



Advisory Circular

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21, Subparts F, G, K, and O

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This advisory circular (AC) provides information for production approval holders (PAH) under Title 14, Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products, Articles, and Parts. This AC guides PAHs in developing and maintaining quality systems for the products and articles they produce. This guidance aids the applicant for a production approval or current PAH in developing a quality system that both meets the needs of the PAH and is compliant with the regulations. You can find this AC at http://www.faa.gov/regulations_policies/advisory_circulars/.

/s/

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CHAPTER 1. GENERAL INFORMATION

1-1. Purpose.

a. This advisory circular (AC) provides information about Title 14, Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products, Articles, and Parts. This AC addresses the manufacturing and production requirements of part 21, subpart F, Production Under Type Certificate; subpart G, Production Certificates (PC); subpart K, Parts Manufacturer Approvals (PMA); and subpart O, Technical Standard Order (TSO) Approvals.

b. This AC provides information on how an applicant for a production approval or a current production approval holder (for this AC both are referred to as a PAH) should develop and maintain their quality systems. This guidance aids the PAH in developing a quality system that both meets the needs of the PAH and is compliant with the regulations.

c. This AC is not mandatory and does not constitute a regulation. This AC describes an acceptable means, but not the only means, to comply with these requirements. However, if you use the means described in the AC, you must follow it in all important respects.

1-2. Audience. This AC affects all PAHs and type certificate holders producing under subpart F, Production Under Type Certificate.

1-3. Effective Date. This AC is effective 18 months after the publication of Production and Airworthiness Approvals, Part Marking, and Miscellaneous Amendments; Final Rule in the Federal Register under docket number FAA-2006-25877-0114.

1-4. Applicability. Sections 21.131, 21.301, and 21.601 prescribe the procedural requirements for issuing production approvals (PC/PMA/TSO) and the rules governing the holders of those production approvals. Section 21.601 also includes procedural requirements for issuing letters of TSO design approval.

Note: Type certificate holders producing under subpart F should review appendix D of this AC for additional information.

1-5. Eligibility. Section 21.132 prescribes eligibility requirements for a production certificate. Applicants for a production certificate are required by the rule to hold the following for the product concerned:

- a. A current type certificate (TC),
- b. A supplemental type certificate (STC), or
- c. Rights to the benefits of that TC or STC under a licensing agreement

1-6. Application. Sections 21.133, 21.303, and 21.603 require that an applicant for a production approval apply in a form and manner prescribed by the FAA. Sections 21.303 and 21.603 contain additional requirements that require the applicant to provide additional information with the application. Applicants should refer to the applicable section for requirements pertaining to the type of production approval they seek.

a. For a PC, an applicant will submit FAA Form 8110-12, Application for Type Certificate, Production Certificate, or Supplemental Type Certificate. This form is submitted to the Manager, Manufacturing Inspection Office (MIO), in the directorate in which the applicant's principal manufacturing facility is located.

b. For a PMA:

(1) If an applicant is applying based on identity or test and computation, the applicant will submit a letter of application to the Aircraft Certification Office (ACO) in the geographical area in which the applicant's manufacturing facility is located.

(2) If the applicant is applying based on a licensing agreement, the applicant will submit a letter of application to the Manufacturing Inspection District Office (MIDO) in the geographical area in which the applicant's manufacturing facility is located.

c. For a TSO authorization, an applicant will submit a letter of application to the ACO in the region in which the applicant's principal manufacturing facility is located.

1-7. Organization Requirements. Sections 21.135, 21.305, and 21.605 require each PAH provide the FAA with a document describing how its organization will ensure compliance with the provisions of the applicable subpart. At a minimum, the document is required by the rule to describe assigned responsibilities and delegated authority. The document is required by the rule to describe the functional relationship between those responsible for quality to management and other organizational components. The FAA recognizes the varying business models and organizational structures of different businesses. The intent of this requirement is to obtain a commitment from top management to—

a. Establish a quality system that complies with this part and ensures that each product and article conforms to its approved design and is in a condition for safe operation; and

b. Continually improve that quality system.

Chapter 2. Quality System

2-1. Purpose. This chapter provides information and describes criteria for establishing and maintaining a quality system. PAHs may use this document in support of their responsibilities under §§ 21.137, 21.307, and 21.607.

2-2. Background. Section 21.137 requires that each PAH establish and describe, in writing, a quality system that ensures that each product and article conforms to its approved design and is in a condition for safe operation. Sections 21.307 and 21.607 require that a PAH establish a quality system that meets the requirements of § 21.137. The intent is for each PAH to develop a quality system that both meets the needs of the PAH and the rule. As such, PAH quality systems are scalable to the size and complexity of the product or article being produced. Examples of this scalability can be found in Figure 1 at the end of this chapter. The quality system requirements contain the following 14 elements outlined in 2-3 through 2-16:

2-3. Design Data Control. Section 21.137(a) requires procedures for controlling design data, and subsequent changes, to ensure that only current, correct, and approved data are used.

a. Procedures. PAHs are required by the rule to have procedures for design data control. These procedures should ensure proper storage, maintenance, and protection of design data. In addition, PAHs should ensure that design data is identified, controlled, and made available to those persons who require them. There also should be procedures for approving, documenting, and controlling changes to the design data.

b. Design Changes. Design, manufacturing, and special process changes should be approved in a manner acceptable to the FAA. Design changes necessary to correct unsafe conditions should be incorporated into the FAA-approved design. Instructions for Continued Airworthiness (ICA) should be kept current with the design changes.

2-4. Document Control. Section 21.137(b) requires procedures for controlling quality system documents and data, and subsequent changes, to ensure that only current, correct, and approved documents and data are used.

a. Procedures. PAHs are required by the rule to have procedures for quality system document and data control. These procedures should ensure proper storage, maintenance, and protection of documents and data. Additionally, PAHs should ensure quality system documents and data, including all tags and forms, are identified, controlled, and made available to those persons who require them.

b. Document and Data Changes. There should be procedures for documenting, approving, and controlling changes to the quality system documents and data.

c. Electronic Storage. PAHs may choose to store documents electronically, as long as printed copies are made available upon FAA request.

2-5. Supplier Control. Section 21.137(c) requires procedures for ensuring that each supplier-furnished product or article conforms to its approved design. This section also requires that suppliers report to the PAH if a product or article has been released from that supplier and subsequently found not to conform to the applicable design data.

a. Procedures. Refer to chapter 3 of this AC for additional information on what procedures a typical supplier control program should contain.

b. PAH Responsibilities. The PAH is ultimately responsible for determining that all products and articles conform to their approved type design and are in condition for safe operation. This responsibility cannot be delegated to, or relieved by the use of, approved suppliers, risk and revenue sharing partners, or co-producers or other service or manufacturing providers.

2-6. Manufacturing Process Control. Section 21.137(d) requires procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.

a. Manufacturing Processes. PAHs should have procedures for ensuring that all manufacturing processes (including special processes) that have been identified and defined by FAA-approved design data are accounted for in the manufacturing process.

b. Work Instructions and Revisions. PAHs should ensure that work instructions and revisions to work instructions are reviewed, approved, controlled, documented, and made available to those persons who require them.

c. Changed Processes. Appropriate personnel should substantiate and approve any new or changed processes.

d. Traceability. Traceability should be maintained throughout the manufacturing process from raw material to completed product or article. Articles introduced into production before full acceptance should have a process for identifying, controlling, and segregating them.

e. Software Use.

(1) Airborne and production software present unique challenges in manufacturing process control. PAHs that develop airborne software may obtain additional guidance from the Society of Automotive Engineers (SAE), Aerospace Standard (AS) 9006, Deliverable Aerospace Software Supplement for AS9100A.

(2) PAHs that use production software for the design, manufacture, inspection, test, acceptance, or calibration of a deliverable product or article may obtain additional guidance from SAE, Aerospace Recommended Practice (ARP) 9005, Aerospace Guidance for Non-Deliverable Software.

(3) Procedures may allow for emergency non-routine use of non-released software in the acceptance process. These procedures should provide a means of locating

and recalling the product that was manufactured, inspected, or tested by non-released software when necessary.

(4) If non-released software is used for product or article acceptance, the product or article should be identified as nonconforming until the software used is approved and released. Each product or article affected should be identified by an individually unique serial number to ensure recall if necessary. The product or article should not be shipped until all acceptance software has been released unless an FAA-approved alternate means of acceptance is used. A recall system is not considered an acceptable alternate means of product acceptance for shipment of products or articles.

f. Software quality assurance. The functional responsibilities for software quality assurance should be part of the quality assurance system submitted to the FAA. The organization responsible for software quality assurance should have functional independence to allow objective evaluations. The organization responsible for software quality assurance should have authority and responsibility to identify and evaluate problems and ensure completion of corrective action on deficiencies. In addition, this organization should—

(1) Ensure all software tasks are clearly and adequately described in documented procedures.

(2) Verify that suppliers that use computer-aided-manufacturing (CAM), computer-aided-inspection (CAI) or computer-aided-testing (CAT) software and related digital input/output data for product or article acceptance, implement appropriate controls.

(3) Have final authority for formally releasing software and related digital input/output data used for product or article acceptance.

(4) Ensure corrective action has been taken on any deficiencies previously discovered.

2-7. Inspection and Testing. Section 21.137(e) requires procedures for inspections and tests used to ensure that each product and article conforms to its approved design. These procedures are required by the rule include the following, as applicable, a flight test of each aircraft produced unless that aircraft will be exported as an unassembled aircraft, and a functional test of each aircraft engine and each propeller produced.

a. Inspection Procedures. PAHs should have procedures documenting inspection methods for each product or article to ensure they conform to their FAA-approved design data. Procedures should include methods that ensure identification of inspection status throughout the manufacturing process and storage. In addition, procedures should ensure that inspection marking devices are controlled and only issued to authorized persons.

b. Testing Procedures. PAHs should establish, maintain, and control test procedures, instructions, and subsequent changes. PAHs should ensure that the appropriate organizations participate in reviewing test instructions or procedures.

Products or articles that have been adjusted or reworked after test acceptance (such that the results of that testing could be affected) should be retested using approved processes.

c. Statistical Processes.

(1) PAHs should document the use of statistical processes in the quality manual. Statistical processes will ensure that criteria for acceptance or rejection prevent the acceptance of nonconforming products or articles.

(2) Statistical sampling should include sampling plans appropriate for the type of product or article being accepted. Personnel should be trained in statistical sampling techniques.

(3) Engineering and manufacturing organizations should participate in the review, implementation, and maintenance of statistical quality/process control techniques used for product or article acceptance. PAHs may use SAE ARP9013, Statistical Product Acceptance Requirements, which sets forth general requirements for implementing any of the following statistical product acceptance methods:

(a) SAE ARP9013/1, Statistical Product Acceptance Requirements Using Isolated Lot Sampling Methods;

(b) SAE ARP9013/2, Statistical Product Acceptance Requirements Using Attribute or Variable Lot Acceptance Sampling Plans;

(c) SAE ARP9013/3, Statistical Product Acceptance Requirements Using Process Control Methods; or

(d) SAE ARP9013/4, Statistical Product Acceptance Requirements Using Continuous Sampling, Skip-Lot Sampling, or Methods for Special Cases.

Note: SAE ARP9013 does not apply to statistical methods that are separate from product acceptance. Many companies use statistical methods solely to monitor and improve their product quality, and those methods are not subject to the requirements of this document. This document series applies only to those statistical methods used for product acceptance.

d. Nondestructive Testing. PAHs using nondestructive testing to verify conformity of products or articles should have procedures addressing acceptance and rejection criteria. Adequate test pieces with known defects should be available to nondestructive inspection (NDI) personnel. PAHs should also have procedures addressing the certification, recertification, and decertification of nondestructive testing personnel. PAHs may choose to use National Aerospace Standard (NAS) 410, NAS Certification and Qualification of Nondestructive Test Personnel (issued February 2003).

e. Flight Test Procedures. PAHs who manufacture a complete aircraft should ensure that flight test procedures and subsequent changes are submitted to and approved

by the FAA. Flight test pilots should be fully qualified, and flight check-off lists should be properly completed.

2-8. Inspection, Measuring, and Test Equipment Control. Section 21.137(f) requires procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard is required by the rule to be traceable to a standard acceptable to the FAA.

a. Approval, Inspection, and Calibration Procedures. PAHs should have procedures ensuring that tools, gages, and equipment are approved, periodically inspected, and calibrated. Standards used for calibration should have adequate accuracy and be traceable to a standard acceptable to the FAA. Any equipment required for special processing, such as tools, gages, instruments, and timers should be available and calibrated. Calibration of thread gages presents unique challenges. The Industrial Fasteners Institute standard IFI-301, Gage Calibration Requirements and Procedures for Thread Gages is an industry standard that has been reviewed by the FAA and found acceptable to provide guidance for initial and subsequent calibration of thread gages.

b. Tool Control Procedures. PAHs should have a tool control procedure ensuring that tools and gages used for product or article acceptance (including NDI equipment) are protected, maintained, and used in an acceptable environment. Procedures should ensure that PAHs conduct an evaluation and take necessary corrective action when a product or article has been accepted by an out-of-tolerance gage.

2-9. Inspection and Test Status. Section 21.137(g) requires procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.

a. Procedures. PAHs should have procedures that define how inspection and test records are generated and maintained. PAHs should ensure that supplier-furnished articles or services conform to the FAA-approved design data and purchase order requirements, as applicable. Records of this verification should be generated and maintained.

b. Inspection. The PAH should ensure the inspection status of production products or articles are identifiable throughout the manufacturing cycle including any storage facility controlled by the PAH. In addition, the PAH is responsible for generating and maintaining records of completed tests for aircraft, aircraft engines, or propellers.

2-10. Nonconforming Product and Article Control. Section 21.137(h) requires procedures to ensure that only products or articles that conform to their approved design are installed on a type-certificated product. These procedures are required by the rule to provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming products and articles. Only authorized individuals may make disposition determinations. Section 21.137(h) also requires procedures to ensure that discarded articles are rendered unusable.

a. Procedures. PAHs should have procedures that ensure a material review board (MRB) is established, documented, and operational. PAHs should have procedures that include how nonconforming products or articles are identified, controlled, and dispositioned.

b. Disposition Determinations. Authorized individuals should review nonconforming material to determine if acceptance of the nonconformance constitutes a major or minor change to FAA-approved data. The FAA, through the design approval process, will approve any MRB disposition identified as a major change.

c. Data Analysis. Senior management should review and analyze nonconforming material data to detect adverse trends and determine appropriate levels of corrective and preventive actions.

d. Disposition of Scrap and Salvageable Aircraft Products and Articles. These products and articles should be disposed of in an acceptable manner. Appendix E to this AC provides additional information on controlling and dispositioning scrap and salvageable aircraft products and articles.

2-11. Corrective and Preventive Actions. Section 21.137(i) requires procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system.

a. Corrective Action. PAHs are required by the rule to have procedures to eliminate the cause(s) of known nonconformities or noncompliances to prevent recurrence. Corrective actions should be appropriate to the effects of the nonconformities or noncompliances encountered and address the following:

- (1) Review of nonconformities or noncompliances;
- (2) Identification of the cause(s) of nonconformities or noncompliances;
- (3) Evaluation of the need for action to ensure that nonconformities or noncompliances do not reoccur;
- (4) Identification and implementation of action(s) needed;
- (5) Recording of the results of action(s) taken;
- (6) Review of corrective action(s) taken; and
- (7) Flow-down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the nonconformities or noncompliances.

b. Preventive Action. PAHs are required by the rule to have procedures to eliminate the cause(s) of potential nonconformities or noncompliances to prevent their

occurrence. Preventive actions should be appropriate to the effects of the potential problems and should address the following:

- (1) Identification of potential nonconformities/noncompliances and their causes;
- (2) Evaluation of the need for action to prevent occurrence of nonconformities/noncompliances;
- (3) Identification and implementation of action(s) needed;
- (4) Recording of results of action(s) taken; and
- (5) Review of preventive action(s) taken.

c. Monitoring of Actions. When processes or procedures result in nonconforming products or articles, PAHs should monitor the response to, implementation of, and effectiveness of corrective and preventive actions.

2-12. Handling and Storage. Section 21.137(j) requires procedures to prevent damage and deterioration of each product and article during handling, storage, preservation, and packaging.

a. Procedures. PAHs should have procedures to ensure that only conforming and properly identified products or articles are placed in storage. These procedures should also ensure traceability for split lots, and control of the removal or issuance of those products or articles.

b. Storage, Handling, Manufacturing, and Assembly. PAHs are responsible for the following:

- (1) Having procedures to ensure compliance with any special environmental controls during material storage, handling, manufacturing, and assembly of products or articles.
- (2) Identifying and controlling shelf-life or environmentally sensitive products or articles.
- (3) Properly separating and identifying products or articles in storage and manufacturing areas.

2-13. Control of Quality Records. Section 21.137(k) requires procedures for identifying, storing, protecting, retrieving, and retaining quality records. A PAH is required by the rule to retain these records for at least 5 years for the products and articles manufactured under the approval and at least 10 years for critical components identified under § 45.15(c) of this chapter.

a. Procedures.

(1) PAHs procedures should account for all records generated by or needed to show compliance to the applicable requirement of subparts G, K, and O, including records generated throughout the supply chain. Additionally, the PAH is responsible for controlling record storage facilities to ensure both against degradation of records and the availability of these records.

(2) Records to be retained should include, but are not limited to, inspection and test records, calibration records, supplier records, special process certifications, MRB records, and production travelers.

(3) Records should be legible, complete, and accurate. Any storage media used for record retention should exhibit legible data, acceptance stamps, and required signatures. Refer to chapter 4 of this AC for additional guidance on computer-generated or stored records.

b. Record Retention Schedule. PAHs should establish a record retention schedule for various types of process, test, and quality and inspection system data.

c. Record Disposition. The procedures should define how obsolete records will be dispositioned or destroyed.

2-14. Internal Audits. Section 21.137(l) requires procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system. The procedures are required by the rule to include reporting results of internal audits to the manager responsible for implementing corrective and preventative actions. Chapter 5 of this AC provides additional information on internal audit programs.

a. Procedures. PAHs should have procedures that establish an internal audit program. The internal audit program should verify compliance with established policies, procedures, and approved data.

b. Reporting. PAHs should ensure that the results of internal audits are reported to the appropriate level of management, and that audits are used for improving the quality system or product.

2-15. In-service Feedback. Section 21.137(m) requires procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures are required by the rule to include a process to assist design approval holders to address any in-service problem(s) involving design changes and determine if any changes to the Instructions for Continued Airworthiness (ICA) are necessary.

a. Procedures. PAHs should have procedures that establish a system for receiving, processing, and tracking of in-service failures, including how records are generated and maintained.

b. Corrective Actions. PAHs should ensure that service problems, unairworthy conditions, unsafe features, and unsafe characteristics reported by the FAA or users are investigated and receive prompt corrective action.

c. Service Bulletins and Maintenance Manuals. PAHs should ensure that service bulletins and changes to maintenance manuals are approved by authorized personnel and coordinated with FAA engineering.

d. Recalls. Users of products or articles should be notified when those products or articles are recalled for suspected or known nonconformance. PAHs are required by the rule to notify the FAA in accordance with §21.3, Reporting of failures, malfunctions, and defects.

2-16. Quality Escapes. Section 21.137(n) requires procedures for identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.

a. Procedures. PAHs should have procedures that document how they will track, evaluate, categorize, and disposition all nonconforming products or articles. These procedures should include actions to correct deficiencies in the quality system that allowed the quality escape.

b. Analytical Tools. PAHs should use trend analysis and risk assessment tools to determine the severity of and long-term effects of nonconformances.

Chapter 3. Supplier Control Program

3-1. Purpose. This chapter provides information and describes criteria for establishing and maintaining a supplier control program. PAHs may use this document in support of their responsibilities under §§ 21.137, 21.307, and 21.607.

3-2. Background. Part 21 requires PAHs to establish and maintain a quality system. Part 21 also requires that this quality system ensure that supplier-produced components (for example, software, articles, and subassemblies), services (for example, special processes and calibration), and customer or buyer-furnished equipment or material conforms to the PAH's requirements.

3-3. Supplier Control.

a. Contract Requirements. A PAH's system is required by the rule to ensure all products or articles furnished by its suppliers, including subtier suppliers, conform to contract requirements. The contract requirements will depend on the complexity of supplied products or articles and whether or not the supplier holds a production approval for similar products or articles.

b. PAH Responsibilities. The PAH should ensure access to, and cooperation of, all involved facilities in the supply chain for the PAH and the FAA. The PAH is responsible for supplier adherence to the requirements flowed-down through the supply chain. A PAH does not delegate responsibility under its production approval to a supplier.

3-4. Use of Suppliers in Other Countries. A PAH may use suppliers in other countries when the PAH has established and implemented a supplier control system acceptable to the FAA. A PAH who plans to use a supplier in another country should notify the FAA as soon as possible to determine the FAA's ability to perform surveillance.

3-5. FAA Surveillance of Supplier Control Systems. The FAA does not approve suppliers, but may conduct surveillance of the supplier control system at both PAH and supplier facilities in accordance with FAA Order 8120.2, Production Approval and Certificate Management Procedures. The FAA may also request technical assistance from a bilateral partner civil aviation authority (CAA) to act on behalf of the FAA. The PAH cannot rely on FAA or CAA surveillance as a means of supplier control.

3-6. Elements of a Supplier Control System. A PAH is responsible for ensuring each product or article conforms to the FAA-approved design data and is in a condition for safe operation. This responsibility remains the same whether the PAH produces the entire product or article at its facility, or uses suppliers to furnish related articles. The supplier control program is required by the rule to be FAA-approved and defined in a manual. Implementation and maintenance of the supplier control system is subject to evaluation by the FAA. FAA production approvals are based on the ability of the quality system to ensure production of conforming products or articles. Therefore, the supplier control system should contain procedures that include the following:

a. Organizational Structure. Establishment of an organizational structure that ensures appropriate authority, sufficient resources, and adequate expertise to control supplier activities.

b. Supplier Arrangement. Documentation of the supplier arrangement, generally through a contract, that defines all necessary elements and procedures between the PAH and a supplier. Appendix F to this AC contains elements that should be defined in the arrangement between the PAH and the supplier.

c. Supplier Evaluation and Selection. A process that evaluates and selects suppliers based on their capability to perform all manufacturing activities, inspections, and tests, necessary to determine conformity of articles to the applicable design data. Additionally, the supplier evaluation and selection process should determine the suppliers ability to meet other PAH specified requirements. The process should include criteria for the initial evaluation, selection, periodic or ongoing evaluations, and disapproval of suppliers. These should include the following:

(1) Initial evaluation of suppliers to determine their capability to meet requirements. The PAH should make this determination before permitting the supplier to furnish any articles. The need for the PAH to conduct onsite evaluations should be based on a supplier control process as described in 3.6.e below. The FAA strongly encourages PAHs to conduct initial onsite evaluations based on risk factors such as:

(a) Category of the part as listed on the FAA's Aircraft Certification Service Category Parts List (available on the FAA website);

(b) Number of supplier tiers, and number of suppliers within each tier, used by the supplier (including, if necessary, onsite evaluations of subtier suppliers);

(c) Design and manufacturing complexity of the article;

(d) Ability of the PAH to inspect the article upon receipt; and

(e) Other risk factors as discussed in 3.6.e.1 below.

(2) Periodic or ongoing evaluations of suppliers to ensure their continued adherence to the requirements.

(3) Methods for determining the extent and type of evaluations (for example, onsite evaluations, process reviews, document reviews, or independent product evaluations). The extent and type of evaluations should be based on the type, complexity, method of control, and criticality of the articles procured. The need for the PAH to conduct onsite evaluations should be based on a supplier control process and verification of supplier product as described in 3.6.e and 3.6.f below. The FAA strongly encourages PAHs to conduct periodic/ongoing onsite evaluations.

d. Approved Supplier List. Suppliers under the PAH quality system are included in or referenced in a controlled list, along with each supplier's associated scope. Procedures ensure that purchase documentation is issued only to suppliers on this list.

e. Supplier Control Process. A process that describes the means of supplier control, based on the criticality and complexity of the article or service provided to ensure conformity. The techniques described below are not all-inclusive but are provided to assist the PAH in developing supplier control procedures applicable to the organization.

(1) Risk assessment, which takes into account the combination of supplier and product risk factors. Product risk factors include safety classification from the design approval process, special process, and design and manufacturing complexity. SAE ARP9134, Supply Chain Risk Management Guidelines (dated 3/3/2004), is an industry guideline that the FAA has reviewed and found acceptable to provide guidance for the identification of supplier risk factors.

(2) Qualification and auditing of a supplier's quality system.

(3) Monitoring continued capability, throughout the supply chain, to perform all manufacturing activities, inspections, and tests to determine conformity of articles to applicable design data. The PAH will determine and apply acceptance standards for the physical condition, configuration status, and conformity of articles (including customer/buyer-furnished equipment). This determination will be made whether the articles are to be used in production or as replacement or spare articles.

(4) First article inspection, to verify that the article conforms to the approved data and any additional contract requirements, including destructive testing. A first article inspection should be conducted for a new production line, changes to the manufacturing or quality processes, or a new supplier. SAE AS9102A, Aerospace First Article Inspection Requirement (revision A, dated 1/13/2004), is an industry standard that has been reviewed and found acceptable by the FAA to provide guidance in establishing first article processes and procedures.

f. Verification of Supplier Product. Methods to verify that articles conform to specified requirements, including customer-supplied materials and customer-designated sources. These methods include, but are not limited to, the following:

(1) For articles accepted at the PAH's facility, inspection may be accomplished upon receipt or when characteristics remain accessible, at any time before the final acceptance of the end item. The procedures should encompass a complete inspection (for example, all dimensional characteristics, nondestructive testing, hardness checks, spectrographic analysis, and functional tests). When the PAH has established that the supplier's production or process methods will consistently produce articles that conform to the approved design data, use of statistical quality control methods may be acceptable. The inspection plan used is required by the rule to preclude the acceptance of any

nonconforming articles. Additionally, when it is necessary to determine material integrity, the following methods should be considered:

(a) Laboratory analysis to verify an article's complete chemical and physical properties when tests can be performed without destroying the article (for example, by test coupon or small section of the article).

(b) When laboratory analysis cannot be performed without destroying the article, a sample of such articles should be subject to a qualitative and quantitative analysis (for example, by test coupon or small section of the article). This analysis will verify the article's complete chemical and physical properties.

(2) For articles that cannot or will not be inspected upon receipt, the PAH's procedures should include, as a minimum, inspection and testing of first articles to verify the articles conform to the approved design data and periodic inspection thereafter. Inspections and tests completed for the purpose of showing conformity to contract requirements may be accomplished at a supplier's facility. These inspections and tests are required by the rule to be conducted according to a documented process within the PAH's FAA-approved quality system. More than one article may require such inspection or testing until the production repeatability of the supplier has been established. These procedures should include methods to control, identify, and segregate articles waiting for testing or inspection from those already approved.

(3) The PAH may allow a supplier to perform an appropriate or major inspection when it has established that the supplier is capable of performing such an inspection function. However, the PAH should approve any delegation of inspection or use of statistical techniques beyond the first tier supplier. Such delegation includes the following:

(a) **Major inspections.** These include properties classified as critical by the approved design holder's engineering drawings, process specifications, test specifications, and quality control procedures; or properties that cannot be verified except by destructive test of each article or extensive disassembly.

(b) **Material review.** This includes the identification and maintenance of relevant MRB procedures that define the scope and authority of the supplier MRB. Material review also includes the process for submitting, to the PAH, supplier nonconformances that are required by the rule to be approved before they can be considered as changes to the FAA-approved type design.

(c) **Statistical techniques.**

(4) The PAH is required by the rule to have supplier, including subtier supplier, information available to the FAA upon request. This information should include, but is not limited to, the following:

(a) The name and address of each supplier.

(b) The name and address of each supplier who performs major inspection or material review for the PAH.

(c) The name and address of each supplier who furnishes articles when conformance to the approved design data cannot, or will not, be made upon receipt at the PAH's receiving facility.

(d) Where, and by whom, the article will undergo inspection.

(e) The title and telephone number of the person to contact at the supplier facility who can furnish the purchase order(s), quality control data, technical data, and other pertinent data or information to the FAA.

(f) Identification of each supplier with direct ship authorization.

(g) Results of the PAH's supplier evaluations, audits, or other surveillance activities.

(5) The PAH is required by the rule to have a method for generating and maintaining inspection records. These procedures should include the following:

(a) Contents of each record used for the article inspected. This should include, as a minimum, the name, part or article number, serial number (if applicable), sample size, type and number of inspections made, conformance or nonconformance, number and description of nonconformances found, and action taken.

(b) Requirements for record legibility, completeness, accuracy, and retention periods.

(c) Requirements that tools used for record retention (for example, tape files and microfilm) exhibit legible data and acceptance stamps or signatures.

g. Supplier Rating. A system that exhibits the performance, capability, and reliability of suppliers.

h. Notification to the FAA. A procedure to ensure advance notification to the FAA of any significant change in the scope of any supplier arrangements.

i. Reporting of Supplier Nonconformances. Processes and/or procedures that require suppliers to report nonconforming articles that may have left the supplier's quality system. Suppliers will report this information to the PAH and, as necessary, to the FAA in accordance with part 21 requirements.

j. Change Control. A system that ensures that changes in requirements are properly controlled and incorporated as agreed between the supplier and the PAH. These include, but are not limited to—

(1) Submittal of supplier designs and changes to the PAH for approval before incorporation, when required;

(2) Submittal of changes of a supplier's manufacturing process to the PAH, when required;

(3) Submittal of changes to a supplier's quality system to the PAH that may affect inspection, conformity, or the airworthiness of the article to the PAH; and

(4) Methods used to act upon notifications of nonconforming articles, and ensuring that proper investigation and corrective action is taken.

k. Direct Ship. Methods for controlling direct shipments from a PAH's supplier to a customer for articles manufactured under the PAH's production approval. The customer may order articles from either the PAH or the supplier. SAE ARP9114, Direct Ship Guidance for Aerospace Companies (dated 9/9/2005), is an industry guideline that has been reviewed by the FAA and found acceptable to provide guidance in establishing direct shipment processes and procedures. There may be restrictions on the direct shipment of articles from suppliers not located in the United States (such as a FAA designee not available to issue FAA Form 8130-3, Authorized Release Certificate). The FAA MIDO may be contacted for more specific information. Direct shipment may only be used when the PAH—

(1) Has approved quality procedures that will compensate for the absence of inspections normally conducted at the PAH's facility. Compensating factors should include onsite evaluations of the supplier and the inspection of the article as either—

(a) A source inspection performed by the PAH, or

(b) An inspection by the supplier under a delegated inspection authority from the PAH.

(2) Provides direct ship authorization to a supplier.

(3) Issues and maintains records of direct ship authorization and makes them available to regulatory authorities upon request.

(4) Ensures that the requirements of the importing country will be met before authorizing direct shipment to a customer located outside the United States.

(5) Obligates the supplier to—

(a) Direct ship the article.

(b) Meet any special customer requirements accepted by the PAH.

(c) Maintain evidence that the supplier has direct ship authorization from the PAH.

- (d) Maintain evidence of direct shipments made on behalf of the PAH.
- (e) Provide a signed direct ship declaration with the shipment.
- (f) Provide a signed or stamped statement of conformance certifying that the article conforms to approved data with the shipment.
- (g) Provide traceability of the shipment to the customer purchase request.
- (h) Provide evidence with the shipment that acceptance or inspection has been accomplished by the PAH or through a delegated inspection authority.
- (i) Provide a statement with the shipment that delegation of inspection authority has been granted by the PAH, and that the inspection was performed on behalf of the PAH when delegated inspection is used.

l. Other-Party Supplier Surveillance. Methods for the use of other-party supplier surveillance may be used by a PAH provided the processes used meet the requirements identified in FAA Order 8120.12, Production Approval Holder Use Of Other-Parties To Supplement Their Supplier Control Program, and are documented in their quality manual.

m. Suppliers Holding a Production Approval. Methods addressing suppliers that hold a production approval for the article to be supplied. A PAH's surveillance of individual suppliers may be reduced, but not eliminated, provided that—

- (1) Satisfactory interface between the two quality systems can be demonstrated to the FAA;
- (2) The articles to be supplied are included in the scope of their production approval, and
- (3) If the supplier is located outside the United States, a bilateral agreement for airworthiness is in effect between the United States and the country of the supplier. The bilateral agreement will include provisions for United States acceptance of the types of articles or products produced under the supplier's production approval.

n. Use of Suppliers Located Outside the United States. Methods for the use of suppliers (including subtier suppliers) outside the United States. These should include provisions for the following:

- (1) The PAH providing early notification to the FAA of the proposed use of a supplier in another country or jurisdiction.
- (2) The PAH is required by the rule to make available to the FAA information on non-U.S. suppliers when requested.
- (3) The PAH should ensure that the FAA has access within the country where their supplier (including subtier suppliers) is manufacturing. They should also ensure

that all necessary processes, agreements, or procedures are in place to mitigate any undue burden on the FAA. Such burdens could inhibit the FAA from performing its regulatory functions and certificate management responsibilities.

(4) The PAH is required by the rule to assure access to their suppliers. Assurance of access should be provided by the supplier, or when no regulatory agreements are in place, the government of the country or jurisdiction in which the supplier is located. This assurance of access will be made available to the FAA. If access is at any time obstructed or denied, the FAA may instruct the PAH to cease using the supplier.

o. FAA Certificate Management in Other Countries. When a PAH uses a supplier in a country or jurisdiction that has a bilateral agreement with the United States, the FAA may use a bilateral partner CAA to perform surveillance activities and/or conduct inspections on behalf of the FAA. The following procedures should be used:

(1) The PAH will afford the FAA or CAA any necessary support in their surveillance activity.

(2) When specifically requested by the FAA/CAA to facilitate surveillance activities, suppliers located outside the United States will make appropriate data available to the FAA through the PAH for certificate management purposes. This data should be in the English language.

NOTE: FAA Order 8100.11, Decision Paper Criteria for Undue Burden and No Undue Burden Determinations Under 14 CFR part 21, is used by FAA personnel when notified by the PAH of their intent to utilize a supplier outside the United States.

Note: When the FAA requests a bilateral partner CAA to conduct surveillance activities or conformity inspection(s) at a supplier facility, the PAH will be responsible for any charges imposed by the CAA to accomplish the request(s).

Chapter 4. Electronic Records

4-1. Purpose. This chapter provides information and guidance to PAHs on managing and controlling information systems that generate and store records used in the manufacture of products and articles.

4-2. Background. Several CFR sections require PAHs to maintain manufacturing and quality records as evidence that products and articles were produced in accordance with approved design requirements. As the aerospace industry has grown, many PAHs have developed or purchased information systems to generate and store manufacturing and quality records. This chapter does not discuss what manufacturing and quality records should contain. Rather, it describes the control mechanisms that a PAH should use for an information system that generates or stores records of products and articles manufactured to CFR requirements.

4-3. Electronic Manufacturing and Quality System Records. The record system should detect and deter unauthorized disclosure, modification, or use of records. Record systems require protection to ensure an accurate history of the manufacturing process of a product or article. An information management system should be protected from intruders. The system should also be protected from employees with authorized access privileges who attempt to perform unauthorized actions. Protection is achieved not only by technical, physical, and personnel safeguards, but also by clearly articulating to all employees the organizational procedures regarding authorized system use.

a. Security Principles of Electronic Record Systems. Although information management systems are diverse, common security attributes should be present in all record systems. An acceptable electronic record system should include the following:

(1) User Identification. Each system user should be uniquely identified in the system with an account number or other identification code. This code identifies who has logged onto the system and is the primary means of verifying access. The information management system should retain the user identification codes entered to verify the requests made upon the system. This information should be available for review by the system manager.

(2) Authentication of User. There should be a means of verifying that the person entering the user identification code is the authorized individual. Typically, this authentication is through a password known only to the authorized user. This password would allow access to the system only when used together with the user identification code. Passwords should be updated periodically.

(3) Principle of Least Possible Privilege. The authorization capability of the record system should follow the principle that each person is limited to only the information and transaction authority required by their job responsibilities. Privacy locks may be used to ensure that this principle is followed. The level of access at which information is guarded within the system will depend on the design of the system. Based on the design of the information management system, privacy locks and keys may control

single data elements or any combination of data elements. Levels of protection may include the following:

- (a) Data items,
- (b) Data aggregates,
- (c) Sets,
- (d) Fields,
- (e) Files, or
- (f) The complete system.

(4) Relation to quality data responsibilities. The system should ensure that authorization privileges coincide with the responsibilities outlined in the organization's quality system. For example, a manufacturing individual should not normally have write capability to an inspection acceptance field within a manufacturing record. Additionally, an inspector should not have access to a material review engineer disposition field within a material review record. The system should be capable of assigning each user the specific access authority needed. The various types of authorization may include the following:

(a) Read only access. Allows the user to read all or specific fields of information, but does not allow any write or data manipulation capability.

(b) Insert or write access authorizations. Allows the user to enter data into specified fields or series of fields.

(c) Change Access Authorizations. Allows the user to change entries in specified fields, but does not allow removal of the original entry. This may be accomplished by adding information to a restricted field (which is only used when the information in a field will be retained) but the information is not correct. For example, when an article has been rejected by inspection, the rejection history may need to be retained even after the article is repaired. Change access authorization may be given to allow a senior inspector the authority to change the inspection status of a reworked article; however, the record retains the original rejection indication and the user identification of the individual making the change.

(d) Delete Access Authorizations. Allows the user to remove entries and leave the fields blank. While authorization to delete information by the user making the entry may be unrestricted, subsequent delete authorization should be closely controlled. Delete access authorization may be issued only to supervisors for deleting incorrect entries by subordinate employees. Subsequent to final approval of a product or article, information should not be deleted. After approval, incorrect data should be changed rather than deleted.

(e) Security Access Authorizations. The system manager should retain the security access authorizations. These authorizations should only be exercised when properly executed documents allow their use, such as an approval letter signed by the director of quality.

b. Auditing Mechanisms. The information management system should include mechanisms that detect security breaches. These breaches should include any attempt to circumvent security or modify data without authorization. When such a security breach is detected, the system should alert the security manager and note any fields that have been accessed. The security breach information should be retained within the system until reviewed by the system manager. Security breach logs should be available only to select individuals and be protected from modification or data alteration at all times. Normally the system operator will be warned of unauthorized activity. Serious events, such as repeated unauthorized access attempts, may generate alarms at the system level.

c. Protection Against Software and Hardware Destruction. Information system records should be protected from destructive computer programs (that is, computer viruses) that attack or degrade the software. Information management systems should include virus detection programs that ensure viruses are not introduced into the environment through contaminated software or hardware.

(1) Inventories. Inventories of all software and hardware configurations and locations should be used to ensure unauthorized hardware/software does not enter the information management system's environment.

(2) Portable Equipment. Portable computer equipment such as laptops represent special risks from destructive software, therefore, procedures should address their use in the information management system's environment.

(3) Network Security. Many PAHs use large information management system networks with several interacting workstations or terminals. If a large interactive system is used, procedures should address additional protection necessary to control the network. The PAH should define the degree of protection, based on the complexity and application of the system.

(4) System Backup. Provisions should be developed for loss of data resulting from system failure. In all cases, lost data will be regenerated. The amount of time between backups will depend on the degree of risk the approval holder wishes to accept to reestablish lost information.

d. Media Control. The media upon which information is stored should be carefully controlled and protected. Transportable media such as tapes, disks, and cartridges should be stored in secure locations. Media from external sources should be subject to validation to ensure that they are from authorized sources. The listing below provides some examples of the types of media available.

(1) Floppy disks and computer hard drives should not be used for long-term storage of quality and manufacturing records. Information that will be retained for more

than 3 months should be transferred to optical disks or magnetic storage media such as chromium dioxide or metal particle tapes. An external or electronic labeling system should be used that ensures retrieval of individual records.

(2) Magnetic tapes should be tested within 6 months of use to verify that the tape is free of errors and complies with the standards of the National Institute of Standards and Technology. Optimally, new tapes that have been maintained in a cool dry environment should be chosen for storing records. Specific storage criteria for magnetic tapes includes the following:

- (a) Environmental temperatures between 62 and 68 degrees Fahrenheit.
- (b) Relative humidity between 35 percent and 45 percent.
- (c) All tapes should be rewound under controlled tension every 3 1/2 years.

(d) All information that will be retained for more than 10 years should be transferred to new tapes before reaching 10 years.

(e) Annually, a statistically valid sample of all tapes should be tested to identify any loss of data. Tapes with 10 or more errors due to storage conditions should have all data transferred to new tapes. If the sample contains defective tapes, all other tapes that might have been affected by the same cause (that is, poor quality tape, high usage, poor environment, or improper handling) should be tested and corrected.

(f) Smoking, eating, or drinking in the magnetic tape storage or test areas should be prohibited.

(3) Chromium dioxide tapes should be handled like magnetic tapes except for periodic rewinding and cleaning. Although unproven, some industry experts believe rewinding and cleaning can be destructive to these tapes.

(4) Before use of any metal particle tapes for long-term storage, the PAH should ensure that the tapes can maintain the integrity of the data stored.

(5) Additional information regarding long-term storage of electronic media can be found in the National Institute of Standards and Technology's Special Publication 500-101, Care and Handling of Computer Magnetic Storage Media. This publication is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(6) Optical disks are recommended for their greater durability over older media such as magnetic tapes or disks.

(a) Gold compact disks or digital versatile disks are preferred over similar media for long-term data storage. This is preferred over aluminum and silver writing surfaces, which are susceptible to corrosion or oxidation.

(b) The PAH should maintain data transferred to storage, and provide access and ensure integrity of information for the long term. This may require migrating data from one media to the next to avoid media obsolescence. The devices necessary to read the discs should also be kept and maintained.

(c) When obtaining archival grade discs, the PAH should consider the following: dye failure, bonding failure, scratches, and production quality. Testing is a highly recommended step in the process as conditions vary from machine to machine and among disks. It is recommended that the PAH keep multiple copies. Ideally one master copy should be stored under optimal conditions; one in-use copy should be stored for access purposes; and one safety copy should be stored at a different location.

(d) Rewritable disk formats are not recommended as their use can lead to accidental, but permanent, loss of data.

(e) Optical disks, for all their resilience, are still susceptible to environmental factors. Optical disks should not be exposed to extreme temperatures or direct sunlight that may cause heat buildup in the disk or damage the data layer with ultraviolet rays. The environment should optimally be maintained between 65 and 75 degrees Fahrenheit, and between 30 and 50 percent humidity.

e. Documentation. The information management system should be properly documented.

(1) All software programs within the system, including program changes, should be fully documented.

(2) Procedures should be developed that control all data entered into the system. The procedures should address all information management system and human interface activities.

f. Availability. The information management system industry is extremely dynamic concerning the systems that are available for recordkeeping. If the PAH changes from one system to another, the records produced by the old system will remain accessible to the FAA in a usable format. The PAH's documented quality control system should indicate how this accessibility is accomplished.

4-4. Information Management System Facility Management. The information management system cannot be properly protected unless the facilities that house the equipment are properly protected from physical threats and hazards. Areas that should be considered include the following:

a. Physical Security. Each area where electronic records will be used should be surveyed for potential physical hazards. Fire and water are two of the most damaging forces regarding electronic information. Although not all hazards can be eliminated, opportunities for loss can be minimized by careful planning.

b. Environmental Conditions. Procedures should address the environmental conditions (for example, temperature, humidity, static) of the areas where the record system computers and stored media are located. Manufacturer specifications provide a useful guide for developing procedures.

c. Disaster Recovery. A contingency plan should be developed that will allow recovery of critical system information in case of a disaster, such as a fire. One acceptable method is to have a remote backup system to which data is regularly transferred.

4-5. Training. Organizations that have elected to use electronic record systems should train each employee who is involved with any portion of that system. The subject matter and objectives should vary depending on the employee's level within the organization and job responsibilities. Training should include security awareness, organizational policy, system operation, and record storage requirements. Training should be documented and those documents made available for review by the FAA.

Chapter 5. Internal Audit Program

5-1. Purpose. This chapter provides information and describes criteria for establishing an internal audit program. This chapter may be used by PAHs, and their suppliers to show compliance with § 21.137 with regard to internal audits.

5-2. Background. An internal audit program is a comprehensive, continuous monitoring process that is initiated and usually managed by top company and quality assurance (QA) management. The personnel conducting the various audits in support of the internal audit program may be internal or external to the process. The objective of this process is to promote attitudes and procedures that focus on controlling processes, rather than depending on corrections of deficiencies, to meet quality goals.

5-3. Types of Internal Audit Programs. An internal audit program should be part of the overall quality system, be approved by top company and QA management, and have a detailed written description of the key elements of the program. Each PAH is unique regarding size, facilities, personnel, resources, and methods of operation. Therefore, different types of programs may be appropriate for individual organizations. The three basic audit programs commonly used are (1) a dedicated internal quality audit department, (2) a dedicated individual manager with part-time auditors provided from throughout the organization, and (3) a combination of internal and external resources.

5-4. Elements of an Internal Audit Program. An internal audit program is required by the rule to provide an adequate level of independence, a reporting process that ensures an accountable manager is aware of the audit results, and an effective corrective action process. The corrective action process should determine the root causes of deficiencies, correct these deficiencies, and prevent the recurrence of deficiencies. The program should have a structure and process designed to improve all system elements and processes that affect product quality. The key elements of an internal audit program are as follows:

a. Audit Planning.

(1) Audit Schedules. Specific audit schedules should identify areas or activities subject to audit and ensure that they are audited in a predetermined frequency and defined timeframe. Audit schedules should be based on the criticality of the activity being audited and should consider factors such as audit result history, production volume, process performance, high-risk areas, and management concerns.

(2) Auditor Selection. The internal quality audit program should specify that auditors receive training in auditing, audit principles, and systems analysis techniques. When full-time dedicated audit resources are not practical, developed procedures should show that persons performing audits or supervising audit teams are not directly responsible for the areas being audited.

(3) Audit Preparation. The auditor needs to be cognizant of internal and external requirements and other factors that may impact the process.

(4) Checklist Development. A thorough audit program should determine and evaluate how an organization's quality manual, operating procedures, process controls, methods, and practices account for and incorporate all internal and external requirements. The questions contained in a checklist, in effect, transpose standards, regulations, or procedural requirements into a series of questions. The checklist denotes points to be checked and helps the auditor determine the correct order in which to proceed with an audit.

b. Conducting the Audit. The auditor should use the audit checklist to gather evidence to determine compliance or noncompliance to the quality system or standard being evaluated. Evidence is gathered via review of products or articles, documents, observation of activities, record checks, and interviews with key individuals in the area(s) under review. Evidence gathered during the audit should be documented as the audit is conducted.

c. Reporting the Results. A report should be prepared documenting the results of the audit. Procedures should be in place allowing straight-line reporting from the audit team to top company and QA management. The audit report should, at a minimum, include the following:

- (1) Date the audit was conducted,
- (2) Auditor performing the audit,
- (3) Standard or procedure the audit was conducted against (for example, part 21 requirements or the PAH Quality Manual),
- (4) Summary of findings. This should include a brief descriptions of the findings and supporting documents (for example, PAH procedures or records),
- (5) Evaluation and relative importance of a finding (major or minor), and
- (6) Summary of observations, both positive and negative.

d. Root Cause/Corrective and Preventive Action. The PAH should determine root cause and develop a corrective and preventive action plan.

e. Close the Audit Findings. After the process owner indicates completion of the corrective action, QA management should verify that process changes effectively corrected the existing deficiency and prevented recurrence. If the verification process indicates that the corrective action was not effective, top company management should be notified. QA management should then request additional corrective action and revalidation from the process owner.

f. File Report. Audit reports, including corrective action and closure data, should be maintained.

Chapter 6. Additional PAH Requirements

6-1. Quality Manual. Sections 21.138, 21.308, and 21.608 state that each applicant or current PAH provide a manual describing its quality system to the FAA for approval. The manual is required by the rule to be in the English language and retrievable in a form acceptable to the FAA.

a. If the quality manual is stored digitally through a computer-based medium, it should be easily available to PAHs and FAA personnel who need to use the manual for performing their duties.

b. PAHs are reminded that the manual is required by the rule to address all of the quality system requirements in 21.137.

6-2. Location of or Change to Manufacturing Facilities. Sections 21.139, 21.309, and 21.609 state that a PAH may obtain a production approval for manufacturing facilities located outside the United States, if the FAA finds no undue burden in administering the applicable requirements of Title 49, United States Code (U.S.C.), and this subchapter.

a. The PAH is required by the rule to obtain FAA approval before making any changes to the location of any of its manufacturing facilities.

b. The PAH is required by the rule to immediately notify the FAA, in writing, of any change to the manufacturing facilities affecting the inspection, conformity, or airworthiness of its product or article.

c. Each applicant for a production approval or current PAH should check with their local MIDO to determine approval and notification methods.

6-3. Inspections and Tests.

a. Sections 21.140, 21.310, and 21.610 state that each applicant or current PAH allow the FAA to—

(1) Inspect its quality system, facilities, technical data, and manufactured products or articles; and

(2) Witness any tests including any inspections or tests at any supplier facility (within the PAH's supply chain) necessary to determine compliance with the applicable subchapter.

(3) The PAH should ensure FAA access to, and cooperation of, all involved facilities in the supply chain. The PAH should also ensure access to and cooperation of all involved facilities in the supply chain for themselves or their representatives.

b. Section 21.310 also prescribes prohibitions unique to that section. PAHs operating under Subpart K should refer to the applicable section to ensure that they are not in violation of those prohibitions.

6-4. Issuance of a Production Approval. Sections 21.141, 21.311, and 21.611 states that the FAA issues a production approval after finding that the applicant complies with the requirements of the applicable subpart.

a. Applicants for a production approval should ensure that they have reviewed and documented how they have met the applicable requirements so the FAA may complete a timely review.

b. Applicants for a production approval that are part of a multinational and/or multicorporate consortium may refer to appendix G to this AC for further guidance on how to comply with § 21.137.

6-5. Production Limitation Record. Section 21.142 states that the FAA will issue a production limitation record (PLR) as part of a production certificate. The PLR lists the TC number and model of every product the production certificate holder is authorized to manufacture. Applicants for a production certificate should ensure that the PLR accurately reflects the product(s) they intend to manufacture.

6-6. Duration.

a. Sections 21.143, 21.313, and 21.613 state that a production approval be considered effective until it is surrendered, suspended, revoked, or terminated by the FAA. There are minor differences between the duration of a PC and that of a PMA or TSO authorization. Applicants receiving a production approval should refer to the applicable section for information on the duration of a particular production approval.

b. Section 21.613 also sets forth the requirements for revised or canceled TSOs. The holder of an affected FAA letter of acceptance of a statement of conformance, TSO authorization, or letter of TSO design approval, may continue to manufacture articles that meet the original TSO without obtaining a new acceptance, authorization, or approval. However, the holder is required by the rule to comply with the requirements of this chapter.

6-7. Transferability. Sections 21.144, 21.314, and 21.614 states that a PAH may not transfer the production approval or letter of TSO design approval.

a. The FAA prohibits that transfer of a production approval, the FAA recognizes that companies do change ownership. In many cases, design data, quality systems, and manufacturing processes are all transferred as part of the change in ownership, and in these instances the FAA will support the establishment of a new production approval.

b. Applicants for new production approvals based on previously issued production approvals should consult their local Aircraft Certification Office and Manufacturing Inspection Office for assistance.

6-8. Privileges. Section 21.145 identifies privileges associated with a production certificate. PAHs should refer to the applicable section to ensure they know these privileges.

6-9. Responsibility of Holder. Sections 21.146, 21.316, and 21.616 prescribe a PAH's responsibilities. PAHs should refer to the appropriate rule section for the type of production approval they wish to obtain or maintain to ensure that they understand all of the applicable requirements.

a. The PAH is responsible for controlling the manufacture of completed products and articles in conformity with the FAA-approved type design data and quality system requirements. This responsibility cannot be delegated to or relieved by the use of approved suppliers, risk and revenue sharing partners, or co-producers.

b. Although this responsibility never changes, the PAH may be relieved of some of the burden of inspection and testing duties when it uses type-certificated products or articles manufactured under another person's production approval. This relief may be extended to include products or articles manufactured in a foreign country and imported into the United States under the provisions of a bilateral agreement in accordance with 14 CFR, part 21, subpart N, Approval of Engines, Propellers, Materials, Parts, and Appliances: Import.

c. All types of PAHs now have substantially similar responsibilities, as described below.

(1) Paragraph (a) of each section requires the PAH to document any organizational changes. Such documentation is accomplished by amending the document required by §§ 21.135, 21.305, and 21.605, respectively, detailing how the organization will comply with the provisions of the respective subpart. The PAH is required by the rule to provide these amendments to the FAA. This requirement ensures that the FAA remains informed of changes in a PAH's organization as well as its continued compliance with the respective subpart

(2) Paragraph (b) of each section requires a PAH to maintain its quality system in compliance with the data and procedures approved for its production approval.

(3) Paragraph (c) of each section requires a PAH to ensure that each product or article conforms to its approved design and is in a condition for safe operation.

(4) Paragraph (d) of each section requires a PAH to mark its product or article in accordance with part 45, including critical parts.

(5) Paragraph (e) of each section requires a PAH to identify any parts of the product or article that leave the manufacturer's facility as FAA-approved. This includes the manufacturer's part number and name, trademark, symbol, or other FAA-approved PAH identification. (Examples of other FAA-approved PAH identification are production approval number, cage code, or a federal supply code for manufacturers (FSCM).) The information may be conveyed in the form of stickers, tags, shipping documents, shipping containers, or by other means. This information may also be applied directly to the subassemblies or component parts in accordance with approved data.

(6) Paragraph (f) of each section requires a PAH to have access to type design data necessary to determine conformity and airworthiness for each product and article produced under its production approval. TSO authorization holders have the additional requirement of retaining this data until they no longer manufacture the article. At that time, copies of the data are required by the rule to be sent to the FAA.

(7) Paragraph (g) of each section requires a PAH to retain the document(s) granting production approval and make it available to the FAA upon request.

(8) Paragraph (h) of each section requires a PAH to make available to the FAA information regarding all delegation of authority to suppliers. This includes delegations for the purpose of performing major inspections, delegations related to direct ship authorization, and delegations related to the disposition of nonconforming material.

6-10. Amendment of Production Certificates. Section 21.147 requires a production certificate holder to apply for an amendment to a production certificate in a form and manner prescribed by the FAA. Currently, the method of applying for an amendment is the PAH's submission to the FAA of a properly executed FAA Form 8110-12, Application for Type Certificate, Production Certificate, or Supplemental Type Certificate.

6-11. Approval for Deviation. Section 21.618 requires a manufacturer requesting approval to deviate from a performance standard of a TSO to show that factors or design features provide an equivalent level of safety and compensate for the standards from which a deviation is requested. The manufacturer will send requests for approval to deviate to the appropriate ACO, along with all pertinent data. If the article is manufactured under the authority of a foreign country or jurisdiction, the manufacturer will send requests for approval to deviate, along with all pertinent data, through the civil aviation authority of that country or jurisdiction to the FAA.

6-12. Design Changes. Sections 21.319 and 21.619 prescribe what constitutes a major or minor design change, as well as who may make those changes. Minor changes will be approved under a method acceptable to the FAA. Major changes are required by the rule to be approved by the FAA before they can be included in the design of the product or article. PAHs who are uncertain if a design change is major or minor should consult with the FAA before implementing the changes.

6-13. Changes in Quality System. Sections 21.150, 21.320, and 21.620 establish that each change to the quality system is subject to FAA review. Additionally, the PAH is required by the rule to immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its product or article. PAHs who wish to initiate changes to the quality system should submit the proposed changes to the MIO, MIDO, or Manufacturing Inspection Satellite Office (MISO) with certificate management responsibilities.

6-14. Issuance of Letters of TSO Design Approval: Import Articles. Section 21.621 prescribes under what conditions a letter of TSO design approval may be issued for imported articles.

Appendix A. Cancellations

This AC cancels, as of its effective date, the following documents.

AC 21-1, Production Certificates.

AC 21-6, Production Under Type Certificate Only.

AC 21-20, Supplier Surveillance Procedures.

AC 21-27, Production Certification Multinational/Multicorporate Consortia.

AC 21-33, Quality Assurance of Software used in Aircraft or Related Products.

AC 21-35, Computer Generated/Stored Records.

AC 21-36, Quality Assurance Controls for Product Acceptance Software.

AIR-200 Best Practice for Direct Shipment.

AIR-200 Best Practice for Internal Quality Audit Program.

AIR-200 Best Practice for Scrap or Salvageable Aircraft Parts and Materials.

AIR-200 Best Practice for Statistical Quality Control.

AIR-200 Best Practice Memorandum on Nondestructive Evaluation Reliability Guidance.

Appendix B. Related Publications

Federal Aviation Administration Orders

Order 8100.7, Aircraft Certification Systems Evaluation Program.

Order 8100.10, Requesting Conformity Inspections at a Supplier Outside a Geographic Area.

Order 8100.11, Decision Paper Criteria for Undue Burden and No Undue Burden Determinations Under 14 CFR Part 21.

Order 8110.4, Type Certification.

Order 8110.42, Parts Manufacturer Approval Procedures.

Order 8120.2, Production Approval and Certificate Management Procedures.

Order 8120.12, Production Approval Holder Use Of Other-Parties To Supplement Their Supplier Control Program.

Order 8120.13, International Cooperative Supplier Surveillance Program Procedures.

Order 8130.21, Procedures for Completion and Use of the Authorized Release Certificate, FAA Form 8130-3, Airworthiness Approval Tag.

Federal Aviation Administration Advisory Circulars

AC 20-115, Radio Technical Commission for Aeronautics Document RTCA/DO-178, Software Consideration in Airborne Systems and Equipment Certification. (Copies may be purchased from the RTCA.)

AC 21-18, Bilateral Airworthiness Agreements.

AC 21-23, Airworthiness Certification of Civil Aircraft, Engines, Propellers, and Related Products Imported to the United States.

AC 21-24, Extending a Production Certificate to a Facility Located in a Country or Jurisdiction that has an Agreement with the United States.

SAE Documents. Copies may be purchased from the SAE.

SAE AS9100B, Quality Management Systems – Aerospace Requirements.

SAE AS9102A, Aerospace First Article Inspection Requirement.

SAE AS9006, Deliverable Aerospace Software Supplement for AS9100A.

SAE ARP9005, Aerospace Guidance for Non-Deliverable Software.

SAE ARP9013, Statistical Product Acceptance Requirements.

SAE ARP9013/1, Statistical Product Acceptance Requirements Using Isolated Lot Sampling Methods.

SAE ARP9013/2, Statistical Product Acceptance Requirements Using Attribute or Variable Lot Acceptance Sampling Plans.

SAE ARP9013/3, Statistical Product Acceptance Requirements Using Process Control Methods.

SAE ARP9013/4, Statistical Product Acceptance Requirements Using Continuous Sampling, Skip-Lot Sampling, or Methods for Special Cases.

SAE ARP9114, Direct Ship Guidance for Aerospace Companies.

SAE ARP9134, Supply Chain Risk Management Guidelines.

Other Documents

National Aerospace Standard (NAS) 410, NAS Certification and Qualification of Nondestructive Test Personnel.

Industrial Fasteners Institute Standard IFI-301, Gage Calibration Requirements and Procedures for Thread Gages.

Appendix C. Definitions

For the purposes of this document, the following definitions apply.

- 1. Airworthiness Approval.** A document issued by the Federal Aviation Administration (FAA) for an aircraft, aircraft engine, propeller, or article which certifies that the aircraft, aircraft engine, propeller, or article conforms to its approved design and is in a condition for safe operation.
- 2. Applicable Design Data.** All necessary drawings, specifications, and other technical information provided by the applicant for, or the holder of, a design organization approval, TC, STC, technical standard order (TSO) authorization, parts manufacturer approval (PMA), or equivalent, and released in a controlled manner for production purposes.
- 3. Approved.** Unless used with reference to another person, means approved by the FAA or any person to whom the FAA has delegated its authority in the matter concerned, or approved under the provisions of a bilateral agreement between the United States and a foreign country or jurisdiction.
- 4. Approved Design Data.** Applicable design data that has been granted an approval (for example, TC, STC, TSO authorization, PMA, or equivalent) by the relevant civil aviation authority (CAA).
- 5. Article.** A material, part, component, process, or appliance.
- 6. Authorizations.** Permission granted by management to individuals authorized full or partial admission to restricted access information management systems.
- 7. Data.** A set of alphanumeric and/or graphic characters organized to represent facts or instructions suitable for communicating, interpreting, or processing by a computer.
- 8. Direct Ship Authorization.** The written authorization granted by a PAH with responsibility for the airworthiness of an article, to a supplier to ship articles produced in accordance with the PAH's quality system, directly to end users without the parts being processed through the PAH's own facility.
- 9. Field.** An element of a computer file that may contain data and whose size is controlled by the program.
- 10. Information Systems.** A computer system designed to automate a specific function, such as records management.
- 11. Licensing Agreement.** A commercial agreement between a TC or STC holder and a PAH (or applicant) formalizing the rights and duties of both partners to use the design data for the purpose of manufacturing the product or article.

- 12. Privacy Keys.** A password or procedure that allows full or partial access to a restricted information management system.
- 13. Privacy Locks.** A procedure that restricts access to a portion of an information system.
- 14. Production Approval.** A document issued by the FAA to a person that allows the production of a product or article in accordance with its approved design and approved quality system and can take the form of a production certificate, a PMA, or a TSO authorization.
- 15. Quality Escape.** A product or article that has been released from the quality system and does not conform to the applicable design data or quality system requirements.
- 16. Quality System.** A documented organizational structure containing responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles
- 17. Read-only Capability.** The authority given to an individual, allowing that person to access or read data in a field without being able to change or enter data.
- 18. Salvageable.** Aviation parts that are unserviceable (or of unknown status) that may have a potential aviation use. Salvageable parts may be considered in different categories:
- a. Non-airworthy parts which may be worth storing until restored to an airworthy condition, or until they are shown to be airworthy with adequate documentation and/or testing; and
 - b. Parts that cannot be found airworthy at the time they are stored; but, there is reason to believe that they are likely to have future aviation value. For example, a part that has reached its present life limit may be stored in an area in anticipation of an increase in that limit based on in-service experience and analysis, or a part that requires repair for which there is currently no approved process may be stored in anticipation of a new approved process.
- 19. Scrap.** Products and articles an owner has disposed of because they are beyond economical repair, considered to be of little value, or unusable for any other aviation reason. Scrap products and articles are placed into four categories:
- a. Products and articles that have no value except for the base material.
 - b. Products and articles whose misuse in aviation poses an insignificant safety risk.
 - c. Products and articles that were used in low-risk safety aviation applications and may have future use in non-aviation applications .

d. Products and articles that were used in safety-critical aviation applications and may have future use in non-aviation applications .

20. Standard Part. A part manufactured in complete compliance with an established Government or industry-accepted specification that contains design, manufacturing, and uniform identification requirements. The specification must include all information necessary to produce and conform the part, and must be published so that any person/organization may manufacture the part.

21. Supplier. Any person as defined by 14 CFR part 1, Definitions and Abbreviations, that furnishes products, articles, or services (at any tier in the supply-chain) that are used or consumed in the manufacture of, or installed on, aviation products or articles.

22. Write Capability. The authority given to a user that allows that person to enter or change data in a field.

Appendix D. Production Under Type Certificate

1. Purpose. This appendix covers only those sections of Title 14, Code of Federal Regulations (14 CFR) part 21, subpart F, Production Under Type Certificate, where further discussion, information, or examples would be helpful. The headings of each of the following main paragraphs refer to the applicable section of subpart F. A manufacturer producing a product under subpart F is allowed to produce and sell articles associated with its product as spares for that product only.

2. Discussion.

a. Section 21.121, Applicability. The term “production under a type certificate” refers to production by a TC holder or its licensee without benefit of a production approval for that product or article thereof.

b. Section 21.122, Location of or change to manufacturing facilities.

(1) If the FAA finds no undue burden in administering the applicable requirements of Title 49, United States Code (U.S.C.), and Subchapter C - Aircraft, the manufacturer may use manufacturing facilities located outside of the United States.

(2) The TC holder is required by the rule to obtain FAA approval before making any changes to the location of any of its manufacturing facilities.

(3) The TC holder is required by the rule to immediately notify the FAA, in writing, of any change to the manufacturing facilities that may affect the inspection, conformity, or airworthiness of its product or article thereof.

(4) Each TC holder should check with their local Manufacturing Inspection District Office (MIDO) to determine approval and notification methods.

c. Section 21.123, Production under type certificate.

(1) Paragraph (c) requires each manufacturer of a product or article thereof under a TC to maintain completed inspection and test records for 5 years. For critical parts identified under § 45.15(c) of this chapter, the record retention requirement is 10 years. The beginning of the 5-year or 10-year record retention for a given product or article thereof corresponds to the manufacturing completion date of that product or article. These records will enable the TC holder to prove to the FAA that it has properly completed and documented all inspections and tests required to ensure compliance with subpart F. Manufacturers are required by the rule to maintain evidence that indicates conformance or nonconformance of the product or article thereof regarding required inspections and tests.

(2) Paragraph (d) requires each manufacturer of a product or article thereof manufactured under a TC to allow the FAA to make any inspection or test (including any inspection or test at a supplier facility) necessary to determine compliance. “Allowing” means that the manufacturer will—

(a) Give free and full access to facilities, information, and relevant data to show compliance with this subchapter, and

(b) Provide appropriate assistance to the FAA to enable the FAA to perform these inspections and tests. Inspections and tests include audits, inquiries, questions, discussions, monitoring, witnessing, checks, flight and ground tests, and inspections of in-process and completed products or articles thereof, and all relegated design data.

(3) Paragraph (f) requires a TC holder to identify any parts of the product that leave the TC holder's manufacturing facility as FAA-approved. This includes the manufacturer's part number and name, trademark, symbol, or other FAA-approved identification (for example, a cage code or a federal supply code for manufacturers (FSCM)). The information may be conveyed in the form of stickers, tags, shipping documents, shipping containers, or by other means. This information may also be applied directly to the subassemblies or component parts in accordance with approved data.

(4) Paragraph (g) requires the manufacturer producing under subpart F to obtain a production approval under subpart G, Production Certificates, within 6 months of the TC's issuance. The following requirements apply:

(a) During the 6-month period from the TC's issue date, each completed product or article thereof is subject to FAA inspection before the issuance of airworthiness certificates or approvals. Because of limited FAA monetary and manpower resources, these inspections may be delayed or be very time-consuming, and would normally allow a very low production rate by the TC holder. It is, therefore, to the TC holder's advantage to develop and implement an approved system in accordance with subpart G as quickly as possible.

(b) If the TC holder does not establish and implement an approved system in accordance with subpart G at the end of the 6-month period, and there are no extenuating circumstances to preclude such establishment and implementation, the FAA may discontinue inspections until an approvable system has been established.

d. Section 21.127, Tests: aircraft.

(1) Before the production flight test of aircraft, any items coming under the provisions of § 21.127(b)(5) should be checked. For example, it is important that—

(a) The means provided to level the aircraft are accurate and in conformity with type design data.

(b) Each aircraft is weighed to determine that the empty weight and center of gravity is in conformity with the type design data.

(2) The flight test procedure and flight check-off form, required to be established and approved under § 21.127, should be submitted to the FAA Aircraft Certification Office (ACO) for approval.

e. Section 21.128, Tests: aircraft engines.

(1) The test equipment used for test runs should be capable of accurate output determinations sufficient to ensure that the engine output delivered complies with official ratings and operating limitations.

(2) Following the tests prescribed by § 21.128, each engine is subject to FAA inspection to determine that the engine is in condition for safe operation. Such inspection may also include internal inspection and examination to ensure that no unsafe condition exists. The degree of internal inspection will normally be determined by the cumulative results of such inspections conducted on the first production engines, and by service experience. The FAA may consider a statistical plan for internal engine inspections if the TC holder submits a proposal based on product uniformity, a satisfactory history of previous internal inspections, and service experience.

f. Section 21.129, Tests: propellers.

(1) An acceptable functional test for variable pitch propellers would include 25 complete cycles of the control throughout the propeller pitch and rotational speed ranges. Additionally, for feathering or reversing propellers, there should be five cycles of feathering operation and five cycles of reversing operation from the lowest normal pitch to the maximum reverse pitch.

(2) Following the functional test, each propeller is subject to inspection by the FAA in a similar manner as that described for engines in paragraph 2e of this appendix.

g. Section 21.130, Statement of conformity. Upon receipt of the statement of conformity, the FAA will inspect the completed product to determine that it conforms to the type design and is in condition for safe operation. If so, an airworthiness certificate will be issued for aircraft, or an airworthiness approval will be issued for an engine, propeller, or articles thereof.

Appendix E. Scrap or Salvageable Aircraft Products and Articles

1. Purpose. The information provided in this appendix may be used by PAHs, and their suppliers. This information may be—

a. Applied to manufacturers involved in the control, distribution, sale, maintenance, or disposition of scrap or salvageable aircraft engines, aircraft propellers, and aircraft articles and

b. Used to identify, segregate, and control rejected products and articles to preclude their use in a finished product.

2. Background. Products and articles may be deemed scrap or salvageable once they are determined as unserviceable or ineligible for installation on an aircraft, aircraft engine, or aircraft propeller. In some cases, it has been common practice to dispose of scrapped products and articles by selling, discarding, or transferring the articles. A lack of proper industry controls may result in an article being copied or repaired, reintroduced into the market, and being falsely identified as an approved article. Use of such products and articles can have serious safety implications and liabilities for the manufacturer, aircraft operator, or repair facility. Using an effective system to control scrap or salvageable products and articles will reduce the chances that these articles will be distributed or sold as serviceable.

3. Documenting the Process. Maintaining a well-defined quality program is fundamental to controlling rejected products and articles. One element to be addressed within this program is the control and disposal of scrap and salvageable products and articles. Quality systems without this element could allow products and articles to migrate back into active inventories.

4. Preventing Misrepresentation of Scrap Products and Articles.

a. Manufacturers should dispose of scrap products and articles through mutilation, when appropriate. Proper and thorough mutilation of products and articles will ensure they are unusable for their original application and render them incapable of being reworked or camouflaged to provide the appearance of being serviceable.

b. Effective mutilation may be accomplished by one or a combination of the following methods: grinding, burning, removal of a major integral feature, permanent distortion of products and articles, cutting a significant size hole with a cutting torch or saw, melting, sawing into many small pieces, and removing manufacturer identification, part, lot, batch, and serial number.

5. Disposing of Scrap Products and Articles. Manufacturers disposing of scrap products and articles may choose to release them for legitimate non-flight use. This non-flight use may include training, education, research and development, tool set up, or non-aviation applications. In such instances, mutilation may not be appropriate. The following methods may be used to prevent future misrepresentation:

a. Permanently and clearly mark the products and articles as “Not for Aviation Use” and “Not Serviceable.” Ink stamping is not normally considered an acceptable method unless indelible ink is used and the products and articles are checked to ensure the ink cannot be removed.

b. Remove part number identification.

c. Remove identification plate and marking.

d. Maintain a tracking or accountability system, by serial number or other individualized data, to record transferred scrap products and articles.

e. In any agreement or contract transferring scrap products and articles, develop written procedures identifying disposition and disposal requirements.

f. Secure a signed certification statement from the purchaser indicating that “the purchaser will not use or convey these products and articles for use in aviation products.”

g. For those articles determined to be scrap and having no further aviation use, manufacturers should—

(1) Establish and maintain procedures requiring documentation (for example, a written contract) from scrap dealers indicating their intent to properly dispose of all products and articles received.

(2) Establish and maintain procedures to audit scrap dealers to their contract requirements.

(3) Maintain records of serial numbers for scrapped life-limited or other critical products and articles. In such cases, the owner who mutilates applicable products and articles is encouraged to provide the original manufacturer with the data plate or serial number and final disposition of the product or article.

6. Preventing Misrepresentation of Salvageable Products and Articles.

a. Manufacturers handling salvageable products and articles should—

(1) Establish secure areas to segregate such articles from active serviceable inventories and to prevent unauthorized access.

(2) Develop procedures to address the retention of records for products and articles exceeding current repair criteria and life limits and that are being held in anticipation of future repair methods or extension to life limits. Caution should be exercised to ensure that these products and articles receive the appropriate final disposition.

b. Aviation safety is best served with sound processes that control scrap and salvageable products and articles. Using the practices identified in this document will

reduce the potential that these articles will be distributed and sold as serviceable products. With aviation safety in mind, the aviation community is responsible for preventing misrepresentation of aviation products and articles. The FAA encourages manufacturers to establish a program that controls scrap and salvageable products and articles as an integral part of their quality management systems.

c. Misrepresented products and articles that are offered for sale, or have been furnished for aviation use, should be reported to the FAA. This may be accomplished by submitting FAA Form 8120-11, Suspected Unapproved Parts Notification, or by calling the Aviation Safety Hotline toll free number, 800-255-1111.

Appendix F. PAH—Supplier Arrangement

The following list comprises elements typically found in the arrangement between the PAH and the supplier, if applicable. Guidance on the content of each element is provided, but this is not intended to be comprehensive.

Note: The supplier arrangement may indicate whenever the PAH finds one or more of the elements to be inapplicable.

1. Scope.

a. Identify articles to be provided by the supplier and the associated supplier facilities.

b. Identify any limitation(s) defined by the PAH.

2. PAH Evaluation. Stipulate that the supplier is acting under the PAH quality system and that all of the corrective actions requested by the PAH will be implemented.

3. Implementation Procedures. Attach a quality plan or equivalent documentation to the contract.

4. Internal Quality System.

a. Identify methods for the PAH to evaluate the internal quality system of the supplier.

b. Describe the interface between the PAH's quality systems and the supplier in the quality plan.

5. Design Data and Configuration Control.

a. Identify the design data package provided by the PAH, including all pertinent data required for the supplied article(s) to be identified, manufactured, inspected, used, and maintained.

b. Establish procedures for managing design changes.

6. Manufacturing Data. Identify the manufacturing data developed by the supplier, if any, based on the design data submitted by the PAH. (Refer to paragraph 5 of this appendix.)

7. Test and Inspections (Including Incoming).

a. Identify procedures to define the necessary test and inspection processes—

(1) To ensure and determine the conformity of the supplied article(s) during the supplier's manufacturing activities, and upon receipt by the PAH.

(2) To be performed for qualification of the supplier (including first article inspection) and related documentation requirements.

b. The PAH may rely on inspections/tests performed by a supplier, provided:

(1) Personnel responsible for these tasks satisfy the quality standards of the PAH,

(2) Quality measurements are clearly identified, and

(3) The records or reports showing evidence of conformity are available for review and audit.

8. Identification and Traceability. Stipulate that the PAH flows-down to the supplier and any subtier suppliers identification and traceability requirements.

9. Supplier Personnel competence. Identify the PAH's requirements for the competence of supplier personnel (i.e., production, inspection, and quality staff) competence, based on qualifications, education, training, skills, and experience.

10. Calibration.

a. Ensure that calibration is traceable to a national standard acceptable to the FAA.

b. Ensure that certificates are submitted where suppliers perform calibration services for the PAH.

11. Handling, Storage (Segregation), and Packing.

a. Identify requirements from the PAH concerning handling, storage, packing, and shelf-life to be followed by the supplier.

b. Address segregation of approved and non-approved articles as well as nonconforming articles.

12. Record Completion and Retention. Identify procedures for document management and retention by the supplier.

13. Nonconformities. Identify procedures for handling and documenting nonconformities between the PAH and the supplier, addressing—

a. The identification, documentation, and classification (major, minor) of nonconformities.

b. The disposition of nonconformities and the subsequent segregation and control of the nonconforming articles. This includes the secure disposition of scrap articles to avoid reuse (refer to paragraph 11 of this appendix).

Note: The disposition of nonconformities is generally the responsibility of the design approval holder. Nevertheless, it may be acceptable to the FAA for the design approval holder to delegate the approval of nonconformities to persons located in the organization of the PAH and its suppliers, thus acting as part of the design approval holder.

c. The immediate notification to the PAH on nonconforming articles that have left the supplier's quality system.

14. Conformity Document. Specify the document by which the supplier certifies conformity to the applicable design data to the PAH.

15. Provisions for Direct Delivery/Direct Shipment. Identify the authorization and the requirements for direct delivery/direct shipment to end users from the supplier's facilities, based on relevant regulatory requirements. (For direct shipment requirements refer to chapter 3, paragraph 3-6k(5)(a through i) of this AC.)

16. Assistance for Continued Airworthiness. Identify procedures for supplier assistance to the PAH for continued airworthiness, including methods to notify and act upon notification of already delivered nonconforming articles, ensuring proper investigation and implementation of corrective action.

17. Subtier Suppliers.

a. Specify the conditions under which the supplier may subcontract to or obtain supplies from a third party.

b. Specify procedures for:

(1) A supplier to flow-down the FAA and PAH requirements to subtier suppliers.

(2) Notification to the PAH in case of further subtier supplier activity and/or significant problems encountered during manufacturing.

18. Significant change to the Quality System. Require that the PAH be notified, as soon as practical, of any changes to the supplier system (evaluated by the PAH) that may affect the quality of the supply.

19. Failures, Malfunctions, and Defects. Specify to the supplier the necessary requirements for reporting failures, malfunctions, and defects to ensure that the PAH can comply with FAA requirements.

20. Access for the PAH and FAA. Ensure access to, and cooperation of, all involved facilities in the supply chain for the PAH and FAA. This will enable—

a. The PAH to verify compliance with the PAH-supplier arrangement and to assess the quality of the contracted articles, and

b. The FAA to investigate the PAH's compliance with the applicable requirements at the supplier level.

21. Language. Identify the language to be used for the exchange of information (including all working documents, such as technical and quality data) that is acceptable to the FAA.

22. Identification of Responsibilities. Identify responsible office/function/positions in charge for all elements of the PAH-supplier arrangement.

23. Duration of the Supplier Arrangement. Identify the duration of the supplier arrangement in terms of time and/or quantity of supply to be delivered to the PAH.

Appendix G. Production Certification: Multinational/Multicorporate Consortia

1. Purpose. This appendix provides information and criteria for evaluating and approving the quality system of a multinational or multicorporate consortium seeking a production certificate (PC). This appendix does not apply to a TC holder who enters into a licensing agreement with a manufacturer holding a PC at the time of license. The FAA does not consider such a licensing arrangement the formation of a PC. PC extensions are addressed in AC 21-24, Extending a Production Certificate to a Facility Located in a Bilateral Airworthiness Agreement Country.

2. Discussion. A multinational/multicorporate consortium consists of a U.S. manufacturer(s) and a manufacturer(s) located outside the United States who have agreed to form a single company for production of a particular product. A consortium company usually exists in name only, in that it does not physically manufacture a product in one location. The consortium company retains responsibility for the design and quality of the product for which the PC has been issued. However, the consortium company may assign the manufacturing task to other partner companies or suppliers located domestically or in combination with manufacturers located outside the United States.

3. Requirements.

a. Section 21.137 requires PAHs to demonstrate that they have established and can maintain a quality system for their product. This ensures that each product or article thereof meets the design provisions of the pertinent TC. The FAA considers the consortium company to be the applicant, and the partner companies to be suppliers.

b. The consortium company will be named on the PC, along with the consortium company address (possibly a corporate office) and the address(es) of the principal and subordinate manufacturing facilities. Extension of a PC to facilities located outside the United States may be authorized when certain criteria are met, as listed in AC 21-24. If a PC is extended to a facility located outside the United States, the FAA remains responsible for certificate management.

c. In the case of multinational/multicorporate consortia, if a partner company or supplier has an FAA-approved quality system for its own product, the PC applicant is still required to have an independent system meeting the requirements of Title 14, Code of Federal Regulations (CFR), part 21, subpart G (Production Certificates).

d. A PC applicant functioning as a corporate entity, distributor, or assembler will have a viable means of ensuring that all articles, processes, procedures, and completed products are properly inspected for conformity to the approved type design.

4. Quality System Documentation.

a. The applicant for a PC is required by the rule to establish to the FAA's satisfaction that its quality system and procedures meet the requirements of § 21.137 before a PC is issued.

b. The quality system data will clearly specify that all facilities (domestic and those outside the United States) will be made accessible to the FAA and to the civil aviation authorities (CAA) acting on behalf of the FAA. If articles or services are provided by a supplier or manufacturer in a country outside the United States, accessibility includes review of the data (drawings, specifications, procedures, and inspection records) and equipment pertinent to the product or articles produced under the PC.

c. The quality system manual proposed by the applicant will contain sufficient details establishing the quality system organization and procedures as a separate and independent entity (rather than simply incorporating by reference the quality systems of its partner companies). This does not preclude the use of, or reference to, applicable portions of a partner company's quality system, but ensures that the applicant's system will be evaluated on its own merits. This also enables the FAA to conduct surveillance to ensure compliance with the regulations.

5. Quality Organization and Authority.

a. The applicant's senior quality manager will have direct access to the consortium's senior management.

b. The applicant's quality system organization will have an independent management organization. This organization will establish departmental control over the partner companies regarding the quality of the jointly produced product. The individuals chosen to fill these management positions will have a clearly defined and separate allegiance to the applicant's top management, rather than to any company for which they have worked or for which they are currently working.

c. The responsibility and authority of the employees in the consortium's management organization will be clearly defined in the quality system data. This includes the consortium's relationship to the quality and production organizations of the partner companies.

d. The applicant may propose to assign inspection authority to a limited number of its employees to ensure that the quality of products being produced. While no minimum number of employees can or should be specified by the FAA, the viability of the proposed quality system procedures will be assessed with respect to the number of employees available to implement the system.

e. It is particularly important to establish accountability for compliance with § 21.137 in the case of a multinational consortium. This is because the responsibilities of suppliers outside the United States, regarding their other products under their own CAAs, may be inconsistent with those required by § 21.137. Compliance responsibility for the consortium product will rest with the PC holder. This direct responsibility will be understood by the applicant's management and the management of the supplier, and be described in the quality manual.

f. The fact that the actual manufacture of the applicant's product may take place in a country outside the United States does not affect the applicability of FAA regulations and orders regarding the management and surveillance of the PC holder.