure that their Quality System is in compliance with the PMA COS system.

5.0 Part Classification Guidance

Guidelines identifying classes of parts e.g. draft AC 33-XX, or various regulatory definitions of “critical” e.g.. 8110.42B, 14 CFR part 45.14, can be used as guidelines when addressing part specific COS needs stated in Section 3.2.

Additional part specific criteria regarding consequences of failures as stated in Order 8120.2D CHG 1or AC 25.1309-1A can also be used in the COS requirement evaluation.

A6.1 List of Abbreviations and Acronyms

AB	Airworthiness Bulletin
AC	Advisory Circular
ACO	Aircraft Certification Office
ACSEP	Aircraft Certification Systems Evaluation Program
AD	Advisory Directive or Airworthiness Directive
AIA	Aerospace Industries Association
AN	Army-Navy Aeronautical Standard
ANSI	American National Standards Institute
APIS	Approved Production Inspection System
ASB	Alert Service Bulletin
CAA	Civil Aviation Authority or Civil Aeronautics Authority
CFR	Code of Federal Regulations
CMACO	Certificate Management ACO
COS	Continued Operational Safety
DER	Designated Engineering Representative
EASA	European Air Safety Agency
FAA	Federal Aviation Administration
FAR	Federal Aviation Regulations
FIS	Fabrication Inspection System
ICA	Instructions for Continued Airworthiness

IPC	Illustrated Parts Catalog
MARPA	Modification and Replacement Parts Association
MIDO	Manufacturing Inspection District Office
MISO	Manufacturing Inspection Satellite Office
NAS	National Aerospace Standards
NHA	Next Higher Assembly
PAH	Production Approval Holder
Part 21	Certification Procedures for Products and Parts
Part 25	Airworthiness Standards: Transport Category Airplanes
Part 33	Airworthiness Standards: Aircraft Engines
Part 43	Maintenance, Preventive Maintenance, Rebuilding and Alteration
Part 45	Identification and Registration Marking
PC	Production Certificate
PI	Principal Inspector
PMA	Parts Manufacturer Approval
PMAH	Parts Manufacturer Approval Holder
PN	Part Number
SAIB	Special Airworthiness Information Bulletin
SAE	Society of Automotive Engineers
SB	Service Bulletin
SDR	Service Difficulty Report
STC	Supplemental Type Certificate
TC	Type Certificate
TCH	Type Certificate Holder
TSO	Technical Standard Order
TSOA	Technical Standard Order Authorization

A6.2 List of References

- 1) Title 14 CFR Part 21, Certification Procedures for Products and Parts.
- 2) Title 14 CFR Part 45, Identification and Registration Marking.
- 3) AC 21-9A, Manufacturers Reporting Failures, Malfunctions, or Defects, 26 May 1982.
- 4) AC 21-1B, Production Certificates, 10 May 1976.
- 5) AC 21-20B, Supplier Surveillance Procedures, 22 April 1996.
- 6) AC 25.1309-1A, System Design and Analysis, 21 June 1988.
- 7) AC 33-75-1, Guidance Material for 14 CFR § 33.75, Safety Analysis, 04 March 2005.
- 8) AC 33-XX, PROPOSED DRAFT-Turbine Engine Repairs and Alterations-Approval of Technical and Substantiation Data, Pending Action.
- 9) AC 39-8, Continued Airworthiness Assessments of Powerplant and Auxiliary Power Unit Installations of Transport Category Airplanes, 08 September 2003.
- 10) FAA Order 8100.7C, Aircraft Certification Systems Evaluation Program, 12 October 2005.
- 11) FAA Order 8110.42B, Parts Manufacturer Approval Procedures, 09 September 2005.
- 12) FAA Order 8120.2D CHG 1, Production Approval and Certificate Management Procedures, 23 September 2005.
- 13) FAA Policy Memo ANE-2004-33.4-4, Design Approval Procedures for Parts Manufacturer Approval of Critical Engine and Propeller Parts, 23 September 2005.
- 14) Proposal for Guidance Material for a PMA Continued Operational Safety (COS) System, MARPA Report No. MA-05-1102 Initial Release, 2 November 2005.

A6.3 PMA COS System Compliance Checklist

PMA COS System Element	Yes	No
2.1 Preventive Systems/Procedures		
2.1.1 Internal Audits Scheduled and Performed?		
2.1.2 TC Holder Part Field Experience Reviewed?		
2.1.3 Defined Design Review and Safety Analysis Process?		
2.1.4 New Part Development Planning Process Exists?		
2.1.5 Independent Part Verification Performed?		
2.1.6 Supplier Control and Performance Metrics Exist?		
2.1.7 Manufacturing Process Change Control Exists as Required?		
2.1.8 COS Organization and Structure, Including Safety Board Exists?		
2.1.9 Design Change Control and Substantiation Process Exists?		
2.1.10 Non-Conforming Material Control and Disposition Process Exists?		
2.2 Part Monitoring		
2.2.1 Closed Loops System Exists for All Field Inquiries?		
2.2.2 Part Specific Performance Data Trend Analysis Exists as Required?		
2.2.3 Part Deliver Statistics are Available for Review?		
2.2.4 Continuing ICA Review Performed?		
2.3 Problem Response Actions		
2.3.1 Reporting as Required under 14 CFR § 21.3 Procedure Exists?		
2.3.2 A Company-Wide Customer Notification System Exists?		
2.3.3 A Response Team has been Developed?		
2.3.4 Failure Analysis Capability Exists?		
2.3.5 The Ability to Identify, Develop, and Implement Field Corrective Action Plans Exists?		
2.3.6 The Ability to Measure the Effectiveness of a Corrective Action Plan Exists?		
2.3.7 A System Exists to Provide Feedback into Preventive Systems and Procedures?		

A6.4 Revision History

September 16, 2007 (Revision 1) – Legal disclaimer added; address updated on page one to reflect MARPA’s new office location.