QUALITY ASSURANCE SYSTEM EVALUATION PROCEDURE

JOB FUNCTION 11

1. Purpose

To perform aviation products and parts quality assurance systems audit and promote aviation product quality standard to enhance aviation safety.

2.General

A. Definition

The words that doesn't present in Regulations Governing the Certification for Aviation Products, Appliances and Parts (06-07A), their definition are as follow:

(1) Quality Assurance System Evaluation Program(QASEP): This Program is an element of certificate management, is a vital element within the FAA's mission of continued operational safety, including the pre- and post-evaluation activities and the certification management information system.(8100.7E P1&7)

(2)Production Approval Holder (PAH)：The holder of Production Certificate (PC)、Parts Manufacturer Approval (PMA)、 Technical Standard Order Authorization (TSOA)。

(3)Priority Part：For the purpose of establishing civil aviation authority surveillance priorities, priority part is defined as any part or assembly in an civil aviation authority approved design that, if it was to fail, could reasonably be expected to cause an unsafe condition in an aircraft, engine, or propeller.

(4)Priority Part Supplier：The manufacturer of a priority part who furnishes products to a PAH。

(5)Principal Inspector: A manufacturing inspector who has been assigned to audit a PAH.

B. Applicability

The QASEP will evaluate holders of a PC, PMA, and TSOA, and associate facilities. The holders could hold one or more than one Certificate. It will also evaluate their suppliers of priority parts.

C. Evaluation Team

CAA should establish teams to evaluate Production Approval Applicant and

Production Approval Holders and according this procedure to perform schedule or non-schedule evaluation. Manufacturer should correct the deficiency found in evaluation. If manufacturer doesn't perform correct action, CAA could suspend, pending or terminate the certificate. If it causes aviation safety accident, CAA could perform enforcement according to relevant regulation.

D. Scheduled Evaluation

CAA will assign Principal Inspector to evaluate the approved PAH according to the types of production approvals. The evaluation frequency to all facilities basically is once for every 12 months. The evaluation frequency can be lengthen or shorten by CAA as appropriate.

E. Non-Scheduled Evaluation

For those PAHs as mentioned in paragraph 2.B., in addition to the evaluation described in paragraph 2.D., CAA may also conduct non-schedule evaluation under the conditions listed below:

(1). Accidents and incidents.
(2). Deliberate violations.
(3). Repetitive Service difficulty reports.
(4). SUP investigations.
(5). Excessive owner/operator complaints.
(6). PAH's or associate facility's refusal/ fail to take appropriate corrective action.
(7). PAH's or associate facility's inability to control suppliers.
(8). Renewal of a PAH's or associate facility's production activity after a prolonged period of inactivity.
(9). Relocation of production facility.
(10). Any other situation as deemed necessary in the interest of safety.

F. Lead Time for Evaluation Notification

CAA should inform the manufacturer before conducting the evaluation, also informs PAH and priority parts supplier. PAH should join the evaluation during all the period.

G. Work of Evaluation Team

(1). CAA assigns certification program manager as team leader, and team leader select inspectors and engineers as team members to organize an evaluation team.

(2). The QASEP evaluation team will evaluate up to 6 major systems including:
(a).Organization Management－The system responsible to establish policy for

and to control engineering and production function. It is to evaluate facility's managemental and organizational structure. (Please refer to Job Function 11.1)

(b).Design Control－The system responsible to establish procedures for and to control continued integrity of the CAA-approved design data subsequent to initial CAA approval. It is to evaluate facility's engineering approval, control and record keeping process. (Please refer to Job Function 11.2)

(c).Software Quality Assurance－The system responsible to establish procedures for continuously maintaining the integrity of software that (a).used in type-certificated aircraft or related products (b).used for product acceptance and hardware that used for the same purpose as well. It is to evaluate facility's planning and integration for continuously maintaining the software and related control procedures. (Please refer to Job Function 11.3)

(d).Manufacturing Processes－It is to evaluate facility's specific functions and operations necessary for the fabrication and inspection of parts and assemblies. Including the acceptance, process, assembly, test, inspection, storage and delivery of materials, parts, and components. (Please refer to Job Function 11.4)

(e). Manufacturing Control－It is to evaluate facility's capability to assure the products are manufactured through the manufacturing processes as mentioned in (d), and conformity to CAA approved design data. (Please refer to Job Function 11.5)

(f).Supplier Control－It is to evaluate facility's capability to ensure supplier materials, parts, and services conform to CAA approved design data. (Please refer to Job Function 11.6)

3. Conduct of the Evaluation

A. Evaluation Plan

The team leader will coordinate with the designated representative of the facility to be evaluated to ensure that all the administrative arrangements are complete.

Evaluation team should prepare a written evaluation plan before conducting the evaluation. The evaluation plan may include the following items:

(1). Name and address of facility to be evaluated.

(2). Date of evaluation.

(3). Names of team leader and members.

(4). Evaluation Objectives.

(5). Types of approvals.

(6). Type Certificate (TC) or Supplemental Type Certificate (STC) number, when applicable.

(7). List of top-level CAA approved procedures (for example, index of procedures

for quality manual, PMA approval letter, TC data sheets.)

(8). Organizational chart.

(9). Special emphasis items recommended by the PI and assigned engineer.

(10). Subsystem assignments for team members.

B. Pre-Evaluation Team Meeting

The team leader and all team members shall meet in advance of starting the evaluation. They shall review the following evaluation elements, for proper coordination and understanding:

(1). Current quality system and corrective action history of the facility to be evaluated in the selected areas.

(2). Team functional assignments

(3). Evaluation plan

(4). Evaluation objectives.

(5). Organizational structure of the facility to be evaluated.

(6). Approved quality system documents, including any quality manual or quality data submitted by PAH.

C. Pre-Evaluation Conference

As soon as the team arrives at the facility, the team leader should conduct a pre-evaluation conference with team members, appropriate personnel of the facility. The team leader should introduce team members and supporting service personnel, give a brief overview of QASEP, provide the evaluation's scope and objectives. Review details of the evaluation agenda, including evaluation criteria and procedure to be used, and arrangements for the post-evaluation conference.

D. Recording the Evaluation Result

During the evaluation, team member use QASEP Check List to record evaluation result, and record discrepancy in CAA Form 8100-06, or electronic equivalent, and indicate the types of noncompliance. Noncompliance can be classified as: (a). Safety related noncompliance (b).Systematic noncompliance (c). Isolated noncompliance (d). Certification related noncompliance.

E. Evaluation Team Meeting

The team leader will hold meetings with team members, PI and assigned engineer daily during the evaluation period. To review and discuss the following items: status of the evaluation, problem encountered, plan of next day's evaluation, evaluation records, evaluation progress, rescheduling and focal points of evaluation in the

coming days.

F. Post- Evaluation Conference

The team leader shall conduct a post- evaluation conference. To give a brief presentation of the overall results of the evaluation, Explain and provide a copy of the completed QASEP evaluation executive summary to the facility, collecting all the noncompliance items.

G. Evaluation Report

When the evaluation was completed, the team leader shall prepare the evaluation report. The report includes CAA Form 8100-06. CAA will use the report as a reference for continuous improvement.

4. Reference

A. Regulations Governing the Certification for Aviation Products, Appliances and Parts (06-07A)

B. Production certification and surveillance procedure

C. FAA Order 8100.7C Aircraft Certification Systems Evaluation Program

5. Forms

Appendix One : Record of Findings/Observations (CAA Form 8100-06)

Appendix Two : Organization Management Check List

Appendix Three : Design Control Check List

Appendix Four : Software Quality Assurance Check List

Appendix Five : Manufacturing Processes Check List

Appendix Six : Manufacturing Controls Check List

Appendix Seven : Supplier Control Check List