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Appendix 6

AIRCRAFT CERTIFICATION SYSTEMS EVALUATION PROGRAM

PRODUCTION APPROVAL HOLDERS STANDARDIZED EVALUATION CRITERIA

May 20, 2004

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

PART A. STANDARDIZED EVALUATION CRITERIA FOR PAHs AND ASSOCIATE FACILITIES

1. PURPOSE. This appendix provides standardized evaluation criteria used to document the evaluation of the system elements listed in figure 1 for PAHs and associate facilities.

FIGURE 1. SYSTEM ELEMENTS

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1	Organizational Management	3
2	Design Control	13
3	Software Quality Assurance	19
4	Manufacturing Processes	27
5	Manufacturing Controls	49
6	Supplier Control	73

2. DESCRIPTION OF SYSTEM ELEMENTS SECTION FORMAT. Each section of this appendix addresses one of the seven system elements listed in figure 1. Each section is formatted as follows:

a. System Element Description. This is a brief description of what the system element is intended to accomplish or control.

b. System Element Standardized Evaluation Criteria. The evaluation criteria are located on the FAA's Web site and AIR's Regulatory Guidance Library Web site and are formatted as follows:

(1) Standardized Evaluation Criteria. Each criterion is identified by a numbered question within a box. The format of each question number is based on the specific system element section number identified in figure 1.

(2) Applicability. This identifies whether the criterion applies to a specific type of production approval (APIS, PC, PMA, and TSO authorization). A table format is used that identifies the type of facility across the top and a code for the type of applicability in the first column. The codes for the types of applicability are defined as follows:

(a) A. This row within the applicability block is used to identify the 14 CFR source requirements applicable to a specific facility. The applicability to a specific facility is indicated by the specific 14 CFR part or section reference (for example, 14 CFR part 21, Certification Procedures for Products and Parts, § 21.143, Quality Control Data Requirements; Prime Manufacturer).

(b) E. This row within the applicability block is used to identify the enforceable 14 CFR requirement applicable to a specific facility. The applicability to a specific facility is indicated by the enforceable 14 CFR part or section reference (for example, § 21.165, Responsibility of Holder).

PART A. STANDARDIZED EVALUATION CRITERIA FOR PAHs AND ASSOCIATE FACILITIES

NOTE: The evaluator must determine the actual applicability of the 14 CFR reference on the basis of the encountered condition. For example, § 21.125(a)(2), Production Inspection System; Materials Review Board, requires an APIS holder to maintain materials review board records for 2 years. However, it does not require the APIS holder to have written procedures on how the records will be maintained.

(c) P. This applicability code is used within the "A" row to identify criteria that reflect industry best practices and accepted total quality management principles. These practices and principles are often contained in FAA-approved data or other facility procedures. The evaluator must determine the actual level of application at each facility.

(d) N. This applicability code is used within the "A" or "E" rows to indicate that the criterion is generally not applicable at a specific facility.

NOTE 1: Applicability indicated for a specific type of production approval includes any associate facilities established under that approval.

NOTE 2: When a "P" or "N" is used in the applicability table, a criterion is applicable and enforceable if it is addressed in the approval holder's FAA-approved data/quality manual. (Reference 21.165 or 21.607)

(3) Statement of Condition. The statement of condition provides guidelines, not requirements, that may assist the evaluator in determining adherence to the criteria. These guidelines are not the only acceptable means of implementation. Evaluators may identify additional practices in FAA-approved data or other facility procedures that indicate adherence to the requirements of the criteria.

SECTION 1: ORGANIZATIONAL MANAGEMENT

1. SYSTEM ELEMENT DESCRIPTION. This system element addresses the evaluated facility's organizational management structure and responsibilities for design control and production functions. This includes procedures and methods used to notify FAA of specific conditions as required by the applicable CFR (such as recording, reporting, investigation, determining cause, and effecting corrective actions of significant or reported failures, malfunctions, or defects). This function also addresses internal audits whereby the facility ascertains its own abilities and procedural compliance to established policy and guidance.

2. SYSTEM ELEMENT STANDARDIZED EVALUATION CRITERIA. The following criteria are used to document the evaluation of this system element.

101. Is the production approval/authorization displayed prominently in the main office of the evaluated facility in which the product is manufactured?

Applicability:

	APIS	PC	PMA	TSO
A	P	§ 21.161	P	P
E	N	§ 21.161	N	N

Statement of Condition

a. There is objective evidence that the production certificate is prominently displayed as required. The display should include all attachments, i.e., Production Limitation Record.

102. Is the evaluated facility operating within the production limitations of the production approval?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.123	§ 21.151	§ 21.303	§ 21.601
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that the evaluated facility is manufacturing, for sale/installation, those products which it is authorized to manufacture under a production approval.

103. Is there an overall policy/procedural document that describes the facility and each organization responsible for various functions; including a description of responsibilities and their levels of authority?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. The policy/procedural document(s) include, as a minimum:

(1) The current purpose and objectives of the evaluated facility, and, as applicable, its function in relation to a PAH having multiple facilities.

(2) A current description of each organization responsible for performing engineering, flight test, manufacturing, and service/product support related functions.

(a) A policy statement establishing the responsibilities and authorities of each of the functional organizations.

(b) A current table or organizational chart that describes the chain of authority and responsibilities within each of the functional organizations and their relationship to management and to the other organizational components.

(c) Identifies individuals with the necessary authority to manage each of the functional programs and lists those who are authorized to make changes to each program (i.e. engineering, quality, manufacturing systems).

(3) A description of the use and functions of FAA designees within the facility.

(a) A policy statement establishing the role of FAA designees and their responsibilities as representatives of the Administrator, ensuring that no conflicting restraints are placed on the performance of their duties.

(b) Identification of designees in an organizational position with sufficient authority and involvement with production and quality activities to enable them to administer pertinent CFRs effectively.

(4) A description of organizational responsibility for managing and coordinating activities requiring FAA notification.

(a) Identifies an individual with the necessary authority to manage the notification program.

(b) Procedures that define the method for establishing and maintaining personnel qualifications appropriate to the various functions performed, including the required training.

(c) The manufacturing organization reviews specifications, procedures, etc., prior to release to ensure that the product can be effectively protected and retain conformity to

FAA-approved design during production.

b. There is objective evidence of adherence to established policies and procedures.

104. Is the policy document reviewed periodically by the evaluated facility for adequacy and currency, and updated as warranted and are the policy and procedures documents available to responsible personnel?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. The policy document provides for periodic review and update, when required.

b. The policy document provides for controlled distribution of policy and procedures.

c. There is objective evidence of observance to established policy.

105. Does the evaluated facility have and use a Quality Manual to describe the management of quality-related subjects, including a description of responsibilities and their levels of authority defined?

Applicability:

	APIS	PC	PMA	TSO
A	P	§ 21.143	P	§ 21.143
E	N	§ 21.165	N	§ 21.607

Statement of Condition

a. There is objective evidence that the quality manual, including electronically stored versions, is available in the major quality and inspection areas, and is subject to periodic review and revision.

(1) Everyone associated with the quality system is performing within their described assigned responsibilities and delegated authority.

(2) A table or organization chart that describes the functional relationship of the quality organization to management and to the other organizational components.

(3) A description of assigned responsibilities and delegated authority to make changes to the quality system.

(4) The individual identified for managing the quality program has the necessary authority and organizational freedom.

106. Is quality system data, and changes thereto, submitted to the FAA?

Applicability:

	APIS	PC	PMA	TSO
A	P	§ 21.147	P	§ 21.143
E	N	§ 21.165	N	§ 21.607

Statement of Condition

a. There is objective evidence that quality system data changes at a PC holder that may affect inspection, conformity, or airworthiness of the product are promptly submitted in writing to the FAA. Implementation of the changes should be delayed until verbal or written FAA approval, as appropriate, is received.

107. Are tags, forms, and other documents described and controlled?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures include, as a minimum:

(1) A sample of each tag, form, and other document with instructions for use as applicable.

(2) A formal change control procedure.

b. There is objective evidence of observance to established procedures.

108. Has the evaluated facility established a record retention schedule for various types of process, test, and quality/inspection system data?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	P	§ 21.303	§ 21.613
E	§ 21.123	N	§ 21.303	§ 21.613

Statement of Condition

a. There is objective evidence that a record retention schedule has been established that complies with applicable CFR and that compliance to retention requirements is periodically verified.

(1) For APIS, TSO authorization, and PMA inspection records, the period is at least 2 years.

(2) For TSO authorization technical data file, the period is until the article is no longer manufactured.

(3) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

(4) Record legibility, completeness and accuracy.

109. Are relocations of the manufacturing facility at which products are manufactured, or expansions to include additional facilities at other locations, reported to the FAA in writing?

Applicability:

	APIS	PC	PMA	TSO
A	P	§ 21.159 § 21.147	§ 21.303	§ 21.621
E	N	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that:

(1) For a PC/TSO holder, any changes to location/expansion that affects inspection, conformity, or airworthiness are immediately submitted to FAA in writing.

(2) Any changes in the location(s) where PMA parts are manufactured, or expansions to include additional facilities at other locations, have been reported to the FAA in writing within 10 days.

110. Are failures, malfunctions, and defects reported to the FAA?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.3	§ 21.3	§ 21.3	§ 21.3
E	§ 21.3	§ 21.3	§ 21.3	§ 21.3

Statement of Condition

a. The organization has established procedures for reporting failures, malfunctions and defects.

b. The organization's procedures for reporting failures, malfunctions, or defects:

1. Establish definitions of conditions that must be reported to the FAA.
2. Establish a method of documenting reportable conditions and a method for reporting them to the FAA.
3. Require prompt evaluation of each condition to determine if it is reportable to the FAA.
4. Require that the condition be reported to the FAA within 24 hours (with provisions for weekends and holidays) after it has determined that the failure, malfunction or defect required to be reported has occurred.
5. Require retention of each reported condition document, the FAA response, and the organization's disposition of the condition.

c. There is objective evidence that these procedures are being adhered to.

111. Are service bulletins and maintenance manuals approved by authorized personnel and coordinated with FAA engineering?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures define specific organizational and individual responsibilities for issuing service bulletins, maintenance manuals, service difficulty reports, and other related communication.

b. Changes are approved by authorized personnel and coordinated with FAA engineering.

c. There is objective evidence of observance to established procedures.

112. Are there provisions for receiving feedback on service problems/difficulties from users/installers of the product or a part of the product?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Identification of a specific function to receive reports of service difficulties.

(2) Determination of appropriate manufacturing or design responsibilities for the reported problem.

(3) A system of tracking for accountability.

(a) Records are generated and maintained.

(b) Contents of each record used, including when the report was received, what was reported, and actions taken.

(c) Record legibility, completeness, and accuracy.

(d) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

113. Are service problems (both design and manufacturing), unairworthy conditions, unsafe features or unsafe characteristics reported by the FAA or users, investigated and prompt corrective actions taken by the evaluated facility?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	§ 21.3(f)
E	N	N	N	§ 21.3(f)

Statement of Condition

a. Procedures provide for:

(1) A method of investigating, identifying, locating and reporting suspected unsafe products.

(2) Prompt corrective action, which includes, as a minimum:

(a) Root cause determination and correction of deficient design or manufacturing.

(**b)** A means of purging, tracking, and accountability of known unsafe products.

(3) Investigating reports of unairworthy conditions or unsafe features or characteristics reported by the FAA.

(4) Reporting investigation results and actions taken or proposed to the FAA.

b. There is objective evidence of observance to established procedures.

114. Do procedures provide a method to notify users and recall products, when necessary, when nonconformances are suspected or known to exist in products in service?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a There is objective evidence of observance to established procedures.

115. Is there a means for keeping users of the product/part informed of service information, including field purges?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for informing product users of service difficulties, and of required field purges for suspected or known unsafe conditions.

b. There is objective evidence of observance to established procedures.

116. Does the evaluated facility have an internal audit program to verify compliance with established policies, procedures and approved data?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Planned and documented internal audits of personnel, procedures, operations, equipment, material, processes performed, and records in all major functional areas.

(2) Criteria for conducting compliance, systems, and product audits.

(3) A formal audit schedule that is available, approved by management and followed.

(4) Requirements for the qualification and training of personnel that are performing the audits.

(5) Auditors who are independent of the activity being audited.

(6) Special audits when significant customer problems are detected, or when there are significant changes to processes or systems.

(7) Methods for identifying and reporting nonconformance and obtaining required corrective action.

117. Are results of internal audits reported to facility management and are the audits used for improvement of the quality system/product?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(**1**) Review of internal audit results and corrective actions by management.

(2) Review of internal audit results by personnel having responsibility for the areas that were audited.

(3) Root cause determination and development of appropriate and prompt corrective action.

(4) Follow-up audits (as necessary) to assure effective implementation of corrective action.

(5) Actions taken to determine if changes are required to the Quality System or other similar processes, which may not have been evaluated, in addition to correcting reported noncompliances.

SECTION 2. DESIGN CONTROL

1. SYSTEM ELEMENT DESCRIPTION. The methods for approving, controlling and documenting FAA-approved designs and design changes. Specific functions necessary include the planning and integration of the evaluated facility's procedures for continuously maintaining the integrity of design data, drawings, part lists, and specifications necessary to define the configuration and the design features of the product. This includes software used in type-certificated aircraft or related products (airborne software).

2. SYSTEM ELEMENT STANDARDIZED EVALUATION CRITERIA. The following criteria are used to document evaluation of this system element.

201. Are there procedures for the control of technical data/documents and do they include storage, maintenance and protection?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for

(1) Storing, maintaining and protecting design data/documents to preserve their integrity, including magnetic storage media used as part of design documentation, if applicable.

(2) Identification of technical data/documents.

(3) Indication of technical data/documents approval, including FAA approval.

(4) A list of technical data/documents necessary to define configuration of the FAA-approved design.

b. There is objective evidence of observance to established procedures.

202. Are the issuance, retrieval, distribution, and currency of design and technical data documents controlled?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.613
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence of:

(1) Control of design and technical data document issuance, including persons authorized to obtain documents, and for retrieval of obsolete documents.

(2) The method for making available to, or notifying, employees concerning changes in technical data.

(3) Verification that correct documents are in use for the product being produced.

(4) Current design and technical data document distribution lists.

(5) That a complete and current file of technical data is being maintained, including design drawings and specifications.

(6) Electronically stored and transmitted technical design and quality data are adequately controlled.

203. Do the manufacturing, quality, and service/support organizations participate in the review of design and technical data changes?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for the manufacturing organization, quality organization, and service/support organization to review design and technical data changes prior to release to ensure that the product can be produced in conformity to FAA-approved design.

(1) The product can be properly evaluated and verified to be in conformity to

FAA-approved design. Inspection equipment is available or can be procured which will adequately verify conformity to FAA-approved design, and which can be controlled for accuracy, when required.

(2) Service/product organization review design data changes prior to release to ensure that appropriate airworthiness and service documents that are affected by the design change are revised as required.

b. There is objective evidence of observance to established procedures.

204. Are there procedures in place to approve, document, and control changes to product design?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures include, as a minimum:

(1) Methods for documenting design changes.

(2) A description of the change approval cycle, including personnel authorized to approve changes.

(3) A means of controlling the issuance and distribution of design changes.

b. There is objective evidence of observance to established procedures.

205. Are changes to technical data referenced on FAA-approved design data (specifications, installation instructions [when applicable], and airborne software documentation) appropriately documented and approved?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide that changes to technical data referenced on FAA-approved design data are documented and approved in the same way as changes to product design.

b. There is objective evidence of observance to established procedures.

206. Are minor design changes approved under a method acceptable to the FAA?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.95	§ 21.95	P	§ 21.611
E	§ 21.123	§ 21.165	N	§ 21.607

Statement of Condition

a. There is objective evidence that:

(1) Minor changes in a type design are approved by the FAA or by a method acceptable to the FAA. For example, a FAA approved procedure whereby the PAH approves minor design changes.

(2) For TSO articles, all necessary revised data is submitted to the FAA when minor changes are made and agrees with any part number plan specified in the original application.

207. Are major design changes, including process specification changes, submitted to the FAA for approval?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.97 § 21.99 § 21.125	§ 21.97 § 21.99	§ 21.303	§ 21.611
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that:

(1) Major design changes are submitted to the FAA for approval, including changes to manufacturing and special process specifications.

(2) Design changes resulting from applicable AD's, and design changes, which contribute to the safety of the product, are submitted to the FAA for approval.

(3) For TSO articles, a new type or model designation has been assigned to a changed article and that there has been prompt application for a new TSO authorization.

208. Have design changes necessary to correct unsafe conditions been incorporated into the FAA-approved design, when applicable.

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.123	§ 21.165	§ 21.303	§ 21.607
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that design changes necessary to correct unsafe conditions have been incorporated into the FAA-approved design. This evidence may include one or more of the following:

(1) Identification of applicable AD's.

(2) Tracking the status of AD incorporation.

(3) Furnishing the customer with the AD incorporation status at the time the product is delivered.

209. Are the instructions for continued airworthiness kept current with design changes, when appropriate; and made available to appropriate persons?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.50	§ 21.50	N	In each TSO
E	§ 21.50	§ 21.50	N	In each TSO

Statement of Condition

a. There is objective evidence of observance to established procedures.

210. Is descriptive data and information on FAA-approved design changes resulting from incorporation of AD's, or which contribute to the safety of the product made available to users of the product?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.99	§ 21.99	P	P
E	§ 21.99	§ 21.99	N	N

Statement of Condition

a. There is objective evidence that all applicable descriptive data and information covering FAA approved design changes or improvements that contribute to the safety of the product are made available to product users.

SECTION 3. SOFTWARE QUALITY ASSURANCE

1. SYSTEM ELEMENT DESCRIPTION. This system element addresses the planning and integration of the evaluated facility's procedures for continuously maintaining the integrity of software used in type-certificated aircraft or related products (airborne software), and also the integrity of software and related hardware used for product acceptance. Document DO–178, Software Considerations in Airborne Systems and Equipment Certification (current edition), of the Radio Technical Commission for Aeronautics (RTCA), or comparable means, should be used as guidance for control of airborne software.

2. SYSTEM ELEMENT STANDARDIZED EVALUATION CRITERIA. The criteria used to document the evaluation of this system element are divided into two parts: Part A, Airborne Software, and Part B, Product Acceptance Software.

Part A. Airborne Software

301. Is there a Software Configuration Management Plan (SCMP) or procedure to control airborne software configuration?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Installation of the correct version of the software in the delivered product in accordance with the FAA-approved design.

(2) Method by which controlled software containing the FAA-approved design data is transitioned into production. The media containing the software installed in the product is directly traceable to the Software Configuration Management (SCM) library.

(3) Documentation of integration of software with hardware to specify a unique version for incorporation into the product.

(4) Cross-reference of software documents to their associated software.

(5) The technical data/documents control system includes software identification methods at the media level and at the product level. The media level identification is incorporated into the software, and the product level identifications are marked on the outside of the product indicating software configuration.

b. There is objective evidence of observance to established procedures.

302. Is there a Configuration Index Document (CID) listing all software documents under configuration control and defining the hardware and software part numbers?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for traceability of hardware and software part numbers to the drawing control system.

b. There is objective evidence of observance to established procedures.

303. Are there practices and procedures for reporting, tracking, and resolving software problems?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Corrective action procedures, for problems found subsequent to the FAA-approved design, include provisions for airborne software and hardware/software combinations. Procedures may parallel or be part of hardware corrective action procedures.

b. Problem reports addressing changes to software code are under change control.

c. The production test procedures have been modified to reflect the software change and successfully executed against the changed version.

d. There is objective evidence of observance to established procedures.

304. Is obsolete and non-current software media recalled and purged, when applicable?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Configuration control procedures for airborne software include methods of purging software for removal of obsolete and non-current media, when applicable. Procedures may parallel or be part of hardware purging procedures.

b. Procedures include methods to identify, store, or dispose of obsolete and non-current media, when applicable.

c. There is objective evidence of observance to established procedures.

305. Are there methods and facilities to protect computer programs from unauthorized access, inadvertent damage, or degradation?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide:

(1) Configuration control of the airborne software within the product design files.

(2) Limited access to software files and protection from unauthorized changes.

(3) Separate archives for masters and duplicates.

(4) That masters and duplicates are not revived by the same machine simultaneously.

(5) Minimized risk of deterioration and regeneration of errors on selected storage medium.

(6) Assurance that the reproduction of code occurs error free.

b. There is objective evidence of observance to established procedures.

306. Are there procedures to ensure documentation and archival for each version of the delivered airborne software version?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures (i.e., version description document) provide for methods to identify, document and archive the software environment for each version of delivered airborne software.

b. There is objective evidence of observance to established procedures.

307. Is software identified/marked externally/internally in accordance with the engineering drawing requirements?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Work instructions detail the identification/marking requirements.

b. There is objective evidence of observance to established instructions.

308. Is airborne software programmed media handled and stored properly (e.g., environmental controls and magnetic interference precautions)?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for special handling of programmed media.

b There is objective evidence of observance to established procedures.

309. Are build and load instructions established, maintained, and used?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide:

(1) Software build and load into hardware components.

(2) Successful testing of the hardware after the software load.

b. There is objective evidence of observance to established procedures.

Part B. Product Acceptance Software

310. Is there a Software Configuration Management Plan (SCMP) or procedure to control product acceptance software configuration?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Identification of software for an application.

(2) Control of approved versions for product acceptance.

(3) Control of obsolete and non-current software.

(4) Identification of software with a Software Configuration Identification.

(5) Documentation of integration of software with hardware to specify a unique version for incorporation into the product.

(6) Cross-reference of software documents to their associated software.

(7) The technical data/documents control system includes software identification methods at the media level and at the product level. The media level identification is incorporated into the software, and the product level identifications are marked on the outside of the product indicating software configuration.

b. There is objective evidence of observance to established procedures.

311. Are all changes to product acceptance software documented and approved?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for the method to change and approve product acceptance software. A procedure patterned after an engineering drawing change procedure is appropriate to provide a permanent record showing reason for change, revisions to the software, approvals, and effectivity.

b. There is objective evidence of observance to established procedures.

312. Are there practices and procedures for reporting, tracking and resolving software-related product acceptance problems?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Corrective action procedures for product acceptance software may parallel or be part of manufacturing's general problem identification and corrective action procedures.

b. There is objective evidence of observance to established procedures.

313. Are there methods and facilities to protect computer programs from unauthorized access, inadvertent damage, or degradation?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide:

(1) Configuration control of product acceptance software to prevent unauthorized changes to the software.

(2) Limited access to software files and protection from unauthorized changes.

(3) Separate archives for masters and duplicates.

(4) That masters and duplicates are not available for corruption in the same machine at the same time.

(5) Minimized risk of deterioration and regeneration of errors on selected storage medium.

(6) Assurance that reproduction of code occurs error free.

b. There is objective evidence of observance to established procedures.

314. Is product acceptance software verified prior to use?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide:

(1) Independent means to verify product acceptance software, and subsequent revisions, to ensure that it accomplishes its intended function.

(2) Means to verify software/firmware/hardware is capable of discriminating between conforming and nonconforming parts or assemblies.

(3) Formal means of identifying approved product acceptance software.

(4) Configuration control of the product acceptance software as it relates to the product being accepted.

b. There is objective evidence of observance to established procedures.

315. Are build and load instructions established, maintained, and used?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide:

(1) Software build and load into hardware components.

(2) Successful testing of the hardware after the software load.

b. There is objective evidence of observance to established procedures.

SECTION 4. MANUFACTURING PROCESSES

1. SYSTEM ELEMENT DESCRIPTION. This system element addresses specialized actions whereby materials, parts, or assemblies are accepted, worked or fabricated, tested, inspected, stored, and prepared for shipment. For purposes of an evaluation these actions are broken down as follows:

a. Manufacturing and Special Manufacturing Processes. Specific functions and operations necessary for the fabrication and inspection of parts and assemblies (some examples are machining, riveting, and assembling). Also included are methods whereby materials, parts, or assemblies are worked or fabricated through a series of precisely controlled steps, and which undergo physical, chemical, or metallurgical transformation (some examples are heat-treating, brazing, welding, and processing of composite materials).

b. Material Receiving, Handling and Storage. The methods used to accept and protect raw materials, parts, subassemblies, assemblies, and completed products during receipt, manufacture, inspection, test, storage, and preparation for shipment.

c. Airworthiness Determination. The function that provides for evaluation of completed products/parts thereof, and related documentation, to determine conformity to FAA-approved design data and their condition for safe operation.

2. SYSTEM ELEMENT STANDARDIZED EVALUATION CRITERIA. The following criteria are used to document evaluation of this system element. The criteria used to document the evaluation of this system element are divided into three parts: Part A, Manufacturing Processes and Special Manufacturing Processes, Part B, Material Receiving, Handling and Storage and Part C, Airworthiness Determination.

Part A. Manufacturing and Special Manufacturing Processes

401. Are work instructions and revisions to work instructions reviewed, approved, controlled, and documented?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Preparation of work instructions and revisions to work instructions to ensure that the work functions to be performed are satisfactorily accomplished. Work instructions include:

(a) Sequence of operations, accept/reject criteria, workmanship criteria, inspection methods, tolerance limits, environmental conditions, sampling plans, special drawing notes, skilled personnel (certified) required, special precautions for critical product protection, part marking and identification, part stamp location requirements when defined by approved data, inspection of assemblies to detect inclusion of foreign objects prior to closure, reinspection of parts and assemblies that are reopened, disassembled, or tampered with, contamination control in hydraulic installations (e.g., purging, filtration, charging, and disposal).

(2) Coordination of initial release and changes to work instructions with affected departments, such as Planning and Quality, to ensure that manufacturing processes are adequately controlled.

(3) Authorized quality organization personnel review work instructions, and changes, prior to release to ensure that:

(a) Inspection points are located in the manufacturing process at points that ensure conformity to FAA-approved design.

(b) Adequate inspection equipment will be available and will be controlled for accuracy, as necessary.

(c) Drawing number and revision level are referred to.

(4) Method by which temporary changes are approved by authorized personnel.

(5) Control of the number of temporary changes allowed before requiring complete incorporation of work instructions.

(6) Control and documentation of revisions to work instructions.

(7) Method by which revisions are identified on the work instructions.

(8) Record of work instruction changes.

(9) Control of obsolete work instructions.

(10) Reflect design changes that correct unsafe conditions identified in ADs.

c. There is objective evidence of observance to established procedures.

402. Are all special processes in use identified and defined by FAA-approved design data and detailed in process specifications?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.31	§ 21.31	§ 21.31	§ 21.31
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that special processes in use are identified and documented in FAA-approved design data and/or process specifications. Process specifications detail personnel qualifications, material and equipment requirements, accept/reject criteria, etc.

b. There is objective evidence that all requirements listed in applicable special processes in use are completed in accordance with the approved process specifications.

403. Are new or changed processes substantiated and approved by appropriate personnel?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence of:

(1) Verification/testing of new or changed manufacturing and special processes by responsible engineering personnel to ensure the process will produce what the design requires.

(2) Process changes are approved by appropriate personnel.

(3) Documentation of change history by responsible personnel.

404. Are special manufacturing process operators qualified and approved in accordance with the specification/manufacturer's procedures?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence of periodic review of personnel certifications to ensure only qualified operators perform special processing.

405. Are records generated and maintained for all significant provisions of the quality/inspection program which have an effect on control of the conformity of the manufactured article to FAA approved design data?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Generation and content of inspection and test records:

(a) Inspection and tests for product acceptance, and include, as a minimum, applicable drawing/specification number and revision levels.

(b) Results of inspection and tests for first production configuration articles.

(c) In-process inspections used to determine acceptability of an article to FAA-approved design data.

(d) Final inspection acceptability of completed end items.

(e) Periodic inspection and control of tools used as a media of inspection, including check fixtures, inspection gauges, and measurement instruments.

(f) Test data directly traceable to the material, parts, or products tested.

(g) Contents of each record should include as a minimum, the nature and number of observations, the number and type of discrepancies found, lot identity and size, sample sizes, and resultant corrective action.

(2) Generation and content of special process records:

(a) Complete and continuous monitoring of special processes per specification requirements.

(b) Product identity and material traceability throughout the processing cycle.

(c) Special process inspection approval, such as unique special process inspection approval stamps.

(3) Record legibility, completeness, and accuracy.

(4) Requirements that storage media used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

406. Is equipment required for special processing, such as tools, gauges, instruments, timers, ammeters, or voltmeters, available and calibrated?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Equipment has evidence of current calibration and is available for controlling and monitoring special processes.

407. Is action taken to correct a manufacturing/special process that is found to be out of control?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence of:

(1) Action when there is loss of control.

(2) Investigation to ensure acceptability of products produced while the process was out of control.

(3) Corrective action as a result of the analysis of trends in process, to prevent nonconforming products.

408. Have lists or charts showing location and type of inspection stations been properly maintained?

Applicability:

	APIS	PC	PMA	TSO
A	P	§ 21.143	P	§ 21.143
E	N	§ 21.165 § 21.147	N	§ 21.607

Statement of Condition

a. There is objective evidence that lists or charts have been maintained identifying the location and types of inspection stations established to determine conformity of the product to FAA-approved design data.

409. Are inspection methods for each product/part selected to ensure that parts will be inspected for conformity with FAA-approved design data?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that parts, components, and assemblies are inspected during production. The inspection system should include:

(1) Documentation and availability of criteria for determining appropriate inspection methods (attribute/characteristics).

(2) Controls of the manufacturing system when physical inspection of parts or processed material is impossible or disadvantageous.

(3) A combination of physical inspection and process control whenever either method alone is not sufficiently capable of determining the quality of parts.

(4) Inspection of assemblies to detect inclusion of foreign objects prior to closure.

(5) Reinspection of parts and assemblies that are reopened, disassembled, or tampered with.

(6) Contamination control in hydraulic installations (e.g., purging, filtration, charging, and disposal).

(7) Procedures for the inspections and tests required to be completed for final acceptance of the completed products/parts.

410. Is the inspection status of products/parts identifiable throughout the manufacturing cycle?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide methods of marking/traceability that ensure identification of inspection status throughout the manufacturing process.

b. There is objective evidence of observance to established procedures.

411. Are inspection marking devices/stamps issued only to authorized persons and are there procedures to ensure proper control.

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Responsibility for control of stamps.

(2) A listing of stamps issued to personnel.

(3) Handling of lost or returned stamps.

(4) Periodic check of all stamps to ensure legibility of stamp impressions and possession of stamps by correct personnel.

(5) The type of stamps to use for the various materials that will require stamp impressions to ensure the material/part is not damaged.

b. There is objective evidence of observance to established procedures.

412. Are special environmental controls (temperature, cleanliness, etc.) utilized in material storage, handling, manufacturing and assembly areas when warranted?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21. 125	P	§ 21.303	P
E	§ 21. 123	N	§ 21.303	N

Statement of Condition

a. Environmental controls may include:

(1) Storage of sensitive materials in original or other appropriate container.

(2) Monitoring and recording of temperature and humidity .

(3) General housekeeping to ensure the product is not adversely affected by storage and handling (e.g., dirt, dust, water damage, corrosion, compression, dropping, ultraviolet light, heat, or cold).

(4) Training of appropriate personnel in maintaining established environmental controls.

b. Corrective action procedures have been established, and that corrective action is taken as required.

Part B. Material Receiving, Handling and Storage

413. Is receiving inspection required to verify that raw materials and supplier-furnished parts/service conform to the FAA-approved design data or purchase order requirements?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.123	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. Procedures provide for:

(1) Conformity of supplier furnished items, software, parts, and assemblies, including the inspection and identification of buyer-furnished material.

(2) Verification and identification of raw material, including process material (such as weld rod, etc.). Methods include:

(a) Review of certification test reports to ensure all requirements are met.

(b) Types and frequencies of analysis required to verify certifications, consisting as a minimum of initial and periodic verifications, dependent on supplier evaluations, past quality performance, and material importance.

(c) Nondestructive inspection techniques employed to verify the quality of castings and forgings.

(d) When specified, Material Laboratory Analysis Records identifiable to batch number, serial number, or heat number for a given part number.

(e) If Material Certificate/Laboratory Analysis is for a quantity of material, then serial numbers, if appropriate, are identifiable to the respective Material Certificate or Laboratory Analysis.

(3) Extent of actual inspection upon receipt, depending upon inspectability for conformity and quality, supplier evaluation results, past quality performance, inspections and reviews conducted at the supplier's facility, and relative importance of the part/material.

(4) First article inspection and test of products produced by new suppliers.

(5) Inspection and documentation requirements to meet current design data.

(6) Evaluation of incoming statistical data.

b. There is objective evidence of observance to established procedures.

414. Are records of receiving inspection generated and maintained?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Contents of each receiving inspection record to include: name, part number, sample size, type and quantity of inspections made, conformance or nonconformance, quantity and description of nonconformances found, and action taken.

(2) Record legibility, completeness, and accuracy.

(3) Requirements that storage media used for record retention, exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

415. Are purchased shelf-life materials and products verified to ensure that specification requirements are met?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. Procedures provide for:

(1) Verification upon receipt of purchased material or products that have shelf-life requirements to ensure they are within specified dates.

(2) Withholding from production, purchased material or products not within the specified shelf life requirements unless special testing is accomplished to verify conformity.

b. There is objective evidence of observance to established procedures.

416 Are age-sensitive products/parts/material identified and controlled?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	P	§ 21.303	P
E	§ 21.123	N	§ 21.303	N

Statement of Condition

a. There is objective evidence that:

(1) Age-sensitive materials, and materials susceptible to deterioration/corrosion, are identified and controlled. This includes, as a minimum:

(a) Determination of shelf life limits by type of material.

(b) Detailed mixing instructions if different from manufacturer's.

(c) Instructions for retest and extension of shelf life.

(d) Permissible amount of time shelf life may be extended.

(e) Identification requirements for shelf life extension dates.

(2) Bins containing limited shelf life items are identified.

(3) Out-of-date items in bonded areas are identified and segregated until re-inspected, re-tested, and dispositioned.

(4) Raw materials used in composites (e.g., pre-preg rolls and epoxy/adhesive materials) are in compliance with manufacturer's specifications. There is a documented trail covering receipt of material, initial testing, usage, storage, retesting, etc.

417. Are material and parts awaiting acceptance segregated?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for control, identification, and segregation (where practical) of material and parts awaiting testing or inspection from those already accepted .

b. There is objective evidence of observance to established procedures.

418. Are traceable components identified in assembly records?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Objective evidence that traceable components are identified in assembly records (i.e. fitted parts/components/assemblies, matched sets).

419. Are completed parts traceable to raw material, when applicable?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence that:

(1) Completed parts can be traced to raw material through records.

(2) Traceable parts are marked and recorded.

(3) Procedures for handling rejected traceable parts are followed.

420. Is traceability for split lots maintained, including accountability for the completion of all manufacturing and inspection operations?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Control of split lots.

(2) Accountability of products through each stage of the manufacturing process.

(3) Accountability for shortages/overages as successive operations are performed.

b. There is objective evidence of observance to established procedures.

421. Are special identification and controls required if materials or parts are introduced into production prior to full acceptance?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Special identification and controls for material or parts introduced into production prior to full acceptance or release.

(2) Conditions in which the pre-release of material or parts will be allowed.

(3) Obtaining appropriate documented approvals prior to pre-release.

(4) Documentation of each pre-release to show approvals, reasons for pre-release, and where in the production line material or parts are allowed to progress until full release is obtained.

(5) Identification of material or parts in such a manner that they can be retrieved if full release is not obtained.

b. There is objective evidence of observance to established procedures.

422. Are appropriate methods used to prevent part damage or contamination?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21. 125	P	§ 21.303	P
E	§ 21. 123	N	§ 21.303	N

Statement of Condition

a. There is objective evidence of:

(1) Instructional guidance on the use of material handling equipment.

(2) Methods for stacking parts.

(3) Methods for tying, wrapping, or properly supporting parts to preclude shifting and falling.

(4) Methods to protect critical machined surfaces, highly polished surfaces, or plated parts. Methods include use of lift fixtures, covering on fork lift contact surfaces, protective containers, wrapping, interlayering with protective material, special racks.

(5) Methods to protect electronic parts from corrosion, pin damage, or contamination from dust or dirt. Sealed type parts (e.g., switches, circuit breakers, or relays) are protected from rough handling and contact damage from like parts or other products.

(6) Methods to protect product from contamination. Methods may include:

(a) Capping all openings in components (e.g., tubing, valves, electrical connectors, pumps, etc.) prone to entrapment of foreign objects.

(b) Bagging, plugging, or capping completed hose and hose assemblies.

(c) Individually packaging or properly protecting oxygen equipment, plumbing, and fittings. Methods also include cleaning instructions and subsequent protection for contaminated items.

(d) Bagging or capping of sensing devices (e.g., instruments, pressure and vacuum transducers, cabin pressurization equipment, gyros, switches, or air data computers), and pressure venting when required.

(7) Special handling provisions (e.g., white gloves or electrostatic discharge (ESD) control), where warranted. These provisions may include:

(a) Protective measures to prevent fingerprints (particularly the by-products of oil, moisture, and salt) from deteriorating the product or causing inadequate adhesion.

(b) Protecting grease-coated products (e.g., control cables, bearings, gears, and rod ends) from dust, dirt, and corrosion.

(c) Training in special handling and storage techniques.

(d) Proper handling of ESD sensitive supplies and parts, including the methods for clearly identifying supplies and parts that require special ESD handling.

(e) Controlled work station conditions for removing ESD parts from special tote trays, boxes, and packaging.

(8) Methods to protect products during transit. Methods may include:

(a) Bagging, boxing, or tying parts and material to prevent intermixing.

(b) Retaining product in original containers as long as possible or practical.

(c) Foam, pads, or special packaging for delicate parts that are susceptible to vibration and shock damage.

(d) Covering, tying, or banding parts and material that may be blown out of carts, trucks, or dollies.

(e) Protecting parts and materials from adverse weather conditions that would affect the product.

(9) Procedures provide for design engineering review of recurrent product damage.

423. Are cleaners, solvents, degreasers, etc. adequately identified and controlled to prevent potential product damage from misapplication?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Decanting and identifying cleaners, solvents, and other fluids used in the work area, specifying types of containers to be used, requirements for re-use, and method of identification.

(2) Identifying the methods to be used when potentially damaging fluids are misapplied to a product.

b. There is objective evidence of observance to established procedures.

424. Is there proper separation and identification of product/parts in storage and manufacturing areas?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence that parts and materials are identified/separated from like or similar parts and material types.

b. Contents of bins, shelves, storage areas and manufacturing areas are identified.

Part C. Airworthiness Determination

425. Are required design changes incorporated into products/parts being stored prior to their release for installation/shipment?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that required design changes are incorporated into a product/part in storage before installation or shipment. This evidence may include one or more of the following:

(1) Establishment of effectivity of a design change.

(2) Use of shop order or traveler.

(3) Stock purge requirements.

(4) Rework to engineering instructions, including re-identification requirements.

(5) Inspection requirements.

426. Are only conforming and properly identified products/parts placed in storage and is removal/issuance of parts controlled?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Placement in stock of products/parts thereof that have met established acceptance criteria. This includes parts that have been previously installed and removed, but not nonconforming material.

(2) Control of parts that are not completed to prevent stocking under an identifying part number until complete as defined by print or specification.

(3) Authorized methods for removal or replacement of parts.

(4) Limited and controlled access to storage areas.

(5) Records to be generated and maintained for parts removed from the stock system.

(6) Issue of raw and process material accountable to a released production order.

(7) Control of parts that have been quarantined as a result of a suspected nonconformance.

b. There is objective evidence of observance to established procedures.

427. Do completed products/parts have proper identification markings?

Applicability:

	APIS	PC	PMA	TSO
A	§ 45.13 § 45.14	§ 45.13 § 45.14	§ 45.15 § 45.14	§ 21.607 § 45.14
E	§ 45.11 § 45.14	§ 45.11 § 45.14	§ 45.15 § 45.14	§ 21.607 § 45.14

Statement of Condition

a. There is objective evidence that:

(1) Completed products/parts are properly identified and legible.

(2) Aircraft and aircraft engines are identified by means of a fireproof plate and have the required identification data.

(3) Propellers, propeller blades, and hubs are identified by means of a plate, stamping, engraving, etching, or other approved method of fireproof identification, and have the required identification data.

(4) Manned free balloons are identified by means of a fireproof plate on the balloon envelope, basket, and heater assembly, and have the required identification data.

(5) For TSO authorizations, articles are identified with the name and address of the manufacturer, the name, type, part number, or model designation of the article, the serial number or the date of manufacture or both, and the applicable TSO number.

(6) For PMA, parts are identified with the letters “FAA-PMA”; the name, trademark, or symbol of the approval holder; the [approved PMA] part number; and the name and model designation of each type certificated product on which the part is eligible for installation. For parts that the FAA finds are too small or impractical to mark, a tag may be attached that must contain the information that can not be included on the part, or may refer to specific part manuals or catalogs.

(7) For critical components, parts are permanently and legibly marked with a part number (or equivalent) and a serial number (or equivalent).

428. Are only conforming and properly identified products/parts shipped under the production approval?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. Procedures provide for:

(1) Packaging and shipping of products/parts that have been manufactured under the production approval that have met established acceptance criteria.

(2) Compliance with shipping instructions.

(3) Methods for preservation, packaging, and shipping of completed products.

b. There is objective evidence of observance to established procedures.

429. Have Statements of Conformity for products been submitted to the FAA for airworthiness determination?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.130	N	N	N
E	§ 21.130	N	N	N

Statement of Condition

a. There is objective evidence that a statement of conformity for the product manufactured by an APIS holder has been submitted to the FAA, and that this statement has been signed by an authorized person who holds a responsible position in the manufacturing organization.

430. If an export airworthiness approval has been issued, have the necessary documents and instructions been forwarded to the aviation authority of the importing country, or to other locations as specified in the special requirements of importing countries in AC 21-2?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.327	§ 21.327	§ 21.327	§ 21.327
E	§ 21.335	§ 21.335	§ 21.335	§ 21.335

Statement of Condition

a. There is objective evidence that:

(1) All documents and information necessary for proper operation of the products being exported have been forwarded to the cognizant aviation authority.

(2) Manufacturing assembly instructions and an FAA-approved flight test checkoff form have been forwarded to the cognizant aviation authority for unassembled aircraft that is being exported.

431. Have authorized personnel issued airworthiness approvals (FAA Form 8130–4 or 8130–3)?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.323	§ 21.323	§ 21.323	§ 21.323
E	§ 21.323	§ 21.323	§ 21.323	§ 21.323

Statement of Condition

a. Procedures provide for identification of personnel authorized to issue airworthiness approvals.

b. There is objective evidence of observance to established procedures.

432. Have export airworthiness approvals been obtained for all products/parts that have left the PAH's quality system?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Methods for applying for export airworthiness approvals (**FAA Form 8130–4 or 8130–3)**, and the responsibilities of personnel authorized to submit applications.

(2) All exported products to meet special requirements of the importing country listed in Appendix 2 of AC 21-2 (current revision). Procedures provide for properly annotating any deviation on the exporting documentation, and including a letter of acceptance from the importing country for such deviations.

(3) Methods for applying for domestic airworthiness approvals (**FAA Form 8130–3)**, and the responsibilities of personnel authorized to submit applications.

(4) Retention of copies of FAA Form 8130–4, Export Certificate of Airworthiness, and/or FAA Form 8130–3, Airworthiness Approval Tags, as applicable.

b. There is objective evidence of observance to established procedures.

FOR AIRCRAFT MANUFACTURERS ONLY

433. Are completed aircraft registered prior to airworthiness certification?

Applicability:

	APIS	PC	PMA	TSO
A	§ 47.3 § 21.173	§ 47.3 § 21.173	N	N
E	§ 21.173	§ 21.173	N	N

Statement of Condition

a. There is objective evidence that completed aircraft are registered prior to issuance of airworthiness certificate.

434. Have aircraft been properly identified with nationality and registration marks prior to airworthiness certification?

Applicability:

	APIS	PC	PMA	TSO
A	§ 45.21	§ 45.21	N	N
E	§ 45.21	§ 45.21	N	N

Statement of Condition

a. There is objective evidence that nationality and registration marks are displayed on aircraft, and are properly located and sized prior to airworthiness certification.

435. Have applicable airworthiness certificates or special flight permits been obtained for the purposes for which the aircraft is flown?

Applicability:

	APIS	PC	PMA	TSO
A	Part 21 Subparts H, I	Part 21 Subparts H, I	N	N
E	§ 91.203	§ 91.203	N	N

Statement of Condition

a. There is objective evidence that proper airworthiness certificates or special flight permits have been obtained prior to using aircraft for their intended purposes.

436. Are flight manuals, supplements, and current weight and balance data furnished with each aircraft at the time of delivery, as applicable?

Applicability:

	APIS	PC	PMA	TSO
A	§ 23.1581 § 25.1581 § 27.1581 § 29.1581 § 31.81	§ 23.1581 § 25.1581 § 27.1581 § 29.1581 § 31.81	N	N
E	§ 21.5 § 31.81	§ 21.5 § 31.81	N	N

Statement of Condition

a. There is objective evidence that aircraft flight manuals, supplements, and current weight and balance data are furnished with each aircraft, as applicable.

437. Have registration and airworthiness certificates been cancelled for aircraft whose title has passed to an importing country purchaser?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.335	§ 21.335	N	N
E	§ 21.335	§ 21.335	N	N

Statement of Condition

a. There is objective evidence that U.S. registration and airworthiness certificates have been cancelled by the FAA (contact FAA aircraft registry office in OKC at 405–954–3116) when title passes or has passed to an importing country purchaser. This evidence includes the return of Registration and Airworthiness Certificates, AC Form 8050–3 and FAA Form 8100–2 to the FAA.

SECTION 5. MANUFACTURING CONTROLS

1. SYSTEM ELEMENT DESCRIPTION. This system element addresses specialized actions whereby a PAH insures materials, parts, and assemblies are worked or fabricated, tested, and inspected to assure conformity to FAA-approved design. Manufacturing Controls also includes methods for review and approval of materials and parts that are withheld because of departures from design data or specifications and are to be considered for installation in the finished product. For purposes of an evaluation these actions are broken down as follows:

a. Statistical Quality Control (SQC). A method which may be used by the PAH to control product quality by statistical methods, and which may be used for continuous improvement and/or product acceptance. SQC includes techniques such as statistical sampling, PRE-control, and statistical process control (SPC).

b. Tool and Gauge. The function which establishes control of precision measuring devices (examples include tools, scales, gauges, fixtures, instruments, and automated measuring machines) used in fabrication, special processing, inspection, test of detail parts, assemblies, and completed products to determine conformity to FAA-approved design.

c. Testing. The function that provides for static, destructive, and functional tests of production products / parts thereof to ensure conformity to FAA-approved design.

d. Nondestructive Inspection. The application of technical methods to examine materials or components in ways that do not impair future usefulness and serviceability. These methods are used to detect, locate, measure and evaluate discontinuities, defects, and other imperfections, to assess integrity, properties, and composition, and to measure geometrical characters.

e. Nonconforming Materials. A method of controlling, evaluating, and dispositioning of any product/part thereof which does not conform to FAA-approved design.

2. SYSTEM ELEMENT STANDARDIZED EVALUATION CRITERIA. The criteria used to document the evaluation of this system element are divided into four parts: Part A, Statistical Quality Control (SQC), Part B, Tool and Gauge, Part C, Testing and Part D, Nondestructive Inspection.

Part A. Statistical Quality Control (SQC)

501. Has a statistical sampling inspection plan been established for acceptance of specified product characteristics at receiving inspection and during manufacture?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence that:

(1) All characteristics essential to ensure compliance to FAA-approved design have been identified. Characteristics which, if not maintained, would, or may, cause an unsafe condition in the end product, are identified separately.

(2) Product characteristics identified as having an impact on the safety of the end product have been 100 percent inspected.

(3) Samples have been selected which adequately represent the lot or process.

(4) Adjustments to the sampling plan are based on acceptance and quality history, and that the sampling plan is tightened to 100% inspection when nonconformances affecting safety are discovered.

(5) Statistical inspection conforms to sampling specifications or approved sampling plan requirements.

(6) Sampling plans do not allow the acceptance of "known defectives" in a lot, or Acceptable Quality Levels (AQLs) with known defectives, that would affect safety.

502. Do the engineering and manufacturing organizations participate in the review, implementation, and maintenance of statistical quality control (SQC) and statistical process control (SPC) techniques used for product acceptance?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for the engineering organization to review SQC/SPC planning prior to release to ensure the maintenance of FAA-approved design.

b. Procedures provide for the manufacturing organization to review SQC/SPC planning prior to release to ensure that the product can be produced in conformity to FAA-approved design.

c. There is objective evidence of observance to established procedures.

503. Has a satisfactory SPC method been established for acceptance of specific product characteristics?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Authority and responsibility for implementation and control of SPC.

(2) Scheduled independent evaluations of the SPC process to verify its continuing acceptability. This includes a conformity check of the product on a periodic basis.

(3) Identification of principal process characteristics, of the product to be controlled, and a determination as to the impact that a nonconformance would have on the safety of the end product.

(4) Identification of the types of control charts to be used to ensure maintenance of in-control processes. Variable control charts include charting for both range and variation around the mean.

(5) Capability studies to determine that the process can yield a product that conforms to FAA-approved design data.

(6) Test and measurement equipment study (e.g., a gauge study) to identify, eliminate, or adjust for, measurement errors that may contribute to process variability.

b. There is objective evidence of observance to established procedures.

504. Are appropriate SPC control limits and subgroup selections used and maintained?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Subgroups representative of the product lot.

(2) Avoidance of subgroup selection biases (e.g., patterns, ease of sampling, or pre-selection).

(3) Determination and adjustment of appropriate control limits for each process.

(4) Criteria for determining when an SPC process is considered to be out of control.

(5) Rules for out-of-control conditions and are available to operators or process checkers.

(6) Regular review of the SPC charts to determine changes (e.g. shifts) in the process.

(a) Review and retention of charts.

(b) Identification of personnel with the authority to stop the process when necessary.

(c) Notification of functional areas when an out-of-control condition is found, their responsibilities, and response time.

(7) Corrective action for an out-of-control condition.

(a) Additional inspection conducted to ensure product is acceptable.

(b) Evaluation of the need for purge action to remove suspected nonconforming products when a control chart used for acceptance shows an out of control condition.

b. There is objective evidence of observance to established procedures.

505. Has a satisfactory PRE-control method been established for acceptance of specific product characteristics?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Authority and responsibility for implementation and control of PRE-control.

(2) Scheduled independent evaluations of the PRE-control process to verify its continuing acceptability. This includes a conformity check of the product on a periodic basis.

(3) Identification of principal process characteristics, of the product to be controlled, and a determination as to the impact that a nonconformance would have on the safety of the end product.

(4) Capability studies using statistical techniques, ensuring process capability is less than the tolerance of the specific product characteristic to be measured.

(5) Test and measurement equipment study (e.g., a gauge study) to identify, eliminate, or adjust for, measurement errors that may contribute to process variability.

(6) Establishment of PRE-control limits, based on the tolerance of the specific product characteristic to be measured, to ensure maintenance of in-control processes.

(7) Qualification of the setup during production, ensuring that a minimum of five consecutive parts measured fall within the target area established by the PRE-control limits.

(8) Periodic measurement during production after the setup is qualified.

(9) Corrective action to adjust the process, requalify the setup, and recall and reinspect suspected products when PRE-control limits are exceeded.

b. There is objective evidence of observance to established procedures.

506. Are pertinent personnel trained in statistical techniques?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Responsibility for training. (Statistical sampling, PRE-control, SPC, etc.)

(2) Training new, or newly transferred, employees in statistical techniques.

b. There is objective evidence of observance to established procedures.

Part B. Tool and Gauge

507. Does the specified equipment used for inspection and test have the degree of accuracy necessary to determine conformity of the characteristic being inspected?

UUUUUUApplicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Engineering involvement in the selection of precision measuring devices used in fabrication, inspection, and test to ensure that the precision and accuracy required to determine conformity to the design feature/characteristic being inspected.

(2) Determinations and adjustments for the effects of tool wear.

(3) The degree of accuracy of all measurement devices and test equipment.

(4) Measurement devices and test equipment capable of the accuracy necessary and adequate for the intended purpose, including measurement devices and test equipment substituted for those specified.

b. There is objective evidence of observance to established procedures.

508. Are tools, gauges and equipment initially approved, periodically inspected and calibrated when applicable?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Initial inspection, calibration and approval of all test and measurement equipment.

(a) Establishment of the accuracy of all measurement devices prior to initial use.

(b) Assignment of calibration methods and initial calibration interval to ensure continued accuracy.

(c) Test and measurement equipment study (e.g., a gauge study) to identify, eliminate, or adjust for, measurement errors that may contribute to variability.

(d) Unique identification of individual measurement devices and standards to provide traceability to the calibration records.

(e) Inclusion in the identification and calibration system of personally-owned gauges used for product acceptance.

(f) Indication of the calibration status of measurement devices and standards. Typically, labels are used but other suitable controls can be provided.

(2) Periodic inspection and calibration of all measurement devices at prescribed intervals, or just prior to use, that will ensure their continued accuracy.

(a) Adjustment of calibration intervals based on analysis of previous calibration results, wear, stability, purpose, and degree of usage.

(b) Calibration by qualified personnel.

(c) Appropriate environmental conditions for calibration to ensure accuracy.

(d) Control of measurement devices and standards that are overdue for calibration.

(3) Tool control procedures for production tooling to ensure accuracy and repeatability for product acceptance prior to use.

(a) Inclusion in the calibration system.

(b) Assignment of unique identifiers.

(c) Availability of current applicable tool drawings.

(4) A documented mandatory recall system to ensure all measurement devices, calibration standards, and production tooling used for product acceptance are recalibrated at prescribed intervals.

(5) Generation and maintenance of tool and gauge records:

(a) Contain nomenclature, unique identifier, location, details of all adjustment, repair or rework accomplished, calibration history, source and date next inspection is due, standard used.

(b) Record legibility, completeness, and accuracy.

(c) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

509. Do standards used for calibration have adequate accuracy and are they traceable to a recognized international standards organization?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Accuracy, stability, range, and resolution of the standard used for calibration appropriate for the measurement device characteristic being calibrated. The accuracy ratio of the standard is dependent on the evaluated facility's measurement requirements (a minimum of 4 times more accurate than the gauge being calibrated, if possible).

(a) Methodology to determine adequacy of the calibration standards.

(b) Certificates, reports, or data sheets attesting to the accuracy of all calibration standards.

(2) Calibrations are traceable to the National Institute of Standards and Technology or other recognized international standards organization. If no national standard exists, the basis for calibration is documented.

510. Are tools and gauges protected, maintained and used in an acceptable environment, when specified, to ensure product conformity to FAA-approved design data?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Methods for handling, transporting, and storing measurement devices and standards to ensure required accuracy and reliability are maintained. Methods are usually in accordance with equipment manufacturer's recommendations and established industry practices.

(2) Actions taken when improper handling or storage occurs. As a minimum, an investigation is made to determine the adverse effects and action to be taken.

(3) Storage of measurement devices and standards appropriate to maintain required accuracy and fitness for use. Vibration, shock, temperature variations, humidity and contamination are some of the detrimental factors the procedure considers.

(4) Replacement of measurement devices and standards, as required, to ensure product conformity to FAA-approved design data.

(5) Identification of environmental conditions that are necessary for use and calibration of measurement devices and standards.

(6) Appropriate use of measurement devices and standards in environmental conditions that might affect accuracy, stability, or calibration, such as: temperature, relative humidity, vibration, electrical interference, cleanliness, or other controllable factors.

(7) Compensating corrections to calibration or measurement results obtained in an environment that departs from acceptable conditions.

(8) Standards, inspection tools, gauges, instruments, jigs, etc., that are inaccurate or beyond the scheduled calibration cycle identified are precluded from use until rework or recalibration is accomplished.

(9) Identification and control of measurement devices and standards that require rework or recalibration.

(10) Appropriate methods for rework of measurement devices and standards, and include sufficient reinspection to ensure accuracy.

b. There is objective evidence of observance to established procedures.

511. When a product has been accepted by a significantly out-of-tolerance gauge, is an evaluation conducted to determine the need for corrective action?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Documenting a significant out-of-tolerance condition, and investigating the validity of previous measurements.

(2) Notification of the significant out-of-tolerance condition to the user of the measurement device or standard.

(3) Investigations of out-of-tolerance conditions to ensure that conditions which adversely affect product quality or safety are reported to the FAA and the user, as required.

(a) Involvement of appropriate organizations, i.e. service/product support.

b. There is objective evidence of observance to established procedures.

512. Are tool control procedures applied to NDI equipment?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Periodic calibration of NDI equipment, and for generation and maintenance of records.

(2) Measurement of black light intensity on a periodic basis (preferably daily) using a calibrated black light meter.

(3) Measurement of white lights on a periodic basis using a calibrated white light meter.

b. There is objective evidence of observance to established procedures.

Part C. Testing

513. Are test procedures/applicable instructions and subsequent changes, established, maintained, and adequately controlled?

Applicability:

	APIS	PC	PMA	TSO
A	P	§ 21.143	P	§ 21.143
E	N	§ 21.165	N	§ 21.607

Statement of Condition

a. Procedures provide for:

(1) Preparation and maintenance of test procedures and instructions applicable to the products/parts produced to ensure that each article conforms to FAA-approved design data. Test documents include the following, as applicable:

(a) Original and recurring correlation and calibration to an established standard or baseline, determined by the facility and approved by the FAA, of aircraft engine test cells for the verification, validation, and repeatability of acceptance testing.

(b) A specified schedule of post-test teardown inspection to verify product quality, followed by rebuild and retest. A higher frequency of post-test teardown inspection for new products until the adequacy of assembly tooling, instruction, and techniques has been demonstrated.

(2) Actions to be taken when tests fail.

(3) Approval and control of all test procedure and instruction changes by authorized personnel.

(4) Requirements for changing test procedures and instructions.

(5) Review and verification of test procedure/instruction changes to ensure product quality is not negatively impacted.

(6) Documentation of test procedure/instruction change history by responsible personnel.

b. There is objective evidence of observance to established procedures.

514. Do procedures ensure that the appropriate organizations participate in the review of test instructions or procedures?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) The appropriate organization (manufacturing/engineering/quality/etc) review test instructions or procedures prior to release to ensure that the product can be tested in conformity to FAA-approved design.

(a) The product can be properly evaluated and verified to be in conformity to FAA-approved design. This includes the identification of inspection points that ensure conformity to FAA-approved design.

(b) Inspection equipment is available, or can be procured, which will adequately verify conformity to FAA-approved design, and which can be controlled for accuracy, when required.

(2) The appropriate organization (manufacturing/engineering/quality/etc.) personnel authorize additions, deletions, or changes to inspection points in the test instructions or procedures, based upon inspection results.

b. There is objective evidence of observance to established procedures.

515. Are products/parts that have been adjusted or reworked after test acceptance, retested to approved procedures?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures outline the requirements for retest of products/parts adjusted or reworked after inspection acceptance when that adjustment or rework could have an impact on the performance of those products/parts.

b. There is objective evidence of observance to established procedures.

516. Are there procedures to ensure records are generated and maintained for completed tests of aircraft, engines, or propellers?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	N	N
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Contents of each record used, including, as a minimum:

(a) Test results.

(b) Test nonconformances.

(c) Corrective action.

(2) Record legibility, completeness, and accuracy.

(3) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

FOR AIRCRAFT MANUFACTURERS ONLY

517. Have flight test procedures and subsequent changes been submitted to and approved by the FAA?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.127	§ 21.143 § 21.147	N	N
E	§ 21.123	§ 21.165	N	N

Statement of Condition

a. There is objective evidence that flight test procedures have been approved by the FAA prior to flight test.

b. There is objective evidence that changes to approved production flight test procedures and flight checkoff form(s) are submitted to and approved by the FAA.

518. In the case of aircraft, is the evaluated facility using flight test pilots that have been fully qualified?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	N	N
E	N	N	N	N

Statement of Condition

a. Procedures provide for

(1) Use of flight test pilots with current FAA medical certificates, who have maintained aircraft currency requirements for the model(s) being flown, and who have necessary qualifications for any special procedures required.

b. There is objective evidence of observance to established procedures.

519. In the case of aircraft, is the flight check-off form properly completed?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.127	§ 21.143	N	N
E	§ 21.123	§ 21.165	N	N

Statement of Condition

a. There is objective evidence that:

(1) Flight checkoff form(s)have been prepared.

(2) Forms are legible, complete, and accurate.

(3) Flight test discrepancies and their correction have been documented.

(4) Satisfactory completion of all flight test requirements has been verified.

Part D. Nondestructive Inspection

520. Are NDI processes, including changes, properly documented, controlled, and reviewed for conformance with FAA-approved design data?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Engineering review of NDI processes to ensure that FAA-approved design is maintained.

(2) Method of identifying and controlling revision levels of released NDI instructions.

b. There is objective evidence of observance to established procedures.

521. Are NDI operators certified, recertified, and decertified by the evaluated facility and performing within their limits of authorization?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Initial qualification testing of inspectors before issuance of acceptance stamps.

(2) Requalification of inspectors on a prescribed periodic basis.

(3) Vision requirements and retest on a periodic basis.

(4) Inspectors to provide identification of various levels of qualifications and various fields of expertise.

(5) Qualification of inspectors by authorized personnel.

(6) Identification and notification when requalification and vision tests are required.

(7) Documentation of employee's qualification.

(a) Qualification records for NDI operators that include:

1 Level of certification.

2 Educational background and experience.

3 Statement of satisfactory completion of training.

4 Results of most recent visual acuity examination.

5 Actual grades obtained in each examination.

6 Percentile weight assigned to each examination.

7 Composite grade of all examinations.

8 Date of certification or recertification, or both.

9 Signature of NDI examiner.

(8) Appropriate decertification methods for operators failing to maintain qualifications.

(9) The limits of authority for conducting and interpreting test results, or writing test reports.

b. There is objective evidence of observance to established procedures.

522. Are applicable NDI procedures/process specifications readily available and used by inspection personnel?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for controlled and detailed methods of inspection in each area of application.

b. There is objective evidence of observance to established procedures.

523. Are the critical NDI parameters identified and controlled?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for RADIOGRAPHIC PROCESS:

(1) Radiographic film processing per written procedures or manufacturer's instructions.

(2) Mixing of solutions in accordance with manufacturer's instructions.

(3) Control of solution temperatures, replenishing rates, and film travel as required to produce film of the required density, free of spots, streaks, fog, or scum.

(4) Periodic development of process control check strips and recording of densities.

(5) Periodic evaluation of uniformity of exposure.

(6) Film identification so as to have sufficient information to provide traceability and date of inspection.

(7) Inclusion of image quality indicator on each film.

(8) Film storage in accordance with recommendations from the manufacturer and monitoring of date limitations.

b. Procedures provide for ULTRASONIC INSPECTION:

(1) Immersion/squirter/bubbler tanks.

(2) Tanks are free of foreign materials that may inhibit adequate inspection.

(3) Wetting agent and/or corrosion inhibitor are used where needed.

(4) Couplant materials that are not detrimental to part being inspected or subsequent manufacturing operations.

c. Procedures provide for MAGNETIC PARTICLE PROCESS:

(1) Evaluation of the viscosity of the system oil on a systematic and periodic basis.

(2) Evaluation of the suspension of magnetic particles on a systematic and periodic basis.

(3) Evaluation of system sensitivity using a serialized test item on a systematic and periodic basis.

d. Procedures provide for FLUORESCENT PENETRANT PROCESS:

(1) Checking developers periodically in accordance with applicable specifications.

(2) Checking and recording rinse water temperature and pressure daily (where applicable).

(3) Checking emulsifiers periodically in accordance with manufacturer’s recommendations, or applicable specifications.

(4) Contamination testing, with results within the prescribed maximum allowable limits. This test is checked on a systematic and periodic basis.

e. Procedures provide for EDDY CURRENT PROCESS:

(1) Appropriate test pieces, eddy current probes, and handling equipment.

(2) Test pieces used to adjust the sensitivity of the electronic apparatus that are free of interfering discontinuities and that contain discontinuities similar in size and composition to those expected in the products to be examined.

(3) Test pieces that provide good signal resolution and have one or more natural or artificial discontinuities, such as notches or holes.

(4) Test areas visually free of grease, oil, rust, scale, or other substances that could interfere with the inspection.

f. There is objective evidence of observance to established procedures.

524. Do procedures address NDI acceptance and rejection criteria?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Acceptance/rejection criteria is coordinated with the FAA.

(2) Additional review of marginal inspection results by authorized personnel prior to acceptance.

(3) Use of acceptance/rejection criteria during inspection.

(4) Identification of personnel authorized to review and update acceptance/rejection criteria.

b. There is objective evidence of observance to established procedures.

525. Is corrective action taken when an NDI process is found to be out-of-control?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for an investigation to ensure continued acceptability of products accepted while the NDI process was out-of-control.

b. There is objective evidence of observance to established procedures.

526. Are adequate test pieces and NDI known-defect samples available and identified to preclude introduction into the production system?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Test pieces and samples that adequately reflect the part configuration.

(2) Test pieces and samples containing minimum size anomalies that would cause rejection of the part.

(3) Availability of American Society for Testing and Materials (ASTM) Standards, or other reference material for radiographic film interpretation.

(4) Method to identify test pieces and samples with known defects used to establish NDI so as to distinguish them from production items and prevent their introduction into the production system.

b. There is objective evidence of observance to established procedures.

527. Are NDI tanks and solutions checked for compliance with specifications?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Periodic samples of tank solutions to ensure compliance with operating specifications.

(2) Processing of lab reports according to procedures to ensure that out-of-control conditions are responded to immediately.

b. There is objective evidence of observance to established procedures.

528. Are NDI inspection records generated and maintained?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Contents of each record used.

(2) Record legibility, completeness, and accuracy.

(3) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

(4) Generation of inspection records that include:

(a) Acceptance of material.

(b) Inspector responsible for each area of test.

(c) Date of acceptance.

(d) Lot or serial number.

b. There is objective evidence of observance to established procedures.

PART E. NONCONFORMING MATERIAL

529. Is a Materials Review Board (MRB) established, documented and operational?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	N	§ 21.143
E	§ 21.123	§ 21.165	P	§ 21.607

Statement of Condition

a. There is objective evidence that:

(1) MRB members have been identified. This includes, as a minimum:

(a) Identification of the required members of the MRB, which should include, as a minimum, representatives of both the quality and engineering departments.

(b) Required qualifications of the quality and engineering members of the MRB, and the means by which personnel are added to the MRB.

(c) A list or electronic equivalent of approved quality and engineering representative members of the MRB, the frequency that MRB lists are updated, the areas where these lists are available, and a facsimile of MRB member signatures or identification stamps.

(d) Approval of MRB representatives of both the quality and engineering departments of MRB documents which disposition nonconforming parts "accept-as-is" and "repair."

(2) The MRB has not exceeded its scope and limits of authority. This includes, as a minimum {§ 21.93}:

(a) Disposition of minor nonconformances as "accept-as-is," "rework," "repair," "scrap," or "return-to-supplier."

(b) Disposition of major nonconformances as "rework" (to eliminate the nonconformance), "repair" (to reduce nonconformance to minor), "scrap," or "return-to-supplier."

(c) The MRB has dispositioned major nonconformances as "accept-as-is" only after the major change has been approved by the FAA as a change to the FAA-approved type design.

(3) Nonconforming material is controlled from presentation to the MRB through final MRB disposition. MRB control may be accomplished through segregation (physical or electronic), marking, or tagging, etc., in a manner to preclude inadvertent release, or release by non-MRB personnel. This includes, as a minimum:

(a) Completion of all necessary MRB documents, including all required signatures of MRB personnel, prior to physical release of products/parts from MRB control.

(b) Identification of MRB material sent to manufacturing areas for rework or repair to preclude subsequent release without MRB approval.

(c) Identification of MRB material sent to manufacturing areas for continued processing and re-inspection of the nonconformance after subsequent operations to ensure re-inspection of the specified characteristic.

(4) There is objective evidence that material review records are generated and retained.

(a) Material review records, include, as a minimum, part number, quantity, date, adequate description of nonconformances (including identification as major or minor change), disposition, and authorized approval.

(b) Application of "electronic" signatures are controlled, as well as authorized access to electronic data for making changes (e.g., password protection).

(c) Records are legible, complete, and accurate.

(5) Nonconforming material disposition authority, delegated to preliminary review personnel, is limited to "scrap," "return-to-supplier," "rework," or "repair to approved Standard Repair Procedures."

530. Are nonconforming products/parts identified, controlled, and dispositioned?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. There is objective evidence that nonconforming products/parts have been identified, controlled and dispositioned. Control includes segregation of nonconforming material, usually through storage in enclosed and secure holding areas, with access limited to authorized personnel. Standard repair procedures should also be controlled.

(1) Nonconforming materials, parts/products that have been dispositioned as "scrap" are properly identified, mutilated or disposed of to preclude inadvertent use.

(2) Parts/products dispositioned as "scrap" that are retained in lieu of mutilation and disposal are properly identified and/or physically segregated to preclude inadvertent use. For example, parts placed in a "scrap retention" crib awaiting a possible repair to be developed, or used in mock-ups or experimental testing.

(3) Parts from assemblies dispositioned as "scrap" are recovered and used only if the material review disposition shows that those parts did not contain the nonconformances that led to the "scrap" disposition.

531. Are MRB dispositions that are identified as major changes approved by the FAA through the design approval process?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.97	§ 21.97	P	§ 21.611
E	§ 21.123	§ 21.165	N	§ 21.607

Statement of Condition

a. There is objective evidence that all nonconformance dispositions that are considered major changes to the design are submitted to the FAA for approval.

532. Does upper management review and analyze nonconforming material data to detect adverse trends and determine appropriate levels of corrective and preventive actions?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for a summary of nonconforming material data reviewed and analyzed by upper management. This includes frequency of reporting.

(1) Appropriate investigations by all relevant facility organizations to reduce, prevent, and correct adverse trends.

b. There is objective evidence of observance to established procedures.

533. Do procedures provide for engineering review of nonconforming material to determine if the documented nonconformance constitutes a major or minor change to the FAA-approved type design?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

534. Is corrective action (in-plant, at suppliers, and in-service) required where processes or procedures result in a nonconforming product/part thereof and are the actions monitored for response, implementation and effectiveness?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Periodic reviews of material review records to identify repetitive nonconformances. There are guidelines for initiating investigation and corrective action for repeated nonconformances that have exceeded an established limit of occurrences.

(2) Corrective action on repetitive nonconformances dispositioned “accept-as-is” to preclude de facto changes to the type design being made through MRB acceptance of those nonconformances, rather than through the FAA-approved change system.

(3) Evaluation of the design if a product/part thereof continually fails to meet the requirements of the engineering drawing.

(4) Control of any deviation system established to allow the production of products/parts thereof to increased tolerances and/or relaxed standards until the completion of corrective action. Some deviations are FAA-approved minor drawing changes to the type design.

(5) Review of material review records (including corrective action statements) for repetitive nonconformances to monitor response, implementation, and effectiveness of corrective action.

(6) Responsibilities of any Corrective Action Board (CAB) or equivalent function established, including tracking of significant corrective action.

b. There is objective evidence of observance to established procedures.

SECTION 6. SUPPLIER CONTROL

1. SYSTEM ELEMENT DESCRIPTION. The system by which the evaluated facility ensures supplier materials, parts, and services conform to FAA-approved design. For the purpose of this section, the term "supplier" includes distributors.

NOTE: **With the onset of profit and risk-sharing ventures by many FAA approval holders, global marketing and procurement strategies, multinational and multicorporate activities, etc., there has been a significant increase in the global expansion of the world's aircraft manufacturing community. Global production includes the use of associate facilities, the issuance and acceptance of import/export airworthiness approvals, and adherence to Bilateral Airworthiness Agreements (BAA) or Bilateral Aviation Safety Agreements (BASA).**

2. SYSTEM ELEMENT STANDARDIZED EVALUATION CRITERIA. The following criteria are used to document evaluation of this system element.

601. Is the use of approved suppliers required?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Criteria for supplier acceptability, based as a minimum on evaluation results and quality performance history for the commodities or services provided.

(2) Collection, evaluation, and reporting of quality performance data.

(3) A list of suppliers that have been reviewed, evaluated and found to be acceptable.

(AC 21–20 latest revision)

(4) Removal of suppliers from the approved list that do not meet stated requirements.

(5) Notification to FAA of new priority parts suppliers.

(6) Methods for procurement from suppliers that require special control.

(7) Furnishing a current list to suppliers containing sources evaluated by the PAH.

b. There is objective evidence of observance to established procedures.

602. Are initial and periodic evaluations of suppliers made, as necessary and corrective actions taken to correct deficiencies found in the suppliers system?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Initial evaluation of suppliers, and periodically as necessary, to determine their capability to meet requirements.

(2) The methods for determining the extent of the evaluations, dependent, as a minimum, on the type, complexity, method of control, and importance of products or services procured, and provide for on-site evaluation, process reviews, document reviews, or independent product evaluations.

(3) Implementing and documenting effective corrective action when deficiencies are found.

b. There is objective evidence of observance to established procedures.

603. Is the supplier's quality manual (or top level document) approved by the PAH?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide the method for reviewing and approving a supplier's quality system data.

b. There is objective evidence of observance to established procedures.

604. Are procedures for the use of other-parties to perform supplier surveillance or assessments on behalf of the PAH contained in the quality manual or other documents?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) A control process which has been fully documented and includes:

(a) Initial and continuing approval of other-parties to conduct supplier surveillance and assessments to include:

(b) Extent of authority given by the PAH.

(c) Verification that checklists used by the other-party are equivalent or better than the PAH's quality procedures and surveillance criteria that are currently in place under the PAH's supplier control program.

(d) Verification that the other–party's surveillance frequency of the supplier is commensurate with the complexity of the product and with the surveillance frequency currently established by the PAH's supplier control program.

(e) Verification that the supplier surveillance was conducted on-site by the other-party.

(f) Verification that the other-party has access to applicable proprietary data to the extent necessary to conduct supplier surveillance functions.

(g) Verification that the surveillance report will be made available to the FAA upon request.

b. There is objective evidence of observance to established procedures.

605. Are procedures for the use of other-party registered suppliers detailed in the quality manual or other documents?

Applicability:

	APIS	PC	PMA	TSO
A	N	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Initial and continuing approval of other-party registered suppliers:

(2) The method used by the PAH to evaluate the registration process of any other-party registration body used. (Note: This applies not only to new suppliers, but also to any decision by the PAH to rely on other-party registration of current suppliers.) The method should include the following items as a minimum:

(a) Verification that registration standards and checklists used by the other–party are equivalent or better than the PAH's quality procedures and surveillance criteria that are currently in place under the PAH's supplier control program.

(b) Verification that the other–party's surveillance frequency of the supplier is commensurate with the complexity of the product and with the surveillance frequency currently established by the PAH's supplier control program.

(c) Verification that the supplier surveillance was conducted on-site by the other-party.

(d) Verification that the other-party has access to applicable proprietary data to the extent necessary to conduct supplier surveillance functions.

(e) Verification that the surveillance report will be made available to the FAA upon request.

(f) Verification that the other-party continues to be recognized or accredited.

b. There is objective evidence of observance to established procedures.

606. Do procedures require that suppliers notify the evaluated facility in writing when there are significant facility or organizational changes such as company name, location, or senior quality management?

Applicability:

	APIS	PC	PMA	TSO
A	N	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

607. Does the evaluated facility make information available to the FAA regarding all delegation of authority to suppliers to make a major inspection/material review of any products/parts?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.123	§ 21.143	P	§ 21.143
E	§ 21.125	§ 21.165	N	§ 21.607

Statement of Condition

a. Procedures provide for:

(1) Delegation of authority for major inspections or material review.

(2) Material review requirements include, as a minimum:

(a) Identification of relevant MRB procedures that define the scope and authority of the supplier MRB.

(b) Maintenance of an MRB system that meets all FAA requirements placed on the evaluated facility's MRB system (e.g., documentation of nonconformances, maintenance of records, members of the MRB, mutilation of "scrap" material).

(c) Process for submittal to the evaluated facility of supplier nonconformances that are considered major changes to the FAA-approved type design.

(3) All delegations of authority to suppliers for major inspection of any products/parts are available for review by the FAA.

b. There is objective evidence of observance to established procedures.

608. Does the PAH notify the FAA of suppliers authorized to direct ship?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for notification to the cognizant FAA office of each supplier authorized to direct ship.

b. There is objective evidence of observance to established procedures.

609. Suppliers with direct ship authorization are controlled to ensure that only conforming parts are released?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Flow down of applicable technical and quality requirements.

(2) Authorization and requirements for direct shipment.

(3) Supplier shipping document requirements for direct shipment.

(4) Appropriate part marking/identification and packaging.

b. There is objective evidence of observance to established procedures.

610. Do procedures require that approved suppliers have a supplier control program in place for their suppliers?

Applicability:

	APIS	PC	PMA	TSO
A	N	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence that suppliers have a supplier control program in place for their suppliers. The program should include at a minimum:

(1) Evaluation, approval and surveillance of suppliers, including a method to ensure corrective action when a problem is identified.

(2) Flow-down of all pertinent quality requirements.

(3) Documentation of parts/materials and special processes obtained from suppliers is submitted to the evaluated facility.

611. Does the evaluated facility flow down applicable technical and quality requirements to both U.S. and international suppliers?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for:

(1) Inclusion of applicable technical data and quality requirements in the purchase documents. Technical data and requirements include, as applicable:

(a) Special processing specifications/engineering requirements for suppliers performing special processing.

(b) Calibration traceable to a national standard and submittal of certificates for suppliers performing calibration services.

(c) Software specification requirements for suppliers providing software.

(d) Submittal of certification test reports for all shipments of raw material.

(e) Identification of raw and process material in accordance with industry and/or customer specifications.

(f) Appropriate identification and marking of products/parts thereof.

(g) Identification of the actual manufacturers of the supplies provided by warehouses and distributors.

(h) Declaration that parts were produced under the terms of the production approval.

(i) Identification of the product on which the part is eligible for installation.

(j) Special packaging and preservation requirements, when warranted for material protection.

(k) Identification of appropriate technical requirement revision levels.

(l) Notice of FAA review of supplier's facilities and products as necessary.

(m) Incorporation of design changes as specified.

(n) Notification to the evaluated facility of any latent defects, or defects listed in § 21.3, in products or parts previously supplied.

(o) Formalized SQC policy, when required.

(p) Requests for copies of control charts and other pertinent statistical data applicable to the time period during which the supplied products/parts thereof were produced.

(q) Submittal of supplier designs and changes to the evaluated facility for approval prior to incorporation, when required.

(r) Submittal of changes to a supplier's quality system that may affect inspection, conformity, or the airworthiness of the product.

(s) Record retention requirements.

(t) Use of English language for quality data (e.g., supplier quality procedures, certificates, reports, or other similar data required by the evaluated facility).

(u) A method to control the issuance and distribution of technical data and quality requirements to suppliers. Control methods include, as a minimum:

(v) Control and documentation of revisions to technical data and quality requirements (including sub-tier and referenced documents).

(w) Control of obsolete technical data and quality requirements.

(x) Determination of receipt status by the supplier.

b. There is objective evidence of observance to established procedures.

612. Does the evaluated facility control supplier design, including changes?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.95 § 21.97 § 21.99 § 21.125	§ 21.95 § 21.97 § 21.99	§ 21.303(h)(7)	§ 21.611
E	§ 21.123	§ 21.165	§ 21.303(h)	§ 21.607

Statement of Condition

a. Procedures provide for control over supplier design and changes thereto.

b. There is objective evidence of observance to established procedures.

613. Are electronically stored and transmitted technical design and quality data adequately controlled and distributed to suppliers?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for

(1) Documentation of release status of electronic documents.

(2) Only properly released data is available on-line.

(3) Other documents, such as purchase orders and engineering data reflect changes to the source document.

(4) Capability determination of in-house and supplier facility to receive and maintain electronic data.

b. There is objective evidence of observance to established procedures.

614. Does the quality organization review purchase documents prior to issuance?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition:

a. Procedures provide for review of purchase documents by the PAH's quality organization prior to issuance to ensure that all pertinent requirements have been incorporated.

b. There is objective evidence of observance to established procedures.

615. Does the PAH act on supplier notifications of suspected problems with previously delivered products?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for methods used to act upon notifications of nonconforming products, ensuring proper investigation and corrective action is taken.

b. There is objective evidence of observance to established procedures.

616. Do procedures require that approved suppliers have a program in place to ensure the proper operation of manufacturing software and equipment used for product/part inspection/test?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. There is objective evidence of established procedures.

617. Does the PAH notify the FAA of all new suppliers located in other countries, and of the receipt of first articles produced by those suppliers?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for notification to the FAA of all new suppliers located in other countries, and of the receipt of first articles produced by those suppliers.

b. There is objective evidence of observance to established procedures.

618. Are product/parts from associate facilities controlled?

Applicability:

	APIS	PC	PMA	TSO
A	§ 21.125	§ 21.143	§ 21.303	§ 21.143
E	§ 21.123	§ 21.165	§ 21.303	§ 21.607

Statement of Condition

a. Procedures provide for:

(1) Control of product/parts from associate facilities.

(2) Collection of quality performance data.

b. There is objective evidence of observance to established procedures.

619. Has an interface quality document been prepared for consortium (international/domestic) manufacturing activities?

Applicability:

	APIS	PC	PMA	TSO
A	P	P	P	P
E	N	N	N	N

Statement of Condition

a. Procedures provide for a quality document, which establishes an interface between the quality requirements of the international/domestic manufacturing activity and the evaluated facility's quality manual or procedures.

b. There is objective evidence of observance to established procedures.

PART B. PREPARATION INSTRUCTIONS FOR FAA FORM 8100–4, ACSEP SURVEY SHEET FOR PRODUCTION APPROVAL HOLDERS

1. PURPOSE. This appendix provides instructions for completing FAA Form 8100–4.

2. SPECIFIC GUIDANCE. Figure 1 shows FAA Form 8100–4. Prepare the form by inserting in the following:

a. ACSEP No./Report No. Block. Insert the ACSEP number and the report number.

b. Project No. Block. Insert the project number(s).

c. Blocks 1 through 7. Check the appropriate box for each system element evaluation criterion. Determine the appropriate box to check for each criterion as follows:

(1) Unable to evaluate. Check this box if you were unable to fully evaluate the criterion due to lack of time, inadequate resources, lack of expertise, or other reasons. You may also check either the "No procedures" box or the "Procedures in place" box if that information is known; see paragraphs 2c(3) and 2c(4) in this appendix. If you were unable to evaluate an entire system element, record the appropriate reasons as part of the lessons learned (see appendix 12).

(2) Not applicable. Check this box if the criterion was not applicable at the facility being evaluated. Do not check any other box for this criterion.

(3) No procedures. Check the box if the criterion was applicable at the facility being evaluated and no procedures were in place relative to the criterion. You may check this box in addition to the "Unable to evaluate" box if no procedures were in place relative to the criterion.

(4) Procedures in place. Check this box if the criterion was applicable at the facility being evaluated and procedures were in place relative to the criterion. You may check this box in addition to the "Unable to evaluate" box if procedures were in place relative to the criterion.

d. New Criteria Block. Insert the system element number and a brief description of the new criteria.

(1) List all new criteria developed.

NOTE: Include the complete text of new criteria in the ACSEP Evaluation Lessons Learned section of the ACSEP evaluation report (see appendix 12).

(2) Assign a system element number to each new criterion. For example, a new criterion developed for evaluation of the tool and gauge system element would be assigned to system element number 5, part B.

PART B. PREPARATION INSTRUCTIONS FOR FAA FORM 8100–4, ACSEP SURVEY SHEET FOR PRODUCTION APPROVAL HOLDERS

FIGURE 1. SAMPLE FAA FORM 8100–4

U.S. Department of Transportation
Federal Aviation Administration

ACSEP Survey Sheet
for
Production Approval Holders

ACSEP No./Report No.
ACSEPNo / 1-1
Project No.
Project No

Unable to evaluate | Not applicable | No procedures | Procedures in-place

					1. ORGANIZATIONAL MANAGEMENT
				101	Is the production approval/authorization displayed prominently?
				102	Is the evaluated facility operating within the production limitations of the production approval?
				103	Overall Policy/procedural document describing the facility and each organization responsible for various functions
				104	Is the policy document reviewed periodically, updated as warranted and available to responsible personnel
				105	Is there a Quality Manual in use and does it describe the management of quality-related subjects, including responsibilities and levels of authority
				106	Is quality system data, and changes thereto, submitted to the FAA?
				107	Are tags, forms and other documents described and controlled?
				108	Has the evaluated facility established a record retention schedule for various types of process, test and quality/inspection system data?
				109	Are relocations of the facility reported to the FAA in writing?
				110	Are failures, malfunctions and defects reported to the FAA?
				111	Are Service Bulletins and maintenance manuals approved by authorized personnel and coordinated with FAA
				112	Are there provisions for receiving feedback on service problems/difficulties from users/installers?
				113	Are service problems, unairworthy conditions, unsafe features/characteristics reported by the FAA or users investigated and corrective actions taken?
				114	Do procedures provide a method to notify users and recall products, when necessary, when nonconformances are suspected or known to exist in products in service?
				115	Is there a means for keeping users of product/parts informed of service information, including field purges?
				116	Is there an internal auditing program to verify compliance with established policies and approved data?
				117	Are results of internal audits reported to management and are the audits used for improvement of the system/product?
					2. DESIGN CONTROL
				201	Are there procedures for control of technical data/documents and do they include storage, maintenance and protection?
				202	Are the issuance, retrieval, distribution, and currency of design and technical data documents controlled?
				203	Do the manufacturing, quality, service/support organizations participate in the review of design and technical data changes.
				204	Are procedures in place to approve, document and control changes to product design?
				205	Are changes to technical data referenced on FAA approved design data appropriately documented and approved?
				206	Are minor design changes approved under a method acceptable to the FAA?
				207	Are major design changes, including process specification changes, submitted to the FAA for approval?
				208	Have design changes necessary to correct unsafe conditions been incorporated into the FAA approved design, when applicable.
				209	Are the Instructions for Continued Airworthiness kept current with design changes, and made available to appropriate persons?
				210	Is descriptive data and information on FAA-approved design changes resulting from AD's made available to users.
					3. SOFTWARE QUALITY ASSURANCE
					Part A — **Airborne Software**
				301	Software Configuration Management Plan
				302	Configuration Index Document
				303	Software problem reporting and tracking
				304	Recall/purge of obsolete software
				305	Software security
				306	Software Development Environment
				307	Software identification
				308	Programmed media handling/storage
				309	Build and load instructions established
					Part B — **Product Acceptance Software**
				310	Software Configuration Management Plan
				311	Change documentation and approval
				312	Software problem reporting
				313	Software security
				314	Verification prior to use
				315	Build and load instructions
					4. MANUFACTURING PROCESSES
					Part A — **Manufacturing and Special Manufacturing Processes**
				401	Are work instructions and revisions to work instructions reviewed, approved, controlled and documented?
				402	Are all special processes in use identified and defined by FAA-approved design data and detailed in process specs?
				403	Are new or changed processes substantiated and approved by appropriate personnel?
				404	Are special process operators qualified and approved in accordance with the specification/manufacturer's procedures?
				405	Are records generated and maintained to reflect compliance with specification requirements?
				406	Is equipment required for special processing available and calibrated, as necessary?
				407	Is action taken to correct a manufacturing/special process, which is found to be out of control?
				408	Have lists or charts showing location and type of inspection stations been properly maintained?
				409	Are inspection methods selected to ensure parts will be inspected for conformity with FAA-approved design data?
				410	Is the inspection status of product/parts identifiable throughout the manufacturing cycle?
				411	Are inspection marking devices/stamps issued only to authorized persons and are there procedures to ensure proper control?
				412	Are special environmental controls utilized in manufacturing and assembly areas when warranted?

FAA Form 8100-4 (10/02)
FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552
Page 1 of 3

PART B. PREPARATION INSTRUCTIONS FOR FAA FORM 8100–4, ACSEP SURVEY SHEET FOR PRODUCTION APPROVAL HOLDERS

FIGURE 1. SAMPLE FAA FORM 8100–4 (CONTINUED)

U.S. Department of Transportation
Federal Aviation Administration

ACSEP Survey Sheet
for
Production Approval Holders

ACSEP No./Report No.
ACSEPNo / 1-1
Project No.
Project No

Unable to evaluate	Not applicable	No procedures	Procedures in-place		
					4. MANUFACTURING PROCESSES
					Part B – Material Handling, Receiving & Storage
				413	Is receiving inspection required to verify conformity to design data and purchase order requirements?
				414	Are records of receiving inspection generated and verified?
				415	Are purchased shelf-life materials and products verified to ensure that specification requirements are met?
				416	Are age sensitive products/parts/ materials identified and controlled?
				417	Are materials and parts awaiting acceptance segregated?
				418	Are traceable components identified in assembly records?
				419	Are completed parts traceable to raw material, when applicable?
				420	Is traceability for split lots maintained, including accountability for the completion of all manufacturing and inspection operations?
				421	Are special identification and controls required if material or parts are introduced into production prior to full acceptance?
				422	Are appropriate methods used to prevent part damage or contamination?
				423	Are cleaners, solvents, degreasers, etc., adequately identified and controlled to prevent potential product damage from misapplication?
				424	Is there proper separation and identification of product/parts in storage and manufacturing areas?
					Part C – Airworthiness Determination
				425	Are required design changes incorporated on products/parts being stored prior to their release for installation/shipment?
				426	Are only conforming and properly identified products/parts placed in storage and is removal/issuance of parts controlled?
				427	Do completed products or parts have proper identification markings?
				428	Are only conforming and properly identified products or parts shipped under the production approval?
				429	Have statements of conformity for products been submitted to the FAA for airworthiness determination.
				430	If an export airworthiness approval has been issued, have the necessary documents and instructions been forwarded to the aviation authority of the importing country as specified in AC 21-2?
				431	Have authorized personnel issued airworthiness approvals (FAA Form 8130-4 or 8130-3)?
				432	Have export airworthiness approvals been obtained for all products/parts that have left the PAH's quality system?
					FOR AIRCRAFT MANUFACTURERS ONLY
				433	Are completed aircraft registered prior to airworthiness certification?
				434	Have aircraft been properly identified with nationality and registration marks prior to airworthiness certification?
				435	Have applicable airworthiness certificates or special flight permits been obtained for the purposes for which the aircraft is flown?
				436	Are flight manuals, supplements and current weight and balance data furnished with each aircraft?
				437	Have registration and airworthiness certificates been cancelled for aircraft whose title has passed to an importing country?

Unable to evaluate	Not applicable	No procedures	Procedures in-place		
					5. MANUFACTURING CONTROLS
					Part A – Statistical Quality Control (SQC)
				501	Has a statistical sampling plan been established for acceptance of product characteristics at receiving inspection and during manufacture?
				502	Do engineering and manufacturing organizations participate in the SQC program?
				503	Has a satisfactory SPC method been established for acceptance of specific product characteristics?
				504	Are appropriate SPC control limits and subgroup selection being used and maintained?
				505	Has a satisfactory PRE-control method been established for acceptance of specific product characteristics?
				506	Are pertinent personnel trained in statistical techniques?
					Part B – Tool and Gauge
				507	Does the specified equipment used for inspection and test have the degree of accuracy necessary to determine conformity of the characteristic being inspected?
				508	Are tools, gauges and equipment initially approved, periodically inspected and calibrated when applicable?
				509	Do standards used have adequate accuracy and are they traceable to a recognized standards organization?
				510	Are tools and gauges protected, maintained and used in an acceptable environment to ensure product conformity?
				511	When a product has been accepted by a significantly out of tolerance gauge, is an evaluation conducted to determine the need for corrective action?
				512	Are tool control procedures applied to NDI equipment?
					Part C – Testing
				513	Are test procedures/applicable instructions and subsequent changes established, maintained and adequately controlled?
				514	Do procedures ensure that the appropriate organizations participate in the review of test instructions or procedures?
				515	Are products/parts that have been adjusted or reworked after test acceptance, retested to approved procedures?
				516	Are there procedures to ensure records are generated and maintained for completed tests of aircraft, engines, or propellers?
					FOR AIRCRAFT MANUFACTURERS ONLY
				517	Have flight test procedures and changes been submitted to and approved by the FAA?
				518	In the case of aircraft, is the evaluated facility using flight test pilots that have been fully qualified?
				519	In the case of aircraft is the flight check-off form properly completed?
					Part D – Non-Destructive Testing
				520	Are NDI processes, including changes, properly documented, controlled and reviewed for conformance with FAA approved design data?
				521	Are NDI operators certified, recertified, and decertified by the evaluated facility and performing within their limits of authorization?
				522	Are applicable NDI procedures/process specifications readily available and used by inspection personnel?

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PART B. PREPARATION INSTRUCTIONS FOR FAA FORM 8100–4, ACSEP SURVEY SHEET FOR PRODUCTION APPROVAL HOLDERS

FIGURE 1. SAMPLE FAA FORM 8100–4 (CONTINUED)

U.S. Department of Transportation
Federal Aviation Administration

ACSEP Survey Sheet
for
Production Approval Holders

ACSEP No./Report No.
ACSEPNo / 11
Project No.
Project No

Unable to evaluate	Not applicable	No procedures	Procedures in-place		
					Part D – Non-Destructive Testing
				523	Are the critical NDI parameters identified and controlled?
				524	Do procedures address NDI acceptance and rejection criteria?
				525	Is corrective action taken when an NDI process is found to be out of control?
				526	Are adequate test pieces and NDI known defect samples available and identified to preclude introduction into the production system?
				527	Are NDI tanks and solutions checked for compliance with specifications?
				528	Are NDI inspection records generated and maintained?
					Part E – Nonconforming Material
				529	Is a Materials Review Board (MRB) established, documented and operational?
				530	Are nonconforming products/parts identified, controlled and dispositioned?
				531	Are MRB dispositions that are identified as major changes approved by the FAA through design approval process?
				532	Does upper management review and analyze nonconforming material data to detect adverse trends?
				533	Does engineering review nonconforming material to determine if nonconformance constitutes a major or minor change to FAA-approved type design.
				534	Is corrective action required where processes or procedures result in nonconforming product/part and are actions monitored?
					6. SUPPLIER CONTROL
				601	Is the use of approved suppliers required?
				602	Are initial and periodic evaluations of suppliers made as necessary and are corrective actions taken to correct deficiencies?
				603	Is the supplier's quality manual approved by the PAH?
				604	Are procedures for the use of other -parties to perform supplier surveillance or assessments on behalf of the PAH contained in the quality manual or other documents?
				605	Are procedures for the use of other -party registered suppliers detailed in the quality manual or other documents?
				606	Do procedures require that suppliers notify the evaluated facility in writing when there are significant facility or organizational changes such as company name, location or senior quality management?
				607	Does the evaluated facility make information available to the FAA regarding all delegation of authority to suppliers to make a major inspection/material review of any products/parts?
				608	Does the PAH notify the FAA of suppliers authorized to direct ship?
				609	Suppliers with direct ship authority are controlled to ensure that only conforming parts are released?
				610	Do procedures require that approved suppliers have a supplier control program in place for their suppliers?
				611	Does the evaluated facility flow down applicable technical and quality requirements to both U.S. and international suppliers?

Unable to evaluate	Not applicable	No procedures	Procedures in-place		
				612	Does the evaluated facility control supplier design, including changes?
				613	Are electronically stored and transmitted technical design and quality data adequately controlled and distributed to suppliers?
				614	Does the quality organization review purchase documents prior to issuance?
				615	Does the PAH act on supplier notifications of suspected problems with previously delivered products?
				616	Do procedures require suppliers to have a program to ensure the proper operation of manufacturing software and equipment used for product/part inspection/ test?
				617	Does the PAH notify the FAA of all new suppliers located in other countries and receipt of first articles produced by those suppliers?
				618	Are products and parts from associate facilities controlled?
				619	Has an interface quality document been prepared for consortium manufacturing activities?

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