PRODUCTION CERTIFICATION AND SURVEILLANCE PROCEDURE

1. General

A. Purpose

This procedure prescribes the requirements for application and issuance of Production Certificate for manufacturing civil aviation products and the rules for surveillance to the production certificate holder after the issuance of the certificate. The following persons may be eligible for the issuance of a PC when the CAA finds after the examination of supporting data, and inspection of the organization and facilities:

（1） Type Certificate holder.

（2） Supplemental Type Certificate holder. (STC holders who only desire to produce the modification parts/kits should be encouraged to apply for PMA)

（3） Agree upon to the benefits of that type certificate under a licensing agreement.

B. General Description

（1） Production Certificate is not transferable and effective until suspended or revoked by CAA, or the location of the manufacturing facility is change.

（2） Production Certificate includes Production Limitation Record.

（3） The PC holder can apply Airworthiness Certificate in according with 06-07A chapter 6.

2. Application

A. The applicant should be advised that：

（1） The applicant can submit the quality control data to fulfill the requirements which describe in 06-07A, Article 29, and also must identify the title and revision.

（2） The PC holder has the privileges specified in 06-07A Article 37.

B. The applicant shall fill out the application form. (CAA Form 8110-12)

C. When filing the application, the applicant shall submit the relevant data

according to Attachment 9 of 06-07A as following：

(1) Design data control: Procedures for controlling design data andsubsequent changes to ensure that only current, correct, and approved data is used.

(2) Document control: Procedures for controlling quality system documents and data and subsequent changes to ensure that only current, correct, and approved documents and data are used.

(3) Supplier control: Procedures that—
(a) Ensure that each supplier-furnished product or article conforms to its approved design;
(b) Require each supplier to report to the production approval holder if a product or article has been released from that supplier and subsequently found not to conform to the applicable design data; and
(c) Make available to the CAA information regarding all delegation of authority to suppliers.

(4) Manufacturing process control: Procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.

(5) Inspecting and testing: Procedures for inspections and tests used to ensure that each product and article conforms to its approved design. These procedures must include the following, as applicable:
(a) A flight test of each aircraft produced unless that aircraft will be exported as an unassembled aircraft.
(b) A functional test of each aircraft engine and each propeller produced.

(6) Inspection, measuring, and test equipment control: Procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard must be traceable to a standard acceptable to the CAA.

(7) Inspection and test status: Procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.

(8) Nonconforming product and article control:
(a) Procedures to ensure that only products or articles that conform to their approved design are installed on a type-certificated product. These procedures must provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming products

and articles. Only authorized individuals may make disposition determinations.

(b) Procedures to ensure that discarded articles are rendered unusable.

(9) Corrective and preventive actions: Procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system.

(10) Handling and storage: Procedures to prevent damage and deterioration of each product and article during handling, storage, preservation, and packaging.

(11) Control of quality records: Procedures for identifying, storing, protecting, retrieving, and retaining quality records. A production approval holder must retain these records for at least 5 years for the products and articles manufactured under the approval and at least 10 years for critical components for which a replacement time, inspection interval, or related procedure is specified.

(12) Internal audits: Procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system. The procedures must include reporting results of internal audits to the manager responsible for implementing corrective and preventive actions.

(13) In-service feedback: Procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures must include a process for assisting the design approval holder to—

(a) Address any in-service problem involving design changes; and

(b) Determine if any changes to the Instructions for Continued Airworthiness are necessary.

(14) Quality escapes: Procedures for identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.

D. PC holder’s responsibilities：

（1） The holder of a PC is responsible for maintaining the quality system in conformity with the data and procedures approved for the PC.

（2） 06-07A, Article32 requires the PC holder to immediately notify the CAA of changes or revisions to quality control data and related

procedure.

（3） The PC holder is responsible for identifying all products and parts.

（4） The PC holder must report all failures, malfunctions and defects as required by 06-07A, Article 3.

E. Within 30 days after receiving the application, CAA should contact a preliminary evaluation in order to confirm whether the applicant’s QA system is in compliance with the applicable requirement.

F. Inform the applicant whether the application is accepted according to the result of preliminary evaluation.

G. A PC holder’s manufacturing complex would normally consist of a principal facility and all associate facilities using the same quality control system approved by CAA. If the PC holder want to change the location of manufacturing facilities, the PC holder must reapply in according with 06-07A, Article 33.

H. If a PC holder desires to add a new TC or a new model or a new process under an existing TC to his Production Limitation record, he must make application in the same manner as for the original issuance.

3. Production Certification Team

A. General

（1） The certification team is on behalf of CAA to conduct a specified product’s certification task.

（2） After the final and overall evaluation for the quality assurance system, and production facilities of the applicant, submit the evaluation report and the proposal of whether the PC can be issued to the applicant.

（3） The team ‘s task will be terminated once the evaluation work is done.

B. Composition of team member

（1） Certification team members include the representatives from CAA and relevant expert.

（2） The members of team are nominated by the CAA.

C. Responsibility of Team

（1） Team Leader

Arranging team member to make plan, informing applicant to

arrangement plan, supervising evaluation team, evaluating the record and signing the report.

（2）Principal Inspector

Making arrangement for meeting, obtaining sufficient copies of QC data, ensuring that applicant has taken all corrective actions.

（3）Relevant department

Responsible for evaluation and approval applicant’s aircraft, aircraft engine and propeller test procedure and check lost.

（4）Other missions

（a） Analyze and evaluate the applicant’s quality assurance system, QC data and production facilities referring to the 「QASEP」.

（b） Evaluate the situation of applicant’s for receiving inspection materials and parts provided by suppliers and quality control for supplier.

（c） Fill in the form「Record of Findings/Observations」(CAA Form 8100-06).

（d） By virtue of the CAA Form 8100-03 to issue evaluation report and inform the applicant.

（e） Follow up the corrections of findings.

（f） After the final and overall evaluation for the quality assurance system, organization and production facilities of the applicant, submit the final evaluation report to CAA and proposal of whether the PC can be issued to the applicant.

D. Team working stage

（1）Team meeting

（a） Review pre-audit results and make suggestion.

（b） The Manufacturer’s compliance attitude and working relationship with the CAA.

（c） Production Certification Evaluation plan.

（d） Meeting schedule and pre-evaluation briefing agenda.

（2）Pre-evaluation conference—attendee include team leader, PI and applicant and others as necessary.

（a） Provide the evaluation’s scope and objectives.

（b） Review the applicant’s quality control system/dada, organization, production facilities and receiving inspection by using 06-07A, attachment 9.

（c） Determining that the applicant’s location of facilities met

requirement.

（3）After pre-evaluation conference, the evaluation team will review the applicant’s quality control system/dada, organization, production facilities and suppliers.

（4）Daily team meeting –when necessary

（a） Team member discussed the status of evaluation and the problems encountered.

（b） The CAA Form 8100.6 prepare during the day to ensure correctness, adequacy and completeness.

（5）Post Evaluation Conference

Upon completion of the evaluation, the PI (and evaluation team leader when practicable) should meet with the manufacturer as soon as possible to orally advise him of any of the evaluation result. The manufacturer should also be advised that the CAA will formally submit the finding along with a request for corrective actions with approximately 10 days.

（6）Final Evaluation stage

（a） Review applicant’s corrective actions, recording on the report and submit to CAA.

（b） Inform applicant whether issued PC or not in according with 06-07A Article 29.

E. Issuing of Production Certificate

（1） When applicant’s quality control system, organization, production capability are found satisfactory by the team, make conclusion for issuance of PC.

（2） PC is including production limitation record, which list the products are authorized to produce, TC number and approval date.

（3） If a PC holder desire to add a new TC to his PLR, he must make application for approval. The process is the same for deletion from the PLR.

4. Records and reporting requirement

A. Conformity Inspection Record (CAA Form8100-01)

This form is the internal working sheet of CAA. During production certification and surveillance, the form is used for recording conformity inspection and is supplemental to system evaluation

B. Record of Findings/Observations (CAA Form 8100-06)

（1） This record is using during the evaluation process and is the part of evaluation team meeting record.

（2） The conclusion should attached with the evidence data ex. Inspection record, copy of quality control data and other data which deem necessary.

（3） The evaluation report will keep in CAA at least two years.

5. Product audit

A. Purpose

The product audit will evaluate the effectiveness of the quality assurance system and the airworthiness of product.

B. General Definition

（1） The product audit shall initiate at the detail part level and progress through the subassembly and assembly cycle, until final assembly of the product.

（2） The auditor shall conduct as many audits as are necessary to provide confidence that the quality control system is effective.

（3） The principal inspector shall provide the audit team a listing of detail parts, subassemblies and assemblies that should be considered for auditing.

（4） The product audit will evaluate the effectiveness of the quality control system and airworthiness of products utilizing critical dimensional characteristics and/or critical processing attributes generated during the manufacturing cycle.

C. Selection of Characteristics

（1）Selecting items

（a） Know service problem area.

（b） Characteristics/attributes that cannot be verified except by destructive test of each item or extensive disassembly.

（c） Engineering drawing, process specifications, test specifications and quality control procedures characteristics/attributes

classified as critical .

（2）Categories of Audits：

（a） Assembly of final products.

（b） Subassembly.

（c） Detail parts.

（d） Raw materials.

D. Recording Audit Result

All product activity will be recorded on 「Conformity Inspection Record」

6. Enforcement Action

The principal objective of the CAA compliance and enforcement program is to promote aviation safety and to protect the public interest by obtaining compliance with regulations.

A. Enforcement Philosophy

Good judgment should be exercised in determining whether or not a valid noncompliance to the CAR or CAA approved quality control system does exist before initiating any enforcement actions. Unsatisfactory conditions which do not constitute a quality control system breakdown, or those which would have no adverse affect on safety, should not be processed as noncompliance. If a PC holder elects to self disclose a noncompliance that has left their control, correct the noncompliance in a timely manner, and take effective preventative action, the CAA will mitigate or alleviate civil penalties.

B. Enforcement Procedures

（1）Compliance and enforcement program should be followed for any noncompliance against civil regulation not self disclose.

（2）When PC holder is found to be in noncompliance with approved QC data.

（3）When such deficiencies are found, the PC holder should be formally requested by separate letter to take appropriate corrective actions in a timely manner.

C. When a number of noncompliance have been noted at a PC holder’s facilities, such as those resulting from audit findings, they should be handled as one enforcement action. They only exception would be when there are different types of enforcement action would be initiated for each type of enforcement action to be taken.

7. Service Difficulty Investigation

A. General

The sources of service difficulty come from:

（1） Failures, malfunctions and defects reports from manufacturer.

（2） Mechanical reliability report.

（3） Mechanical interruption summary report.

（4） Repair station reports of unairworthy condition.

（5） Incident and accident report.

（6） User complaint.

（7） Information from foreign civil aviation authorities.

B. CAA responsibility

When the PI or other inspectors are assigned to investigate service difficulty in the manufacturer facilities, they must be completed as expeditiously as possible. The inspector must witness any teardown inspection or testing to be performed on defected product.

C. Investigation

The assigned manufacturing inspector will make an investigation, independent of that perform by the manufacturer, of service difficulties, in accordance with the criteria contained in this procedure, and record of investigation result.

D. Corrective Action

When investigation discloses unsatisfactory conditions in conformity, QC or workmanship, if justified, airworthiness directive action should be recommended to the CAA.

E. The investigation report is composed of the following information at least:

（1） Name and address of manufacturer.

（2） Type and number of certificate.

（3） Maker, model and part number as appropriate to positively identify the defective product/part thereof.

（4） Inspector’s conclusion as to the cause for the service difficulty.

（5） All corrections requested by CAA and/or taken by the manufacturer. Recommendations and/or further action required.

8. Surveillance and methods

A. General

（1） All manufacturers which hold as CAA production approval are subject to CAA surveillance to ensure each product/part thereof in conformity with the CAA approved design.

（2） When it has been determined that the manufacturer has a poor compliance history and/or extensive service difficulties or when manufacturer does not have an adequate self-audit procedure in place, the manufacturer should be subject to more stringent surveillance.

B. Certificate Management Responsibility

A principal manufacturing inspector shall be assigned to each PC holder to manage the surveillance of all aspects of PC holder’s QC system. PI’s responsibilities are as following:

（1） Notify the PC holder within 30 days after receipt as to whether or not a revision is acceptable.

（2） Evaluation, inspection and approve the following quality control system:

（a） The change of quality control system whether affects with product inspection, conformity and airworthiness.

（b） Manufacturing inspection, quality control requirement and special process.

（3）Conducting compliance/conformity inspections on prototype and productions and parts thereof, as necessary.

（4）Providing guidance and assistance to the certificate holder as necessary.

（5）Investigation of service difficulties which involve QC problem in accordance with relevant requirement.

（6）Notifying the PC holder in written when any unsatisfactory conditions are noted, related to QC or production systems, alone with request for appropriate corrective action.

（7）Determining the need for the audits and making the arrangement for such audit.

（8）Conducting/participating in main inspection and audit as necessary.

（9）Monitoring of certificate holder’s suppler facilities to determine the need for surveillance in accordance with this procedure.

（10）Conducting and surveillance or investigation activity within the

guidelines contained in this procedure to ensure continued compliance with requirement.

C. Task of surveillance

There are three basic type of CAA surveillance activity. They are list as follow:

（1）Random

This includes any of those surveillance tasks, which may be accomplished on an as-required basis; e.g., investigation of a service difficulty at a suppler facilities.

（2）Ongoing

This includes any of those surveillance task referred to this paragraph which may be accomplished on a continuing basis, e.g., monitoring of a PC holder's QC system.

（3）Audit

This type of surveillance includes any audit activity accomplished in accordance with the instructions contained in QASEP.

D. Surveillance Reporting

All surveillance activity will be recorded on relative records.

E. CAA may conduct supplier surveillance as necessary.

F. Supplier management and surveillance

（1）Suppliers must fulfill its responsibility for ensuring that each product or parts conforms to approved design and is in condition for safe operation：

（a） Approving the supplier by ensuring tat the particular supplier has the capability to furnish parts or services in conformance with the approved technical data and the manufacturer's CAA approved quality control system.

（b） Advising suppliers that they are subject to CAA surveillance.

（c） Providing orientation as necessary to its suppliers to ensure that they are knowledgeable with all applicable requirements.

（d） Making certain information readily available to the CAA upon request in according with 06-07A Article 29.

（2）Determining Need for Supplier Surveillance：

The following guidelines should be used in making these determinations：

（a） The manufacturer has delegated to its supplier the authority to perform major inspections.

（b） It has been determined that the manufacturer has failed to control its supplier.

（c） There is any question as to the supplier’s capability to furnish the particular part or service in compliance with manufacturer’s quality/inspection procedure and/or the applicable requirement or affect on safety.

9 Reference

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

B. Quality Assurance System Evaluation Procedure

C. FAA Order 8120.2A Production Approval and Surveillance Procedure