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Quality Manual

FAA-Approved TSOA and PMA

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Approvals:

President	Mark Scheuer	Jab Slun	Date: 3-18-16
Quality Manager	Gary Picou	Duce	Date: 4 FETS 16
Federal Aviation Administration	Letter on file	Click to open letter	

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Company Vision Statement

PS Engineering is committed to providing a cost effective solution for aircraft audio controls and entertainment that balances the customer expectation for performance, features and reliability with value and affordability.

1.0 Scope

PS Engineering, Inc. is a designer and manufacturer of aviation related products; these include, but are not strictly limited to, audio control articles and cabin entertainment systems within general aviation aircraft. It is the policy of PS Engineering, Inc. to apply this Quality System described within, to all articles and materials manufactured and received at our facility.

This Quality Systems Manual is written in harmony with Society of Automotive Engineers (SAE) Aerospace Standard AS9100 Revision C. This International Standard provides a basis for a process approach to our operations. As an avionics manufacturer, PS Engineering needs to demonstrate our ability to consistently provide product that meets customer and applicable regulatory requirements, and to enhance customer satisfaction through the effective application of the Quality System, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements. This document incorporates elements from AS9006, the *Deliverable Aerospace Software Supplement for AS9100*, and Dated July, 2013.

In addition, this Quality Systems Manual is derived from the regulatory requirements in 14 CFR Part 21, Subpart K, Parts Manufacturing Approvals, and Subpart O – Technical Standard Approvals under 14 CFR §21.307 and §21.607. In addition, the Quality Manual addresses malfunction and defect reporting requirements in 21.3. This manual describes the quality assurance practices in place at PS Engineering, Inc., located at 9800 Martel Road, Lenoir City, TN 37772.

Although this manual is structured for AS9100:C, it also references the required elements by the FAA under *Certificate Management of Production Approval Holders*, in FAA Order 8120.23 Appendix H.

This manual provides personnel and suppliers of PS Engineering, Inc., written corporate policy for maintaining an effective and consistent quality assurance system. Procedures to implement these policies described shall be established as deemed necessary by the complexity of the product design and manufacturing techniques employed.

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The quality assurance system in place is devised to assure that all articles are subject to adequate, consistent and repeatable quality control. This system provides for discrepancy detection through 100% functional testing of the final product. If any discrepancies are detected before shipment, positive corrective actions will be taken as described herein.

PS Engineering's Quality System also includes provisions of a Safety Management as well as Quality Management, as safety on flight is paramount for all activities in the work flow environment that produces articles that meet type design, and are in condition for safe operation.

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2.0 Manual Locations, Reviews and Updates

Using the following guidelines, revisions or updates will be submitted to this manual when necessary:

All revisions or additions will be reviewed by the Quality Control Manager and approved by the President prior to publication. The Quality Control Manager will perform a complete manual review on an annual basis.

All revisions or additions will be FAA approved prior to the implementation of such revisions or additions.

Once approved, this manual will be saved and stored electronically where it can be accesses as a read-only file by all interested parties. A master hard copy will be maintained in the file area of PS Engineering.

No changes to this manual or our quality assurance procedures are valid until approved by the President, Quality Control Manager and the FAA.

ACO	Aircraft Certification Office (FAA)
Accident	An unplanned event or series of events that results in death, injury,
	occupational illness, damage to or loss of equipment or property.
ACP	Audio Control Panel
C/A	Corrective Action
CAA	Civil Aviation Agency
COTS	Commercial Off the Shelf (electronic components of a general nature)
CRS	Certified Repair Station (FAA)
Customer	Person, company or agency that receives products or services from PS
	Engineering
EASA	European Aviation Safety Agency
FAA	Federal Aviation Administration
ICAR	Internal Corrective Action Request
ICS	Intercom
IFE	In-flight Entertainment
Input	Document, information or requirements needed for a process
MIDO	Manufacturing Inspection District Office (FAA)
Output	Records or documents generated from a process or meeting
P/A	Preventative Action
PC/MRP	Material Requirement Program for desktop computers

3.0 Acronyms, Terms and Definitions

The following terms and abbreviations are used in the Quality System at PS Engineering

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Manual
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РО	Purchase Order
РСВ	Printed Circuit Board
QAM	Quality Assurance Manual
SCAR	Supplier Corrective Action Request
SMS	Safety Management System- the formal, top-down business-like
	approach to managing safety risk.
SMT	Surface Mount Technology
SRM	Safety Risk Management
SOP	Standard Operating Procedure
Supplier	Provider of parts, assemblies or services to PS Engineering
TH	Through-Hole component technology
VOCP	Voice of the Customer
WI	Work Instructions

3.1 Definitions

Baseline: The approved and recorded configuration of one or more configuration items, that serves as the basis for further development, and is changed only through the Engineering Change Control (ECO) process.

Critical Items: Items having a significant effect on the article realization and use; including safety, performance, form, fit function, manufacturability or service life that must be adequately managed.

Firmware: An ordered set of instructions and associated data stored in a way that is not dynamically changeable, such as microprograms stored in Read-Only Memory.

Hazard: A hazard is defined as a Condition, occurrence, or circumstance that could lead to or contribute to an undesired event. Sometimes termed "threat." An "undesired event" can be, but is not limited to: injury, illness, or death; damage to or loss of a system, equipment, or property. A hazard is a condition that is a prerequisite to an accident or incident.

Incident A near miss episode with minor consequences that could have resulted in greater loss. An unplanned event that could have resulted in an accident, or did result in minor damage, and indicates the existence of, though may not define a hazard or hazardous condition.

Key Characteristics: An attribute whose variation has a significant effect on article form, fit function, performance, service life or manufacturability, which requires specific action to control variability.

Nonconformity, Non fulfillment of a requirement. This includes but is not limited to noncompliance with Federal regulations. It also includes company requirements,

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requirements of operator developed risk controls or operator specified policies and procedures

Release: A particular version of a configuration item made for a particular purpose, such as production or test.

Risk: An undesirable situation that has both a likelihood of occurring and a potentially negative consequence.

Software: Computer programs and associated documentation and data pertaining to the operation of a computer system. Executable programming logic and data embedded in Hardware devices is considered to be included in the definition of software.

Safety assurance SMS process management functions that systematically provide confidence that organizational products/services meet or exceed safety requirements.

Special Requirements: Those requirements identified by the customer or PS Engineering which has high risk to being achieved, and require their inclusion into the risk management process.

4.0 Quality Management System

PS Engineering has established and implemented a Quality Management System, based on SAE AS9100 Revision C, and Title 14 of the Code of Federal Regulations, Part 21, Subpart K and O. It is PS Engineering's policy to execute our operations in accordance with this standard, and continuously improve the effectiveness of our quality system.

Quality Management Mission Statement

To be recognized as the resource in PS Engineering, Inc. for the promotion of quality concepts, principles, and techniques for the purpose of exceeding the customer's expectations.

4.1 General Requirements

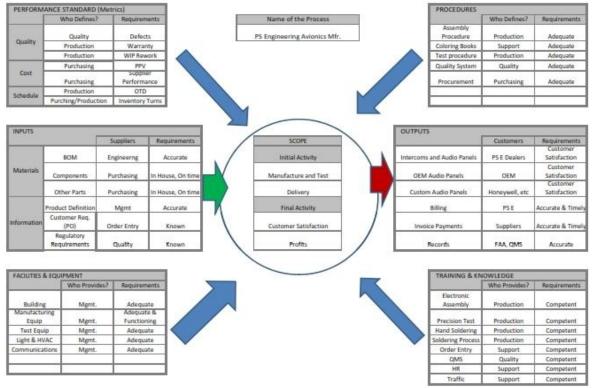
PS Engineering's corporate quality policy is to:

- a. Determine the processes needed for the quality management system and their application throughout the organization through the use of Quality Policy See Section 5.3), procedures and work instructions,
- b. Determine the sequence and interaction of these processes,
- c. Determine required key characteristics criteria and test or measurement methods needed to ensure that both the operation and control of these processes are effective,

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- d. Ensure the availability of necessary resources and information required to support the operation and monitoring of these processes,
- e. Monitor, measure as applicable and analyze these processes, and
- f. Implement actions necessary to achieve planned results and continual improvement of these processes.
- g. Implement quality system requirements imposed by customers, or by the FAA and other regulatory or statutory authorities, such as, but not limited to Federal Regulations, Technical Standard Orders and industry standards (RTCA, Inc. SAE, etc.).
- h. Ensure appropriate control over any outsourced processes.
- i. Implement, Maintain, and Improve a Safety Management System
- j. Establish clear standards for acceptable operational behavior for all employees.





4.1.1 Changes affecting the Quality System (§21.320, §21.620)

PS Engineering shall present any changes in the FAA-approved quality system for review by the FAA Certificate Holding District Office (CHDO); and shall immediately notify the FAA,

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in writing, of any change that may affect the inspection, conformity, or airworthiness of article produced.

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation at PS Engineering, Inc. includes the following elements:

- a. A quality policy (see § 5.3) and quality objectives (see §5.4.1),
- b. A quality manual (this document),
- c. Documented procedures required to support this Quality Manual,
- d. Other documents needed by PS Engineering, Inc. to ensure the effective planning, operation and control of its processes (see §4.2.3),
- e. Records required to support this Quality System (see §4.2.4), and

This documentation is, by policy, available to internal users, and changes are communicated in accordance with change procedures and document policies (002-423-1005).

4.2.1.1 Document Media

PS Engineering, Inc. maintains documents electronically, and distributes on paper or electronically at Point of Use. Document maintenance policy and procedure is contained in Policy Document <u>002-423-1005</u>.

4.2.2 Quality Manual (§21.308, §21.608)

PS Engineering has established, and shall maintain <u>this</u> document as a quality manual that includes:

- a. the scope of the company's quality management system.
- b. the documented procedures established for the quality management system, and/or reference to them, including the relationship to the requirements of AS9100, and the documented procedures shall be clearly shown.
- c. a description of the interaction between the processes of the quality management system and the company operation (See Figure 4-1).

4.2.3 Control of Documents (§21.137(b))

All documents required by the PS Engineering quality management system shall be controlled.

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A documented procedure, <u>002-423-1005</u>, has been established to define the controls needed:

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin that are necessary for the QMS are identified and their distribution controlled, and
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

It is PS Engineering policy to coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

4.2.4 Control of Records (§21.137(g) and §21.137(k))

Records have been established and controlled that provide evidence of conformity to requirements and of the effective operation of the quality management system.

It is PS Engineering's policy that all required records shall remain legible, readily identifiable and retrievable. A documented procedure, 002-424-1105, is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records, tags, and forms. Retention of completed records shall be at least as long as required by regulatory and/or contract requirements.

This documented procedure defines the method for controlling records that are related to the activities of suppliers. In addition, records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

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5.0 Management Responsibility (§21.305, §21.605)

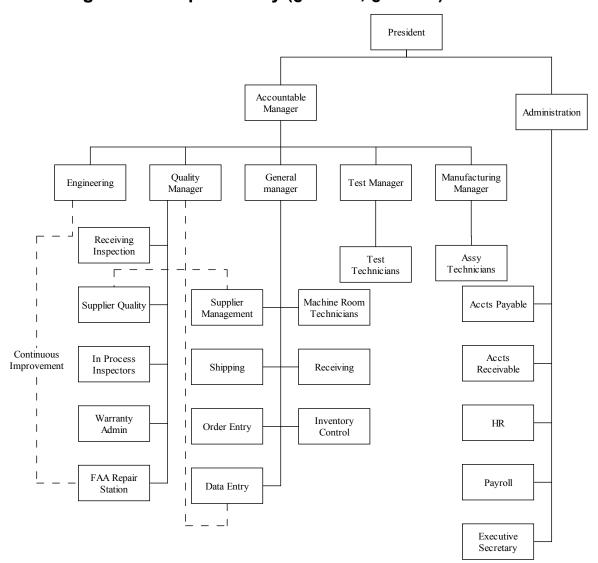


Figure 5-1 Organizational Chart for PS Engineering

5.1 Management Commitment

It is the policy of PS Engineering that management is committed to the development and implementation of the quality and safety management systems and continually improving its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- establishing the quality policy,

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- ensuring that quality objectives are established, conducting management reviews,
- and ensuring the availability of resources

5.2 Customer Focus

It is the PS Engineering policy that management ensures customer requirements are identified and are met, including product performance and on-time delivery with the aim of enhancing customer satisfaction, and action is taken if the planned results are not achieved. See Voice of the Customer, § 7.2.1 and §8.2.1.

5.3 Quality Policy

It is our *Quality Policy* that encourages us to:

- Produce each item, part, document, or customer interaction to meet the highest standards possible,
- Comply with all company procedures, regulatory and customer requirements,
- Seek ways to improve each facet of our business on a continual basis,
- Practice Organizational Excellence when relating to each other, each customer or agency,
- Use an appropriate amount of time and resources for all tasks

PS Engineering's management is responsible for determining that the quality policy remains appropriate to the purpose of the organization, includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, provides a framework for establishing and reviewing quality objectives, is communicated, and understood within the organization, and is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality and Safety Objectives Planning

Quality objectives have been established within the company to ensure that the products meet customer and regulatory requirements. Measurable Quality Objectives in use include:

- Production Defect Reduction
- Labor efficiency improvement
- Cost reduction through waste reduction
- Throughput improvements in manufacturing
- Customer communication improvements
- Warranty cost reduction and reliability improvement
- Safety Objectives are planned

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• Safety and reliability attribute of airborne software products are considered and addressed

PS Engineering, Inc. defines and documents how the requirements will be met. Quality plans are generically addressed by the overall quality system documentation. Any unique requirements that are beyond the scope of the Quality System are documented.

Details of the measurable Quality and Safety Objectives are contained in document <u>002-541-0707</u>, "Quality Objectives," which is updated as needed by management to maintain consistency with conditions and quality policy.

PS Engineering management will review the objectives to determine that they continue to be appropriate. See § 7.1(a).

5.4.2 Quality Management System Planning

PS Engineering Quality Management reviews the quality manual at least on annual basis to ensure that it meets the requirements and objectives for the organization. Management will review any changes, which will be approved through our document process. In addition, Quality System elements relating to the regulatory requirements will be presented to the FAA for review and approval of changes prior to being implemented.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority: (§21.305, §21.605)

Top management ensures that the responsibilities and authorities are defined and communicated within the organization. The duties and responsibilities are defined in document <u>002-621-1011</u>, Human Resources, Competence and Training policy, and removed from the Quality Systems Manual.

5.5.1.1 Accountable Manager

PS Engineering designates an Accountable Manager in accordance with 14 CFR 21.605 In addition to serving as a PS Engineering's primary contact with the FAA, the accountable manager is responsible within the PS Engineering organization for, and has authority over, all production operations.

In addition, an accountable manager confirms that all quality manual procedures are in place and that the PS Engineering satisfies the requirements.

The accountable manager may delegate functions and identify alternate points of contact. Any such delegations shall be noted in §6.2.3

The name of the current Accountable Manager is Gary Picou, Vice President.

5.5.1.2 Authorized Release Documents

PS Engineering will use FAA designees to issue Authorized Release Documents (such as FAA Form 8130-3) in accordance with 14 CFR 21.137(o).

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5.5.1.3 FAA Designees

- a. PS Engineering has Designated Manufacturing Inspection Representatives (DMIR) in the facility. This is an individual appointed in accordance with part 183, section 183.31 who possesses aeronautical knowledge, experience, and is employed by the company This individual meets the qualification requirements in accordance with Order 8100.8.
- b. The company DMIR issues export certificates of airworthiness and airworthiness approval tags in accordance with Subpart L of Part 21 of 14 CFR. These individuals will conduct any inspections that may be necessary to determine that any prototype parts conform to PS Engineering design specifications; and parts manufactured by PS Engineering parts conform to the approved type design and are in condition for safe operation.
- c. PS Engineering's policy provides complete authority for these individuals to function in their capacity as an FAA-designee.
- d. There will be no conflicting restraints placed on the performance of their duties.
- e. The designees are the Manufacturing & Test Manager, and the General Manager, and therefore have an organizational position with sufficient authority and involvement with production and quality activities

5.5.2 Management Representative

The Quality Control Manager is appointed as Management Representative by the President to implement and maintain the Quality System.

The Representative is delegated the responsibility and authority that includes:

- a. Ensuring that the quality management systems requirements are established, achieved and maintained,
- b. Reviewing the overall quality system effectiveness and need for improvement with the President and other managers. These reviews include assessment of opportunities for improvement and the need for changes to the Quality Management Systems, including the related policies and objectives.
- c. The Quality Control Manager is responsible for ensuring that the company is aware of all customer requirements; and regulatory liaison. See Section 5.5.1.3.
- d. The Quality Representative is also given the organizational freedom and unrestricted access to the company president to resolve matters pertaining to Quality Management System.
- e. The Quality Representative is also appointed as the management representative responsible for the actual implementation of the Safety Management System (SMS). Refer to SMS Policy document, 002-767-0511.

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5.5.3 Internal Communication

To ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management, software plans and safety management systems.

5.5.3.1 Management to organization

The primary means management flows information down to the organization is through internal email. All stakeholders are copied on the information as necessary.

In addition, public area bulletin boards contain information for broader dissemination.

Company-wide meetings occur as needed to full information dissemination.

The information flow down is typically:

Item-specific actions, corrective actions and follow through activ	vities email
Document review, changes and development specifications	e-document collaboration
Organization wide goals (including SMS), reports and results	Bulletin Board
State-of-the company, major policy or organizational changes	Group Meetings
Organizational or individual corrective action	Written document

5.5.3.2 Organization to Management

The primary means used by the organization to flow information flows up to management is through internal email. All stakeholders are copied on the information as necessary.

A scheduled weekly meeting is used as a forum for managers to provide regular information regarding ongoing projects and issues.

The other methods of information flow include:

Item-specific actions, results of corrective actions and follow through activities email		
Organizational or individual corrective action	Written document	
Progress reports, issue specific information exchange	small meetings	
Records are kept of the following items, routing for internal communi	cations, weekly	
management meetings, internal and external corrective actions.		

5.6 Management Review

5.6.1 General Policy

PS Engineering's Management Review Policy is to perform a top-down management review of the Quality and Safety System twice each year, in the first and third calendar quarter. This review is intended to verify the effectiveness of the quality elements, systems and processes, and their objectives.

Records, in the form of reports, agenda and minutes, will be maintained as objective evidence of the output from these meetings.

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5.6.2 Management Review Input

The following information is used as input to the review agenda:

- a. Results of internal and external audits (see §8.2),
- b. Customer feedback from surveys, contact and contract management,
- c. Process performance and product conformity as measured by 4-up charts,
- d. Status of open preventive and corrective actions, effectiveness of completed actions
- e. Follow-up actions from previous management reviews,
- f. Changes that could affect the quality and safety management systems, and
- g. Recommendations for improvement.

5.6.3 Review Output:

The output from the management review, in the form of minutes and notes, will include any decisions and actions related to:

- a. Quality management system improvements
- b. Improvement of products related to new customer requirements or design efficiencies, and
- c. Any specific resource needs.

6.0 Resource Management

6.1 Resources provided

On a continuous basis, documented during the management review, PS Engineering will determine the resources required for our quality and safety systems, and make necessary provisions. PS Engineering uses the customer and internal feedback from contract and surveillance to ensure that the requirements are satisfied or exceeded.

6.2 Human Resources

6.2.1 General

It is PS Engineering's company policy that all personnel performing work affecting product quality shall be competent and skilled on the basis of appropriate education, training, skills and experience. PS Engineering's policy containing details for employee competence is contained in document <u>002-621-1011</u>.

6.2.2 Competence

a. PS Engineering determines the necessary skill level requirements for personnel performing work affecting product quality, through continued evaluation of the quality results and performance.

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- b. The company shall provide training or take other actions to satisfy these skill requirements
- c. PS Engineering shall evaluate the effectiveness of the training and actions taken,
- d. and will ensure that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,
- e. PS Engineering maintains appropriate records of education, training, skills and experience (see § 4.2.4).
- f. PS Engineering will ensure that the appropriate personnel are competent in the knowledge, skills, and abilities required for the Safety Management System.
- g. Skills of the personnel performing software tasks, at a minimum, shall be maintained at a level required to meet process objectives and regulatory requirements.

6.2.3 Delegations

The accountable manager, Gary Picou, may delegate functions and identify alternate points of contact. The accountable manager shall always ensure that any such delegates have adequate authority over the production operations conducted under Part 21.

6.3 Infrastructure:

6.3.1 Definition

Infrastructure- includes, as applicable:

Buildings, workspace and associated utilities,

Manufacturing process equipment (both hardware and software), and

Supporting services (such as transport or communication).

6.3.2 Inputs to Infrastructure:

The following considerations are used to determine if the PS Engineering, Inc. infrastructure will produce a quality product.

6.3.2.1 Manufacturing Capacity

The manufacturing planning is based on sales forecasts, revised 4 times each year, and adjusted on a case-by-case basis to accommodate sales changes.

The manufacturing capacity is known, determined by the throughput of the machine room (Pick and place, infrared reflow, wave solder) and the available personnel man-hours for manual assembly and test.

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Considerations shall be made for manufacturing capacity of software and programmed devices, such as coding stations and computers, gang programmers and media protection/generation.

If the forecast build rate exceeds the available capacity, the organization management considers changes to the infrastructure.

6.3.2.2 Customer delivery requirements

Customer specific delivery requirements are considered as an input to the infrastructuretools, equipment or building space may be added as needed to accommodate contractual requirements.

Customers may also request, either by contract or informally, that PS Engineering add infrastructure such as software or other handling requirements. These will be considered as inputs to the infrastructure process.

6.3.2.3 Quality and reliability results

Changes to the infrastructure are considered when there is an opportunity to increase reliability, or if there is a failure to meet the quality targets.

6.3.2.4 Manufacturing throughput

Infrastructure changes may be considered to improve manufacturing throughput, even absent any need to increase capacity. This may be justified as a cost saving adjustment.

6.3.2.5 Regulatory requirements

PS Engineering is a FAA-approved manufacturing (14CFR21 Subparts K & O) and Certified Repair Station (14CFR145), and as such must meet any housing or infrastructure requirements imposed by regulation, including future regulatory action.

6.3.2.6 Engineering requirements

Engineering may provide input to the infrastructure, either through the recommendation for advanced tools for design, (including software or software tools) or improvements in infrastructure to advance the technology in product capability.

6.3.2.7 Supplier requirements

PS Engineering maintains bonded and consignment stock, and may need to change the infrastructure to accommodate storage requirements imposed by suppliers.

In addition, PS Engineering may need to address the infrastructure based on supplier recommendations for handling or product application utilization.

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6.3.3 Management output

Management will weigh the various inputs from the stakeholders, and determine if the capital expenditure for infrastructure changes is warranted, based on economic and long term planning.

Management will maintain the facilities and equipment in good working order, as well as condition for safe operation.

The facilities shall meet the legal requirements dictated by OSHA and TOSHA for safety and emergency egress.

6.4 Work Environment:

PS Engineering management shall determine and manage the work environment needed to achieve conformity to product requirements. The work environment is evaluated through the use of time studies, efficiency reviews and employee operator inputs.

The work environment shall be safe from safety and environmental hazards. It shall be well lit and temperature controlled to be conducive for effective production.

The work environment shall include considerations for protection of software products, including unauthorized access to online storage or master media, media degradation due to age, humidity, temperature, magnetic sources, or handling and transportation damage.

All workstations shall be clean and neat, with no eating, drinking or use of tobacco products in designated work areas.

Electronic assemblies are never stacked, and always placed on proper carriers and trays for transport.

All handling, assembly, and testing of static sensitive components and assemblies must be performed at static controlled workstations.

All parts and products are packaged appropriately when shipped. All packaging is evaluated by quality management to ensure proper protection for articles during transport from the supplier or to the customer.

ESD safe workstations are tested according to company policies and work instructions.

7.0 Product Realization

Product realization relates to the process from product concept to customer delivery.

7.1 Planning of Product Realization:

PS Engineering shall plan and develop all the processes needed for product realization. Planning of product realization must be consistent with the requirements of the other processes of the quality management system (see 4.1).

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In planning product realization, the company quality management shall determine the following, as appropriate:

- a. Quality objectives and requirements for the product, that are based on customer specified requirements, or derived from industry standards and expectations which include consideration of the following aspects;
 - i. product and personal safety (including SMS inputs),
 - ii. reliability, availability and maintainability,
 - iii. producability and inspectability,
 - iv. suitability of parts and materials used in the product,
 - v. selection and development of embedded software, and
 - vi. recycling or final disposal of the product at the end of its life in accordance with regulations.
- b. the need to create, write or modify the processes, documents, and provide resources specific to the product;
- c. software life cycle planning shall ensure the compatibility of the requirements definition, design, coding, maintaining testing, and delivery processes and applicable documentation;
- d. all required verification, validation, monitoring, inspection and test activities, including software, specific to the product and the criteria for product acceptance based on customer requirements, practices and regulatory requirements;
- e. any records that may be needed to provide evidence that the realization processes and resulting product meet requirements, and;
- f. the identification of other resources necessary to support deployment, operation and field support of the product.

The output of this planning shall be recorded as part of the Product Definition, and included in Contract Review if applicable.

7.1.1 Project Management

PS Engineering shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

Project Management policy is contained in document <u>002-711-1111</u>, Project Management Policy.

7.1.2 Risk Management

PS Engineering has a process for managing risk to the achievement of applicable requirements, that includes, as appropriate to the organization and the product:

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- a. assignment of responsibilities for risk management, b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
- b. identification, assessment and communication of risks throughout product realization,
- c. identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
- d. acceptance of risks remaining after implementation of mitigating actions.

PS Engineering's Risk Management Policy is contained in Document 002-712-0809.

7.1.3 Configuration Management

PS Engineering has established, documented, and maintains an appropriate configuration management based on ISO 10007-2003. PS Engineering maintains an active Configuration Management system that includes the following elements:

- a. configuration management planning,
- b. configuration management tools, methodologies, and techniques used
- c. configuration identification,
- d. baseline establishment when items are brought under configuration control
- e. change control,
- f. configuration status accounting, and
- g. configuration audit

All articles at PS Engineering are identified with unique part number and serial number, and software configuration if applicable. The part number identifies the item as a specific functionality, while the serial number can be used to trace the specific build and configuration.

Additional details of how configuration management is accomplished is contained in document 002-713-0514.

7.1.4 Control of Work Done by Outside Contractors

PS Engineering shall treat any work by an outside contractor in the same manner as internal processes.

Each article shall be described by purchase order and detailed drawings, which have been approved through the existing process. Items or work done by the outside contractor shall be checked during the production process, in the same method as a normal production article.

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7.2 Customer-Related Processes:

7.2.1 Determination of Requirements Related to the Product

PS Engineering shall determine the product requirements by:

- a. Understanding of the marketplace, competition, and inputs from our dealer network.
- b. Review of any requirements specified by a particular customer contract or purchase order, including the requirements for delivery and post- delivery activities,
- c. Implied requirements which are not stated by the customer but necessary for specified or intended use, where known,
- d. Statutory and regulatory requirements specified by FAA-TSO, RTCA, etc, that are related to the product, and
- e. Any additional requirements determined by the organization, including special requirements.
- f. Any post-delivery requirements such as, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of Requirements Related to the Product:

PS Engineering's engineering and quality management review the requirements related to the product. In the case of a "standard" product, the requirements are based on the review of product definition created by Marketing.

In the case of a particular customer, this review shall be conducted prior to the company's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

- a. Product requirements are clearly defined,
- b. Contract or order requirements are resolved,
- c. The company has the ability to meet the defined requirements, and
- d. The company has reviewed the software requirements related to the product and has the necessary tools and skills to meet them.
- e. Risks such as new technology or short delivery time scale have been evaluated.
- f. Safety Risk Analysis is reviewed

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Records of the results of the review and actions arising from the review are found on the Contract Review Checklist (002-722-0507) form, which is maintained on file with the contract documents.

Where product requirements are changed, engineering shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication:

PS Engineering determines and implements effective arrangements for communicating with customers that are detailed in our company "Voice of the Customer Policy," <u>002-723-0905</u>.

7.3 Design and Development:

PS Engineering maintains an engineering department that is dedicated to the development of products, using customer requirements, experience and product feedback, industry standards and regulatory guidance.

7.3.1 Design and Development Planning

It is PS Engineering's Policy to plan for, and control the design and development of products. PS Engineering maintains documented procedures to control and verify the design of product to ensure that the specified requirements are met.

During the design and development planning, the PS Engineering uses the written Product Definition document, for each article, to determine and record the necessary:

- a. Design and development stages, including the task sequence, required sequence of design steps, significant stages and configuration control activities,
- b. The review, verification and validation that are appropriate to each design and development stage, and
- c. The responsibilities and authorities for design and development, including analysis of tasks and the resources for design and development. This analysis shall be made by and identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed by the responsible person to ensure consistency with requirements.
- d. The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.
- e. The Quality Organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

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- f. Design and development planning shall consider the ability to produce, inspect, test and maintain the product.
 - i Identification of the software standards, protocols, rules, practices, conventions, tools and configuration management.
 - ii Methods for controlling software used to support development, procedures for archiving, back up, recovery, and contingency planning; methods for virus protection.
- g. Planning output shall be updated, as appropriate, by revising the Product Definition as the design and development progresses.

7.3.2 Design and Development Inputs:

The design inputs relating to product requirements are determined and recorded in the Product Definition Document, which are maintained (see 4.2.4) throughout the product life. These inputs include, but are not limited to:

- a. Functional and performance requirements,
- b. Applicable statutory and regulatory requirements,
- c. Where applicable, information derived from previous similar designs, and
- d. Any other requirements essential for design and development.

These inputs shall be reviewed for adequacy. PS Engineering's Engineering Manager is responsible for verifying that the requirements defined in the Product Definition are complete, testable, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs:

The outputs of design and development are recorded in the Product Definition, and translated into the Configuration Control Documents, which enable verification against the design and development input contained in the Definition and shall be approved by engineering prior to release.

Design and development outputs recorded in the documentation shall show: and:

- a. Conformity Documents meets the input requirements for design and development,
- b. Product Definition provides appropriate information for purchasing, production and for service provision,
- c. Conformity Documents contain or reference product acceptance criteria,
- d. Conformity Documents specify the characteristics of the product that are essential for its safe and proper use, and

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- e. Product Definition and Conformity Documents specify key characteristics, when applicable, in accordance with design or contract requirements, and any specific actions to be taken for these items.
- f. Documents necessary for the service and or preservation of the products.
- g. Documents necessary for the software certification activities and software life cycle.

7.3.4 Design and Development Review:

At stages that are specified in the product definition, PS Engineering performs systematic reviews of design and development in accordance with planned arrangements (see 7.3.1(c)):

- a. To evaluate the ability of the results of design and development to meet requirements,
- b. To identify any problems and propose necessary actions,
- c. To authorize progression to the next stage.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are created and maintained with the Product Definition.

7.3.5 Design and Development Verification:

Verification is the process used to determine that the design has met the stated requirements from the customer. "Does it meet what we told you we want"?

Verification activities are performed in accordance with the specifics contained in the Product Definition (see 7.3.1) to ensure that the design and development outputs have met the input requirements.

In cases where the results of the design and development processes in software cannot be fully verified exhaustively and conclusively, PS Engineering shall demonstrate alternative methods of verification such as simulation testing or Failure Modes and Effects Analysis.

Records of the results of the verification and any necessary actions shall be maintained as part of the Product Definition evolution, and maintained as specified in Section 4.2.4.

Verification activities recorded include, but are not limited to:

- a. Comparing the new design with a similar proven design, if available,
- b. Undertaking tests and demonstrations, and
- c. Reviewing the design stage documents before release.

7.3.6 Design and Development Validation:

Validation is the process used to determine that the product meets the intended function, and all of the unstated requirements. "Does it do what we really want it to in the real world?"

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Design and development validation shall be performed in accordance with planned activities specified in the Product Definition (see 7.3.1) to ensure that the resulting product meets the requirements for the specified application.

In cases where the results of the design and development processes in software cannot be fully verified exhaustively and conclusively, PS Engineering shall demonstrate alternative methods of validation such as operational simulation or system safety and hazard analysis.

Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Design and/or development validation follows successful design and/or development verification.

Validation is normally performed under operating conditions that are consistent with aircraft operation, and RTCA DO-160 environmental testing, unless specified by customer.

Validation is normally performed on the final configuration of the article, typically an engineering unit that has been built with production-type procedures, although not released. Validation may be necessary in earlier stages prior to product completion, at engineering discretion.

7.3.6.1 Documentation of Design and/or Development Verification and Validation:

All necessary tests for verification and validation are planned during the product definition phase, controlled, reviewed, and documented by engineering to ensure compliance with the requirements listed, and include the following:

- a. test plans define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;
- b. test procedures describe the method of operation, the performance of the test, and the recording of the results;
- c. the correct configuration article is used for the test;
- d. the requirements of the test plan and the test procedures are observed;
- e. and the acceptance criteria listed in the configuration document are met.

7.3.6.2 Design and/or Development Verification and Validation Testing:

At the completion of design and/or development, the PS Engineering Quality Management and the Engineering Manager will review the reports, calculations, test results, etc., and verify that the product definition meets the specification requirements for all identified operational conditions. These documents are forwarded to the FAA as part of the certification technical data, and maintained on file at PS Engineering in accordance with Section 4.2.4 of this manual.

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7.3.7 Control of Design and Development Changes: §21.137(a)

Design and development changes are identified and records maintained through the ECO system, after the product definition has been released. The changes shall be reviewed, verified and validated, under the ECO system, and approved by PS Engineering before implementation.

Software changes shall be evaluated for impacts upon the life cycle, and assessed for impact on system safety, reliability and maintainability.

Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3).Records of the results of the review of changes and any necessary actions shall be maintained as a company record under section 4.2.4 of this document.

7.4 Purchasing and Supplier Control: (§21.137(c))

To assure continuous manufacturing to FAA-approved design data, PS Engineering maintains an approved supplier chain. The company maintains documented procedures, which assure that supplied items and services conform to specified requirements.

7.4.1 Purchasing Process

PS Engineering quality system is responsible for the conformity to PS Engineering requirements of all items, parts or components purchased from suppliers, including items from customer-defined sources.

PS Engineering evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established in Supplier Relations Policy, 002-740-1205. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

PS Engineering maintains a register of its suppliers in document <u>002-008-0000</u>. This document includes the scope of the approval (approved, priority, non-priority, etc.); results of periodic reviews, results of supplier quality reviews and actions.

7.4.2 Purchasing Information

Procedures in place at PS Engineering detail the supplier selection and qualification process.

Supplier are evaluated initially to determine suitability, and periodically thereafter to assure continued compliance.

Purchasing information shall describe the items to be purchased, including, where appropriate:

a)	requirements for approval of product, procedures, processes and
	equipment,

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- b) requirements for qualification of personnel,
- c) quality management system requirements,
- d) the identification and revision status of specifications, drawings, process requirements, inspection /verification instructions and other relevant technical data,
- e) requirements for design, test, inspection, verification (including production process verification), use of any applicable statistical techniques for product acceptance , and related instructions for acceptance at PS Engineering, and as applicable critical items including key characteristics, communication protocol, software architectural specification, engineering standard,
- f) any special requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection /verification, investigation or auditing,
- g) requirements regarding the need for the supplier to notify PS Engineering of nonconforming items
 - obtain PS Engineering approval for nonconforming item disposition
 - notify the PS Engineering of changes in parts and/or process, changes of suppliers, change of manufacturing facility location and,
 - where required, obtain PS Engineering approval, and
 - flow down to the supply chain the applicable requirements, including customer requirements
 - notify PS Engineering of any goods or services that are discovered to be non-conforming after they have been delivered to PS Engineering.
- h) records retention requirements, and,
- i) right of access by the PS Engineering, our customers, and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

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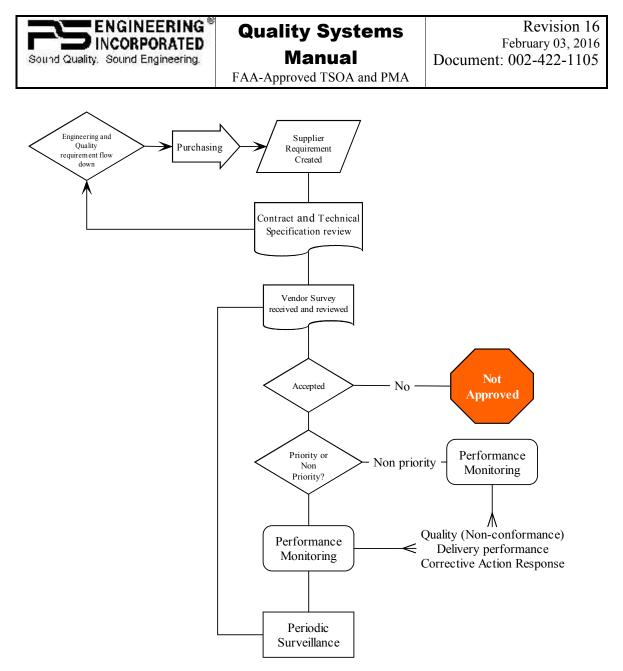


Figure 7-1 Supplier selection and approval flow chart

Supplier performance is measured through the comprehensive testing of the articles in production. Parts and assemblies that are nonconforming to their technical data are detected and corrected. Corrective Action data is maintained and supplier qualification reviewed based on performance and nonconformance information.

PS Engineering has two tiers of approved suppliers, priority, and non-priority.

Priority suppliers provide components, assemblies and services that must be controlled. A non-conforming article from a priority supplier may result in a failure of the final products to meet the FAA-approved design data. In addition, the characteristics (electrical or physical) cannot be readily verified by PS Engineering at incoming inspection, but are directly

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traceable to the COTS manufacturer and part number. Electronic components are an example of a priority-supplied item.

Priority parts must be adequately identified and marked, and shall be kept in the original packaging until used.

Non-priority suppliers provide parts, components assemblies and services that would not have an effect on the final product meeting the technical design data. In addition, many non-priority parts can be readily verified at incoming inspection. Packaging materials, article labels and cosmetic parts are examples of non-priority supplied parts.

PS Engineering, Inc. shall notify the FAA suppliers in foreign countries, and of the first piece received from that supplier.

Based on the responses to the questionnaire, the Quality Manager may request additional information or perform an on-site survey.

Copies of all purchase orders are on file electronically and available for review.

7.4.2.1 Purchase Order Review

Prior to the issuance of Purchase Orders, purchasing department will provide the Engineering Manager all required drawings, part numbers, and/or specifications to assure the approved and correct part is ordered. Subsequent to the issuance of the Purchase Order, a copy of Purchase Order is forwarded to receiving department for receiving inspection.

In addition, the Quality Manager shall review purchase orders to verify that the pertinent requirements are met for supplier qualification and order detail.

All PS Engineering purchase orders will be annotated with the two statements as follows: "The requirements of this purchase order may include quality provisions required by the FAA" and "All Suppliers of Parts and Services to PS Engineering are advised that they are subject to surveillance and investigation by the Federal Aviation Administration.

PS Engineering, Inc. delegates inspection authority to suppliers, as their responsibility to provide conforming parts per the Purchase Order, and supply Certification of Conformance documentation. This documentation is on file, and available to the FAA on request.

7.4.2.2 Initial and Periodic Supplier Evaluation

Priority/Critical component suppliers will be evaluated by PS Engineering, Inc. prior to Purchase Order.

Each approved supplier shall be surveyed/evaluated once every twenty-four months to assure continuous compliance with the quality requirements set forth in the FAA quality approvals rendered in support of Production Approvals held by PS Engineering.

PS Engineering, Inc. does not have any "direct ship" authorized suppliers.

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In the event that specification or drawings changes occur, purchasing will issue an approved Engineering Change Order (PS-08) to establish the correct part with the supplier. Supplier agreements and purchase orders shall prohibit design changes to supplied materials without explicit PS Engineering, Inc. approval.

Qualified list of suppliers are maintained and on file, the FAA is notified of new priority suppliers. Suppliers who ship PS Engineering non-conforming material must provide a return authorization. Material will be shipped with a copy of Material Discrepancy Report Form PS-03 and discrepancy clearly marked on the shipping documents.

7.4.3 Verification of Purchased Product

7.4.3.1 Material Receiving, Handling and Storage

PS Engineering's purchase order documents reflect the right of the company, certain specific company customers, or Federal Aviation Administration to verify product conformity to approved design data requirements. This verification may take place at the supplier or at PS Engineering and does not absolve the supplier of the responsibility to provide acceptable product. In addition, this verification activity does not preclude subsequent rejection by the PS Engineering. Material Handling is contained in procedure 002-005-0000, and Manufacturing Policy, 002-010-0199.

7.4.3.2 Receiving Inspection

The incoming production material is verified by receiving inspection to determine that it meets the documentation, which shall include reference to a purchase order, placed with an approved supplier, and includes either a certificate of conformity, or reference to a certificate of conformance that is on file with PS Engineering. Material Handling is contained in procedure 002-005-0000, and Manufacturing Policy, 002-010-0199.

7.4.3.2.1 Receiving Inspection records

Records are created and stored for each shipment received, which include: part name, part number, documentation conformance or nonconformance, quantity and description of any such nonconformance found, and any action taken.

If a discrepancy is found during inspection of an incoming part, the part is handled in accordance with the non-conforming parts procedure, <u>002-830-0106</u>.

Discrepancies in paperwork will result in the discrepant items being rejected in receiving until review by a member of the Material Review Board (MRB), or it being returned directly to the supplier. It shall not enter the PS Engineering production system.

7.4.3.3 Life Limited Materials

Age-sensitive materials are limited to consumable supplies used in manufacturing. These are identified on the purchase order, and the expiration recorded on the package, to preclude use

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beyond their expiration. Instructions for Life limited Items, is contained in document 002-002-0507

Operators that use shelf life limited items are trained, and those items are listed in the work instructions as a step to verify that the expiration date has not been exceeded.

7.4.3.4 Segregation of material

All incoming parts are inspected by purchasing department against Purchase Order requirements and Incoming Verification Records completed. All Incoming Verification Forms are available for FAA inspection. All parts are subject to consistent and repeatable quality control through 100% functional testing.

Any items that do not have the correct documentation are held in receiving until disposed of by a member of the MRB, or an assigned inspector, in accordance with the non-conforming parts procedure, <u>002-830-0106</u>.

7.4.4 Supplier Quality Escapes (21.137(c)(1)

PS Engineering's Standard Terms and Conditions shall include a statement that:

Suppliers of parts or services to PS Engineering are required to notify PS Engineering if they determine that any components, parts, or services previously delivered, fail to meet the requirements flowed down to them.

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7.5 Production

7.5.1 Production Control (§21.137(d))

All manufacturing processes are covered on specific work instructions. These work instructions contain the inspection and test processes in sequence to verify the processes.

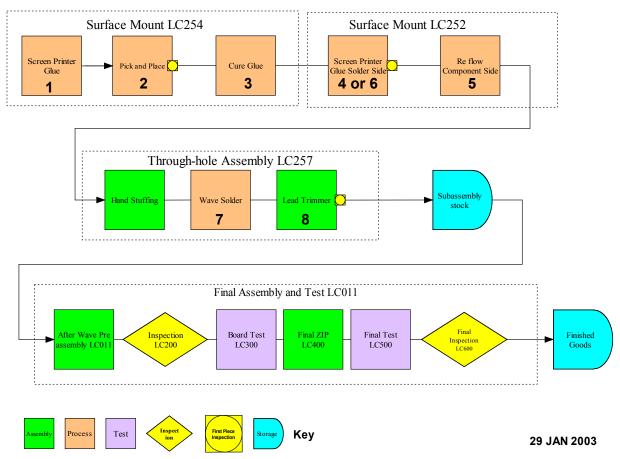


Figure 7-2 Typical Production Controls

ITEM	DOCUMENT NUMBER	DESCRIPTION
1	002-101-0800	Screen Printer- Procedure
2	002-101-0698	Celmacs Procedure
3	002-104-0698	ETS Curing Glue Procedure
4	002-104-1019	Screen Printer-Solder Paste

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5	002-102-0698	ETS re-flow Procedure
6	002-101-0199	Dover-drying Glue Procedure
7	002-100-0997	Dover-Solder Procedure
8	002-202-0199	Operation Flying Lead Cutter
9	002-178-1013	Coded Device Production

Figure 7-3 - Manufacturing Document Overview

Manufacturing at PS Engineering is described in Manufacturing Policy Document Policy Document, <u>002-001-2299</u>, and referenced Standard Operating Policies.

All Manufacturing processes are covered by specific work instructions. These instructions contain, at a minimum:

- Sequence of operations
- Component assemblies and placement documents used
- Appropriate measuring and monitoring equipment, and special tools to be used (if necessary)
- Workmanship criteria specified in the clearest manner (e.g. samples, illustrations, etc.).
- Document numbering and revision level
- Inspection methods and criteria.
- Identification method as evidence of in process and completed operations and inspections
- Accountability for all articles during production
- Provisions for the prevention, detection and removal of foreign objects or debris

Work Instruction Process flow down is described in the following chart:

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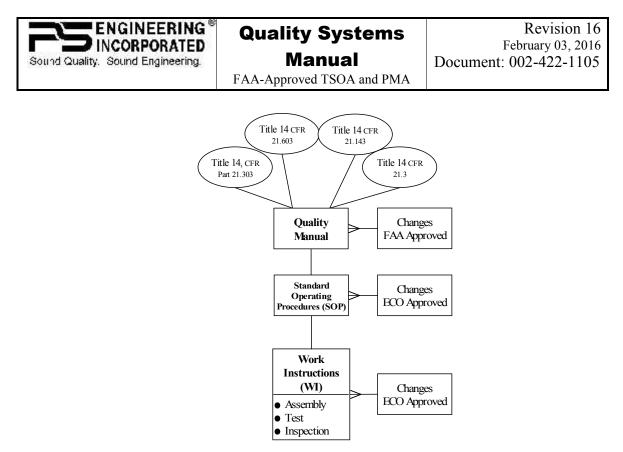
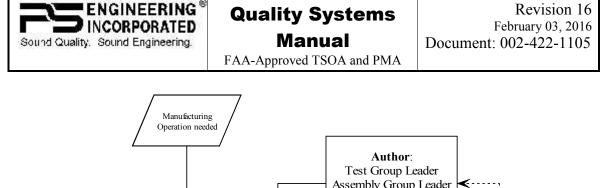


Figure 7-4 - Work Instruction Flow Down

Before initial release, or change, work instructions are reviewed by Quality Manager and Engineering to verify that the work instructions, inspection points and criteria assure that the process will result in meeting the FAA-approved type design.

All procedures and work instructions are controlled and identified according to their document number and revision level. Obsolete printed instructions are purged by the supervisors. Obsolete electronic work instructions are removed from the "Current" directory, and are not accessible from work stations.

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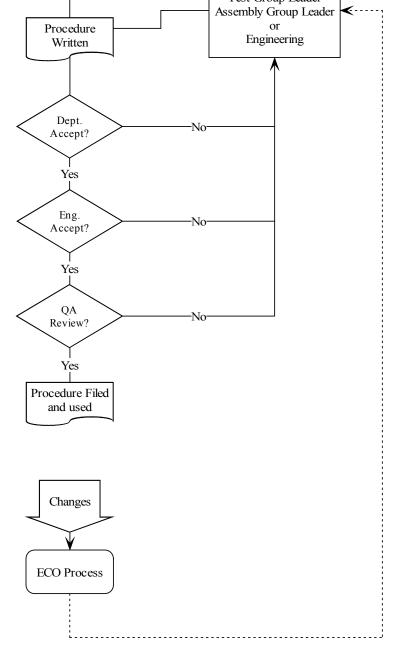


Figure 7-5 - Work Instruction Release and Revision Coordination

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a. Control of Software-related Production Processes

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For software, production means the deployment of approved, released software for loading into the target device. PS Engineering has a documented process for configuration controlled build and release, replication, and installation of software items. The Software Production Process is contained in Coded Device Production Policy, document 002-178-1013.

7.5.1.1 Production Process verification (FAI)

PS Engineering considers the primary First Article Inspection (FAI) as the representative article that has been tested and verified according to the customer requirements and applicable FAA TSO-STC standards.

PS Engineering uses the unit specific Final Test Data Sheet and quality approved test and inspection documentation that provides a process for the inspection, verification, and documentation of a representative item from the first production run (First Piece) of a new part, or following any subsequent change that invalidates the previous first article inspection result.

7.5.1.2 Control of Production Process Changes

PS Engineering controls the personnel that are authorized to make changes in the processes, documents, production equipment tools or software through the Engineering Change Order process (<u>002-099-0001</u>).

After the initial release or change instructions are completed and verified, First Piece Inspection is performed by the Engineering Manager for verifying the part complies with FAA-Approved Design.

All operators at PS Engineering are trained and qualified for specific processes by their supervisor, and ultimately the Test and Manufacturing Manager or General Manager. Manufacturing process specific qualifications are maintained for operators, with training records on file.

Any production operator that is not fully trained in a process shall work directly under the supervision of a trained operator or manager.

No production runs are made until First Piece Inspection is completed and found acceptable.

Records specific to the article production (tied to serial number and production lot) are created during the manufacturing process that document the conformity with the FAA approved type design. These records are maintained on file for at least five (5) years.

Any assemblies or articles in production can be identified to their inspection status through the work order documentation attached to the lot. All articles in the lot can be traced through the serialization

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Production personnel are responsible for filling out Component Assembly and Final Assembly inspection records completely and accurately. The Component Assembly Form verifies all detail parts are properly placed in compliance with Approved Technical Data. The Final Assembly form verifies all articles are completed in compliance with Approved Technical Data.

The Quality Control Manager, Production Test Manager, or test technicians under their supervision are responsible for filling out Final Inspection/Functional Test Form completely and accurately. This information signifies that the article meets the FAA-Approved Design Data.

Final Inspection/Functional Test processes verify that all parts and assemblies comply with Approved Technical Data and all final detail parts are installed. This process assures 100% compliance of the final product to FAA-approved data through inspection and test.

Records of First Piece Inspections, Assembly Inspections and Final Inspection /Functional Test are placed in Production Data File. All forms are available for review by the FAA.

All inspection, manufacturing and test records shall reference the technical data for process document number and revision.

All inspection and test personnel are assigned a unique identification number and stamp. This is detailed in "Employee Identification and Control" Document <u>002-824-0306</u>.

PS Engineering shall have adequate test equipment available to meet the requirements for testing articles to the FAA-approved technical data.

Multiple testing of the articles is done to ensure that any process or test equipment that is not in control can be detected, and the item corrected prior to the article being delivered to finished goods.

Individuals using the test equipment shall be trained in the proper use, and the Manufacturing and Test Manager is responsible for qualifying these operators.

Work Instruction Procedures created for each article shall show inspection points and criteria. These procedures shall be included as part of the FAA-Approved design data.

7.5.1.3 Control of Production Equipment, Tools and Software Programs.

President and Engineering Manager select and approve all production, test and monitoring equipment and software used in product realization to ensure that the equipment used will meet the accuracy requirements for verification to design data.

All test and measuring equipment standards used to ensure product acceptability must have evidence of current calibration, in the form of a sticker indicating the date of calibration, expiration, identification of the individual performing last calibration and traceability to calibration certificate. Where test standards are used as references for product acceptance,

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they are checked to prove that they are capable of verifying the acceptability of the product, prior to release for use in production. They are also rechecked at regular intervals.

All inspection gages and instruments used for the final acceptance and functional test of the product shall be calibrated with trace-ability to National Institute of Standards and Technology (NIST).

Calibration intervals for precision tools and electronic test equipment will be based on manufacturer's specifications and usage, but do not exceed 12 months. Required preventative maintenance is performed on all manufacturing and test equipment.

Manufacturing and Test Manager and Quality Control Manager review calibration dates for possible adjustments.

Documentation indicating last calibration date and calibration due date will be on file for inspection by the FAA. File is labeled Technical Data File-Instrument Calibration

Manufacturing and Test Manager and Quality Control Manager are responsible for ensuring that all equipment is operable, calibrated and appropriate for the tests conducted. The General Manager is responsible for preventative maintenance on equipment other than precision test equipment.

Tools used in software coding, such as computers and coding accessories are identified and calibrated in accordance with manufacturer's requirements.

Test procedures; check sum outputs, and 100% functional tests during production assure that the digital code programmed in the units will be correct.

When any precision tool or electronic test equipment becomes unserviceable, it is so marked with a tag, removed from operation and sent to a qualified instrument service supplier for repair and recalibration.

All test equipment is maintained in the appropriate test environment in accordance with manufacturer's recommendations and best industry practices.

PS Engineering maintains a multiple test inspection system that will preclude shipment of articles that have been tested with an out-of-tolerance tool. Continuous feedback from the Product Support and Certified repair Station will allow any product-wide discrepancies to be quickly detected.

No personal tools or test equipment is used at PS Engineering that is not completely identified and controlled in the calibration cycle and system.

7.5.1.4 Post Delivery Support

PS Engineering was granted a Certified Repair Station (CRS# P34R133O) in April 1998. This Certified Repair Station provides the return for service responsibilities under 14 CFR, Section 145.201.

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PS Engineering operates the Certified Repair Station within the limitations of the certificate and Operation Specifications.

PS Engineering, Inc. maintains FAA-certificated repairmen as supervisors within the repair station.

PS Engineering, Inc. returns articles to service from the Repair Station using the same technical deign data used in the TSO and PMA production.

Date is collected from the Repair Station Operation, based on Repair Work Orders, including the types of parts failures, manufacturing errors, and non-confirmed problems.

The data collected is used to analyze and investigate in-service problems. This includes regular reports on warranty units provided to Engineering. When problems are detected after delivery, corrective actions may be deemed necessary resulting in a Corrective Action request and subsequent Engineering Change to the product to correct the problem.

The Certified Repair Station uses Maintenance/Repair/Overhaul processes developed by PS Engineering and validated by Engineering. The data is updated and maintained through the ECO process.

PS Engineering does not permit others to provide repair services, except with prior permission, and using documents or procedures provided by PS Engineering.

7.5.2 Validation of special processes

PS Engineering's engineering is responsible for the validation of any special processes that cannot be verified in production test. In addition, the Quality Manager shall collect data from production, test, and field service, to track these processes.

PS Engineering has stipulated the following are special processes:

- Hand soldering
- Wave Soldering
- Infrared soldering

As such, personnel shall be trained in the operation of the equipment, including inspection methods and techniques.

PS Engineering gathers and maintains records of the process throughput, such as defects, in the periodic 4-up defect reports.

7.5.2.1 Special Processes Standards

PS Engineering manufactures units in accordance with IPC J-STD-006B "Joint Industry Standard for Electronic Grade Solder Alloys and Fluxed and Nonfluxed Solid Solders for Electronics Soldering Application, January 2006, (or later revision,) and IPC A-610E, Acceptability of Electronic Assemblies, April 2010 (or later Revision).

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7.5.3 Identification and Traceability (§21.137(j))

Material handling is contained in Material Handling policy <u>002-005-0000</u>.

All materials shall be handled in accordance with best practices to preclude the possibility of physical damage, contamination, or damage from electrostatic discharge. Sensitive parts shall be kept in their original packaging until used. See material handling Policy, <u>002-005-0000</u>.

All parts, components, subassemblies, in-process and completed items will be identifiable through their attached paperwork to allow traceability of their condition and status, throughout the production process.

All bins and shelves shall be clearly identified. All chemicals are clearly labeled to prevent misapplication.

PS Engineering controls the authority media used (e.g., stamps, electronic signatures, passwords), in accordance with the Stamp Control Policy, 002-824-0306.

The General Manager is responsible for approving all material handling procedures and engineering changes to those procedures, and to comply with all required standards and practices as specified in the Material Handling Policy (Document 002-005-0000).

If a component, assembly part or completed product is damaged during shipping, the receiving inspector fills out Form 06 (Shipping/Receiving Damaged Item Report). Quality reviews these reports to determine if packaging changes are necessary for protecting products if repetition of damage is noticed.

PS Engineering, Inc. does not manufacture life-limited products. The Manufacturing manager is responsible for shelf life limited production supplies. Supplies with expired shelf lives are removed from production area to the segregated area until disposition.

7.5.3.1 Inspection and Test Status (§21.137(g))

All articles in production can be identified and traced to determine their inspection and test status through the use of board serialization and in-process tracking sheets. See Manufacturing Policy Document (002-001-0199).

7.5.3.2 Marking of articles (§45.15)

PS Engineering shall mark the completed articles in accordance with 14 CFR 45.15.

For the items produced under PMA and TSO. PS Engineering shall permanently and legibly mark—

PS Engineering, Inc 9800 Martel Road Lenoir City TN 37772

And the letters "FAA-PMA" or "FAA-TSO" as appropriate.

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On each TSO article shall be marked with the TSO number and letter of designation, all markings specifically required by the applicable TSO, and the serial number or the date of manufacture of the article or both.

Part marking of the FAA-Approved items is submitted to the Atlanta ACO during the certification process for approval.

PS Engineering does not produce critical or life-limited parts.

7.5.3.3 Determination of Airworthiness

Through the Engineering Change Order process (Ref. Form PS-08), any approved changes can be applied to the completed product if necessary, as specified on the effectivity listed on that form. These items are removed from the finished goods segregated area at the request of the Quality Manager, and returned to the production cycle at the appropriate step. All required tests and inspections are performed following the incorporation of such changes to ensure the article meets the technical design data.

No product will be prepared for shipping or placed in the finished goods area until Final Inspector's signature and date of inspection acceptance card has been completed. (Ref., Form No PS-17)

Only authorized persons are authorized to place completed articles into the finished goods area, remove articles or ship articles from PS Engineering. These individuals are trained and use the shipping procedure 002-111-0299.

When products are shipped from PS Engineering, Inc., the destination organization or individual is recorded in the shipping log, enabling traceability to the receiver. A statement appears in Installation manuals that requests installers and customers to return warranty registration cards. This enables PS Engineering, Inc. to track articles in service if necessary to notify end users of airworthiness problems.

Adequate marking shall appear on the packaging to provide positive identification of product, in accordance with 14 CFR 21.607 and 14 CFR 45.15. The marking information is maintained in the technical design file.

PS Engineering's DMIR issue FAA Form 8130-3 on domestic shipments in accordance with Order 8130.21C (or later revision), *Procedures for Completion and Use of FAA Form 8130-3, Airworthiness Approval Tag.*

7.5.4 Customer Supplied and Intellectual Property

PS Engineering has an established policy for the control of products, special tooling, test equipment, shipping containers supplied by customers, and in-process services for items supplied by customers.

This policy shall also apply to customer's intellectual property (IP) that is provided to PS Engineering, Inc. for business purposes.

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It is PS Engineering, Inc. policy that the items, designs, copyrights and other intellectual property rights of third parties be respected, and not infringed by PS Engineering, Inc. or any of its employees, suppliers, consultants, or other person acting on behalf of the company.

The Quality Control Manager is responsible to assure compliance with the Sales, Marketing and Contracts portions of this policy.

The Production Supervisor is responsible to assure compliance with the Purchasing, Receiving, and Receiving Inspection portions of this policy.

The Engineering Manager is responsible for the control of Intellectual Property (IP) used in design or development of products, as well as any IP in software tools.

The control of customer-supplied items is established by the General Manager. The General Manager will coordinate the supply of customer product to PS Engineering, Inc.

Upon receipt of the product, the Receiving Department notifies the Production Manager regarding its arrival. The Receiving inspector reviews the incoming documents to determine that the correct item has been received.

The Receiving Inspection Department inspects the item in accordance with the purchase order requirements and notifies Production regarding its disposition. If the item is rejected, the General Manager notifies the customer to obtain disposition. The Receiving Inspection Department generates an inspection record, (Receiving and Inspection) for acceptable items and identifies them with part number, quantity and evidence of inspection. Copies of the documentation are forwarded to the General Manager. The accepted item is then forwarded in accordance with the purchase order instructions. Customer supplied products are forwarded to the stockroom.

A copy of the documentation is maintained by the Receiving Inspection Department for inventory purposes.

The General Manager notifies the customer in writing (fax or email) regarding any lost, damaged, or defective product and requests appropriate disposition.

A copy of the documentation is maintained by the General Manager for customer contact purposes.

7.5.4.1 Shipping Containers

The control of customer supplied Shipping Containers/cartons is established by the General Manager.

The General Manager will coordinate the nature and supply of containers with the customer.

Upon receipt of the containers, the Receiving Department notifies the production supervisor regarding its arrival. The Receiving Department reviews the incoming documents to determine that the correct item has been received.

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A copy of the customer supplied shipping container list is maintained by the Receiving Department for inventory purposes.

The General Manager notifies the customer in writing regarding any lost, damaged, or defective containers and requests appropriate disposition. The General Manager maintains a copy of the disposition documentation for customer contact purposes.

7.5.4.2 Intellectual Property

Intellectual property (IP) is defined as designs, processes, or concepts that belong to any entity besides PS Engineering, and may be used in the design, manufacture or service of products that are sold for the benefit of, or to the property owner.

Specific items of intellectual property are defined either by contract, or marked as such on the drawing or document. This includes drawings marked as "proprietary" or "company confidential."

Software that is licensed to a party besides PS Engineering, but intended to benefit the IP owner is also considered intellectual property.

IP drawings and documents used in design are held in Engineering; and the responsibility of the Engineering Manager.

IP drawings and documents that refer to components, materials or processes are the responsibility of the General Manager, and maintained in a secure location with restricted access.

Software that is considered IP is installed only on computers designated by the Engineering Manager for the purpose and benefit of the owner.

Software access is limited by the Engineering Manager, using passwords and restricted access to the programs and files designated as IP.

7.5.4.3 Disposal

When IP is no longer necessary, it is returned to the owner, and such a shipment is noted in the company's shipping log.

The Engineering Manager erases software products and programs from the computer when no longer needed.

7.5.5 Preservation of Product (§21.137(j))

PS Engineering preserves the product during internal processing and delivery to the intended destination in order to maintain the conformity to the requirements.

As applicable this preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

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Preservation of product shall also include, where applicable in accordance with product specifications, work instructions, and/or applicable statutory and regulatory requirements (14 CFR 21.137(j)

Articles shipped by PS Engineering and intended for aircraft use shall be packaged properly to protect against damage or contamination, and assure a good state of preservation. Packaging instructions are available for all articles shipped by PS Engineering for aircraft use.

7.6 Control of Measuring and Precision Test Equipment (§21.137(f))

The Engineering Manager is responsible for selection of test equipment. The selection is determined by the requirements for meeting the customer and regulatory specifications (i.e. TSO and RTCA specifications).

All test equipment standards used to ensure product acceptability must have evidence of current calibration. Where test standards are used as references for product acceptance, they are checked to prove that they are capable of verifying the acceptability of the product, prior to release for use in production. They are also rechecked at regular intervals.

Details are contained in the Calibration/Recall Procedure 002-760-0507.

All inspection gages and instruments used for the final acceptance and functional test of the product shall be calibrated with traceability to National Institute of Standards and Technology (NIST). A roster of the test equipment is maintained in document <u>002-000-0304</u>, which identifies the equipment, the Asset tracking number, the NIST-traceable calibration certificate number, the calibration expiration date and the condition of last calibration. This information is available for inspection by customers and regulatory authorities.

Calibration intervals for precision tools and electronic test equipment will be based on manufacturer's specifications and usage, but do not exceed 12 months. Required preventative maintenance is performed on all manufacturing and test equipment.

Manufacturing and Test Manager is responsible for ensuring that all equipment is operable, calibrated and appropriate for the tests conducted. Equipment that is not calibrated, not showing evidence of current calibration, is removed from the production area and not used for article acceptance testing. Equipment labeled or labeled "Calibration not required," is not used for article acceptance testing.

The General Manager is responsible for preventative maintenance on equipment other than precision test equipment.

All equipment shall be protected from damage and tampering, and the environmental conditions are suitable for the calibration, measurements and testing process.

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8.0 Measurement, Analysis and Continuous Improvement

8.1 General Provisions

PS Engineering produced articles shall be 100% functionally tested to confirm that they meet the requirements specified by the customer, design guidance, or regulations.

PS Engineering reviews product reliability reports from the field and the Lenoir City facility, as design and maintainability verification.

PS Engineering does not use Statistical Quality Control to determine the conformity to approved design data in production. All completed TSO and PMA articles manufactured by PS Engineering are inspected and tested to determine conformity with the design data.

Quality Manager, manufacturing and test Manager, and Engineering Manager review inspection and test discrepancies to improve processes, reduce nonconformance in production, and improve inspection points.

The Manufacturing Manager produces monthly reports on the defects that are discovered and corrected during the production process.

The data collected from in-process defects and field repairs is used to support:

- design verification (e.g., reliability, maintainability, safety),
- process control,
- selection and inspection of key characteristics,
- process capability measurements,
- inspection, and
- failure mode, effect and criticality analysis

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, the PS Engineering monitors information relating to customer perception as to whether the organization has met customer requirements.

Voice of the Customer is the company policy (002-050-0700) that describes the focus upon the marketplace stakeholders for product designs. This includes the following aspects of PS Engineering activities:

- Specification and functions
- Human interfaces
- Product utility
- Installation practices
- Servicing capability
- Repair and overhaul policies

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- End of product actions
- On time delivery
- Customer complaints
- Customer corrective action requests and their effectiveness

Monitoring customer perception includes obtaining input from customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

In the PS Engineering Quality Management System, the Voice of the Customer is used to enhance the positive quality attributes of the products and services. Added quality will create value, and greater customer satisfaction, leading to greater industry success.

The company President endorses the PS Engineering, Inc. VCP. The policy covers design, manufacturing, and service activities within the company. The Policy is be reviewed annually by top management, communicated to all employees.

8.2.2 Internal Audit

PS Engineering, Inc. maintains documented procedures in document <u>002-822-0206</u> for internal Quality and Safety System audits. The effectiveness of, and compliance with, procedures that influence quality is determined by an independent audit.

Internal audits are performed on a published scheduled (002-822-0509) that is based on the status and importance of the element audited, or planned in accordance with any customer contractual requirements.

PS Engineering considers that an external audit that provides written reports will also serve the internal audit purpose. Such audits may be completed by regulatory agencies, customers, or contractors.

The results of the internal audits are recorded and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

The internal auditor performs follow-up activities, which verify that corrective action has been implemented and has been effective.

Management reviews the results of these audits, at minimum, on an annual basis.

A tool, in the form of a checklist for the internal evaluations is used to record the audits. Completed evaluation Forms will be in Master File in front office under "Internal Audit."

8.2.3 Monitoring and Measurement of Process

PS Engineering Quality System monitors the manufacturing processes. These methods shall demonstrate the ability of the processes to achieve desired results. When expected results are

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not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

The manufacturing department shall provide a monthly report that is based of recorded defects, collected on a weekly basis.

The data collected includes:

Solder defects, parts defects, including misplaced, damaged or missing, assembly errors, and mechanical defects.

In the event of process nonconformity, PS Engineering;

- a) takes immediate, appropriate action to correct the nonconforming process,
- b) evaluate whether the process nonconformity has resulted in product nonconformity, and
- c) notify the customer, installer, and or FAA if appropriate,
- d) identify and control the nonconforming product in accordance with clause 8.3.

8.2.4 Monitoring and Measuring of Product (§21.137(e))

PS Engineering, Inc. measures and monitors the characteristics of the articles to verify that requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

PS Engineering's policy is to consider the type and extent of monitoring or measurement appropriate to each process in relation to the impact on the conformity to product requirements and on the effectiveness of the quality management system.

All test procedures and instructions are covered as Work Instructions. These are reviewed under the ECO process to ensure that the article will be tested to determine conformity with key characteristics, product requirements and FAA-approved type design data.

The manufacturing and Test Manager is responsible for ensuring that the proper test equipment is available to ensure that produced articles conform to the FAA-approved type design.

Any articles that fail to meet the design data during production process are reworked and retested in accordance with the work instructions, until they meet the design data requirements. PS Engineering will determine if any nonconformity is limited to a specific case, or if other products or processes have been affected.

Final inspection and test reports are maintained by the Quality Control Manager and on file for minimum of five (5) years. Inspection and test records are filed by Lot Number and stored in the Master File for review by FAA.

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Key characteristics have been identified, as the requirements for FAA-TSO or customer requirements, and the other defined attributes, and they are monitored and controlled.

PS Engineering does not use sampling inspection as a means of final article acceptance.

Articles produced by PS Engineering shall not be shipped to the customer until it has been tested, inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required activities.

Evidence of conformity with the acceptance criteria shall be indicated on Passed Inspection Form (PS-17) that is present at delivery to the customer, and maintained on the article specific Final Test Data Sheet(s). Records indicate the person(s) completing the final test and inspection prior to the release of articles to the customer (see 4.2.4).

Article delivery shall not proceed until all the requirements and documentation have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.2.4.1 Inspection Documentation (§21.137(g))

All operations, inspections and tests are covered by work instructions, which include specific measurement requirements for the article acceptance. The work instructions include as necessary:

- a. criteria for acceptance and/or rejection,
- b. the sequence of the measurement and testing operations performed,
- c. a record of the measurement results, and
- d. the specific measurement instruments used and the specific instructions associated with their use.

PS Engineering articles are tested using a final test procedure, which relates to a unit-specific Final Test Data Sheet record, which is kept on file for a minimum of three years.

PS Engineering personnel shall ensure that documents required to accompany the product are present throughout the process, and that the proper inspection tags and documents are protected against loss and deterioration.

8.2.4.2 Inspection Identification and Stamp Control.

PS Engineering operators and inspectors are identified either by their initials, operator number, or through the issuance and control of appropriate marking stamps.

The policy for Stamp Control is contained in document <u>002-098-0206</u>, and provides for:

- **a.** Responsibility for control of stamps.
- **b.** A listing of stamps issued to personnel

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- c. Handling of lost or returned stamps.
- **d.** Periodic check of all stamps to ensure legibility of stamp impressions and possession of stamps by correct personnel. And
- e. The type of stamps to use for the various materials that will require stamp impressions to ensure the material/part is not damaged.

8.3 Control of Nonconforming Articles (§21.137 (h) and §21.137(n))

PS Engineering's nonconforming material policy (002-830-0106) is structured to prevent the delivery of any product to the customer that does not meet its specific requirements.

PS Engineering has procedures in nonconforming material policy (002-830-0106) for identifying, analyzing, and initiating appropriate corrective action for articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements. These procedures include actions to correct deficiencies in the quality system that allowed the quality escape.

For nonconforming units (failed, etc.) in the field, PS Engineering has an FAA Certified Repair Station, which is an independent entity, and has its own Quality Manual and procedures.

See §8.4(b) and §9.1.1 for supplier quality escape processes.

8.3.1 Scrap material procedure (§21.137(h) (2))

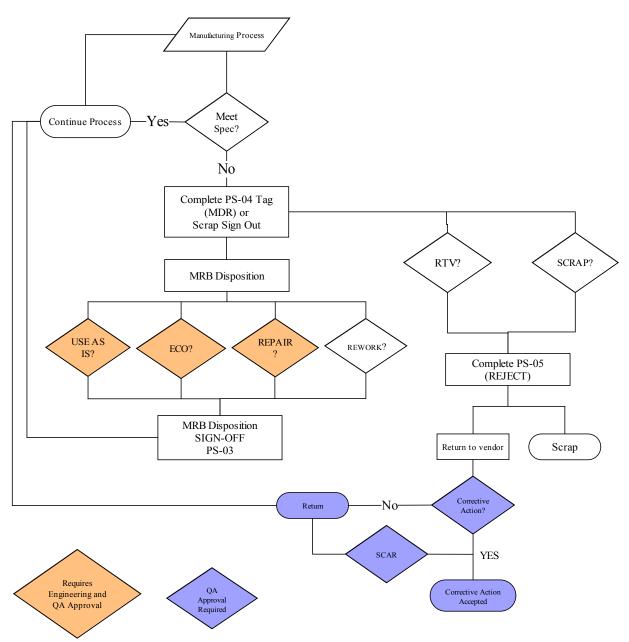
Nonconforming material that cannot be returned to the vendor or otherwise disposed by the Material Review Board must be disposed of in a manner that precludes reuse in any FAA-approved product. Scrapped parts, components, and assembly are disposed by placing in commercial waste disposal. These items can not be reused by any other person because they are damaged beyond use, and the nature of electronic parts and assemblies precludes any future aviation value. Details are contained in the Scrap Material Procedure (<u>002-011-0301</u>).

After scrap determination, the form (PS-03) remains with the item until is it destroyed or rendered unusable.

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Nonconforming Material Process



Types of nonconformance- PS Engineering differentiates the material nonconformance into two categories, Major and Minor.

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- Major- A nonconformance involving safety, performance, interchangeability, reliability, or maintainability of the item or its repair parts, effective use or operation, or weight.
- Minor- a defect that is not likely to reduce materially the usability of the unit or product for its intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the unit and is not in conflict with contract or military specification requirements.

PS Engineering maintains Nonconforming Material Procedure, <u>002-830-0106</u>, which ensures product that does not conform to specific requirements is prevented from unintended use or installation. This control provides for the identification, documentation, evaluation, segregation (when practical), disposition of nonconforming material and internal and external notification.

All non-conforming products are evaluated, re-processed, and subjected to the same manufactured product specifications. All articles which do not meet the FAA-approved design data are reworked and completely retested to ensure that they do meet approved technical data before being issued Form PS-17, Final Inspection tag.

PS Engineering shall have an active Materials Review Board, comprised of the Engineering Manager and the Quality manager.

The Engineering Manager is qualified to make MRB decisions based on the training and experience in electronic engineering, and can make qualified judgment regarding the effects on the type design of nonconforming materials and anticipated rework action.

The Quality Manager is qualified to make MRB decisions based on knowledge and experience of the quality system, inspection process, requirements of the FAA-approved type design data, and supplier qualification.

No non-conforming parts will be accepted for "use as is" or "repair" without written documentation from both quality and engineering departments. No non-conforming parts classified as "Major" will be considered for "Use as is" unless the FAA approves a change to type design.

When product or part is initially found to be nonconforming, the product is identified with tag PS-15. The product is then examined by Operations, Quality, and/or Engineering representatives, as necessary, to determine if the nonconforming product can be reworked, scrapped, returned to supplier, repaired in accordance with standard repair procedures, or referred to the Material Review Board (MRB) for disposition. MRB dispositions may include acceptance without repair and alternate applications, provided the details of MRB disposition actions are recorded.

Re-work material is segregated from other material until the Quality Assurance Manager establishes conformance of material.

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After corrective action, the equipment will be completely re-tested in accordance with Final Inspection/Functional test procedures before placement into inventory.

Quality Control Manager is responsible for monitoring of nonconformance to assure corrective action and follow-up to prevent recurrence. The Engineering Manager is responsible to review nonconforming material to ascertain if any nonconformance or action would constitute a major or minor change in type design.

8.4 Analysis of Data (§21.137(m))

PS Engineering collects and analyzes data from several areas to demonstrate the effectiveness of the quality and safety management systems, and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

This shall includes data from monitoring and measurement and from other relevant sources as described:.

- a. customer satisfaction (see 8.2.1) information from online surveys, customer comment cards on warranty applications, ad other avenues as described in the Voice of the Customer policy (<u>002-723-0700</u>).
- b. conformity to product requirements (see 8.2.4), through the review in process defects and in-service feedback, in accordance with Product Support Policies, (<u>002-006-0000</u>),
- c. characteristics and trends of processes and products including opportunities for preventive action, as recorded in Internal Corrective and Preventative Action, and
- d. monitoring of the performance of PS Engineering suppliers (<u>002-740-1205</u>).
- e. Safety Assessments, including employee reporting and feedback system

8.5 Improvement (§21.137(i))

8.5.1 Continual Improvement

It is PS Engineering, Inc. policy to use this Quality System to continually improve the processes at the company, including the design, manufacturing, sales and support activities.

PS Engineering will monitor the implementation of improvement activities, including lessons learned, problem resolution, and benchmarking of best practices, and shall evaluate the effectiveness of the results.

8.5.2 Corrective Action

PS Engineering maintains procedures (Internal Corrective Action, document 002-013-0704 and Supplier Corrective Action, document 002-852-0206) to initiating and tracking Corrective Action activities to eliminate nonconformance as it is detected, to prevent recurrence. Such activities include:

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- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4),
- f) reviewing the effectiveness of the corrective action taken,
- g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,
- h) specific actions where timely and/or effective corrective actions are not achieved, and
- i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

The main Non Conforming Material Procedure is contained in document 002-830-0106

The Quality Manager reviewed the field repair reports on a regular basis, to look for a trend of problems. In the event that a trend develops, an Internal Corrective Action Request (ICAR) is initiated.

8.5.2.1 Internal Corrective Action Request

The ICAR can be initiated by anyone at PS Engineering. The ICAR form is document 002-013-0704, which is completed by the requestor. This form is tracked and discussed as a regular agenda item at each weekly meeting, and the tracking form is available for all to review.

The ICAR Form tracks the following information:

- a. reviewing nonconformities from various sources, such as production defects and including customer complaints,
- b. determining the causes of nonconformities, through completion of root cause analysis blocks,
- c. evaluating the need for action to ensure that nonconformities do not recur,
- d. determining and implementing action needed, through departmental routing,
- e. records of the results of action taken (see 4.2.4), which includes ECOs or flow down of the corrective action requirement to a supplier through a SCAR, when it is determined that the supplier is responsible for the root cause, and,
- f. reviewing corrective action taken,

Each ICAR has a tracking number, which is shown on an Engineering Change Order, or a Supplier Corrective Action Request (SCAR Document <u>002-852-0206</u>) as appropriate to complete the action.

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If the activities do not result in a correction, the department or supplier is subject to discipline or removal. The timing of the correction is determined during the weekly meeting when the Corrective/Preventative actions are discussed.

8.5.3 Preventative Action

PS Engineering has a process to determine action to eliminate the causes of *potential* nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

PS Engineering uses Risk Management (see § 7.1.2), customer comments, field problems and company design FMEA as inputs to Preventative Action.

The company also implements a Safety Management System (SMS) and uses inputs from Safety Risk Management (SRM) and Safety Assurance (SA) processes as part of the Preventative Action process.

The Preventative Action Procedure is under the same format as the Corrective Action, with the exception that the organization has a quality objective with identifying areas for preventative action analysis, and to write up a ICAR document to record:,

- a. the potential nonconformities and their causes,
- b. evaluating the need for action to prevent occurrence of nonconformities,
- c. determining and implementing action needed,
- d. records of results of action taken (see 4.2.4) and
- e. reviewing the effectiveness of the preventive action taken.

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9.0 FAA Reporting Requirements

Engineering Manager, Quality Control Manager and Manufacturing & Test Manager review Field Service Information, in accordance with Product Support Policy (002-006-0000, or later revision) If the Engineering Manager determines a corrective action is major, FAA is notified and product is held until approval is met.

Major design changes affecting FAA STCs and PMA/TSO authorized commercial products (Ref: 14 CFR Part 21, Subparts K and O, respectively) require; a new type or model number designation, a submittal of substantiating data to and written approval of the FAA, Atlanta Aircraft Certification Office, prior to incorporation into the product.

9.1 Reporting of failures, malfunctions, and defects. (§21.3)

Quality Control Manager shall report specific failures, malfunctions, and defects as required by Title 14 CFR 21.3(c)(1), except where not required by Title 14 CFR 21.3 paragraph (d)(1). Such reports shall be made to the ACO-MIDO within 24 hours after it has determined that the failure, malfunction, or defect required to be reported has occurred. However, a report that is due on a Saturday or a Sunday may be delivered on the following Monday and one that is due on a holiday may be delivered on the next workday.

Any descriptive data and information on FAA-approved design changes resulting from incorporation of Airworthiness Directives or that contribute to the safety of the product will be made available to users of the product.

9.1.1 Quality Escapes (21.137(n))

Quality Escapes are items that have a non-conformity that is discovered after they have left PS Engineering's quality system. PS Engineering handles Quality escapes by identifying, analyzing, and initiating appropriate corrective action in accordance with the non-conforming material procedure, <u>002-830-0106</u>.

9.1.1.1 Recalls

PS Engineering maintains a record of the destination, an authorized PS Engineering Installer, for all articles shipped from the manufacturing and repair facilities. If any nonconforming item needs to be recalled, the installer can be contacted for retrieval of the article.

9.2 Changes to manufacturing facilities (§21.309, §21.609)

PS Engineering shall immediately notify the FAA, in writing, of ANY change to the manufacturing facilities that may affect the airworthiness of the articles produced. PS Engineering shall obtain prior approval of any proposed facility relocation.

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9.3 FAA Inspections and tests (§21.310)

PS Engineering shall allow the FAA to inspect the quality system, facilities, technical data and any FAA-approved articles, and to witness any tests on FAA-approved articles, to determine compliance with the regulations. In addition, any article presented to the FAA for inspections and tests shall have been inspected and tested by PS Engineering, to determine conformity with the applicable data, and shall not be changed after PS Engineering determines conformity and it is presented to the FAA.

9.4 Responsibility for PMA/TSO (§21.316, §21.616)

PS Engineering shall:

(a) Amend this document and he Quality Management Systems as necessary to reflect changes in the organization, and provide these amendments to the FAA;

(b) Maintain this quality system in compliance with the data and procedures approved for the FAA manufacturing authorization;

(c) Ensure that each manufactured article conforms to its approved design, is in a condition for safe operation, and meets the applicable TSO requirements;

(d) Mark the PMA or TSO article for which an approval has been issued. Marking must be in accordance with 14 CFR Part 45;

(e) Identify any portion of the TSO article (e.g., sub-assemblies, component parts, or replacement articles) that leave PS Engineering as FAA approved with the PS Engineering part number and name, trademark, symbol, or other FAA approved identification;

(f) Have access to design data necessary to determine conformity and airworthiness for each article produced under the TSO/PMA authorization. PS Engineering shall retain this data until it no longer manufactures the article. At that time, copies of the data shall be sent to the FAA;

(g) Retain each TSO authorization and PMA documents, and make them available to the FAA upon request; and

(h) Make available to the FAA information regarding all delegation of authority to suppliers.

10.0 Design Data Control (§21.319, §21.619)

For PMA products, submittal of data and approval from the Manager of the Engineering and Manufacturing Inspection District Office.

Minor design changes against STCs and PMA/TSO products do not require prior FAA approval, but copies are forwarded to the appropriate FAA office for review semiannually, or as otherwise directed.

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PS Engineering, Inc. maintains a comprehensive system of documented procedures to identify and control all data that relates to the requirements of the FAA-approved design data and Quality Management.

The document and data approval and issue system provides document storage for access and preservation purposes, and controlled accessibility to document originals.

Procedures in place (detailed in <u>002-423-1005</u>) provide for document review and approval to ensure adequacy by authorized personnel prior to issue, identification of the current revision status of documents, including revision level and date.

In addition, the Manufacturing and Test Manager, General Manager, and Quality Manager are responsible for the removal of invalid and/or obsolete documents from all points of issue and assurance against unintended use.

Work Instructions have document revision and release date information that is also contained on production orders to ensure that the current revision is used for each operation.

When a change is made to product design or technical data, the Engineering Manager completes the engineering change order (ECO) form. Instructions for completing the ECO Form PS-08 are contained in instructions <u>002-099-0001</u>. The form contains routing information that will require review by Quality Manager (including product field support), Manufacturing & Test manger before implementing any change that may affect design data.

Upon receipt of an approved change, the Vice-President of Quality systems will make any required changes to field documentation, such as installation, operation, or service manuals. In addition, any field service notification will be handled through the Vice President of Quality Systems.

Upon receipt of an approved change, the Quality Control Manager reviews and places changed data into Current Master Tech Data File.

If a design change is necessary to correct an unsafe condition of the product, it is considered major. Upon receipt of FAA approval for the change, all affected operators of the product previously certified will be notified by responsible parties as specified in Section 1.

10.1 Master Production Document File

Any authorized user when removing documents from the Master Production File must complete Checkout Form. The checkout form contains the following:

Name of person checking out

Nomenclature or number of document (Rev. No.)

Date checked out

Required return date

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PS Engineering maintains a company-wide document control and part numbering system. Drawings are on file for all components used in production. A PS Engineering part number is assigned to all parts and drawings. The part number consists of a 10-digit number. The first three digits are specific to the type of part (resistor, metal bracket, process). The three center digits identify the item (2N2222 transistor, intercom bezel or final test procedure), while the last four digits provide precise identification of the value, process stage or revision.

The drawings on file typically have a 4-digit suffix of -0000, particularly if they cover multiple component parts. In this way, PS Engineering can identify the part specification at all times, and reference it for any configuration. Any changes to the part drawings are referenced on an Engineering Change Order (ECO) form, PS-08.

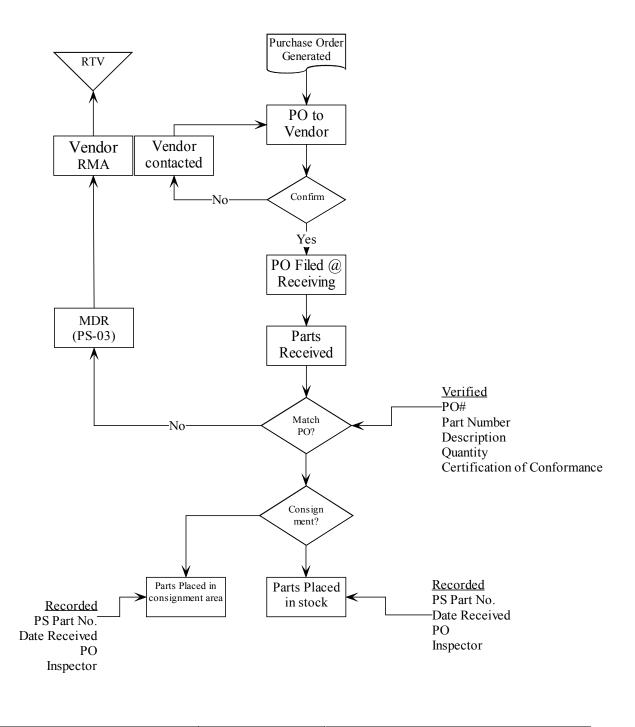
11.0 Programmed Device Quality Assurance

The programmed devices contained in any PS Engineering product are designed and integrated in accordance with a Coded Device Configuration Management Plan (Document 002-710-0000). This document is promulgated in accordance with RTCA DO-178C/DO-254 and details the software life cycle in the product.

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Incoming Material Process



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12.0 Export Airworthiness

PS Engineering, as a global supplier, will export our products where possible. The DMIR on staff will issue an FAA Form 8130-3 for the articles, in accordance with 14 CFR 21.331 and Part 183. The DMIR shall be aware of any special requirements of importing countries listed in AC 21-2, and use the FAA website,

<u>http://www.faa.gov/aircraft/air_cert/international/export_aw_proc/sp_req_import/</u> as a reference to ensure compliance with those requirements.

Copies of the Airworthiness Approval Document 8130-3 are maintained on file for a minimum of five (5) years from date of shipment.

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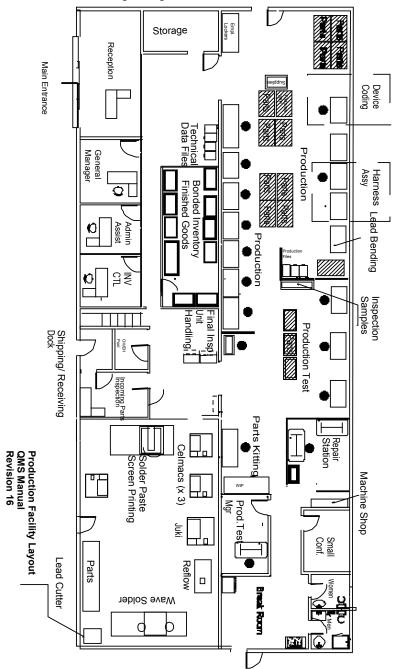
13.0 Manufacturing Maintenance Facility

This is controlled by FAA-Certified repair Station, P43R133O, under the surveillance of the Nashville FSDO.

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14.0 Appendix A – Facility Layout



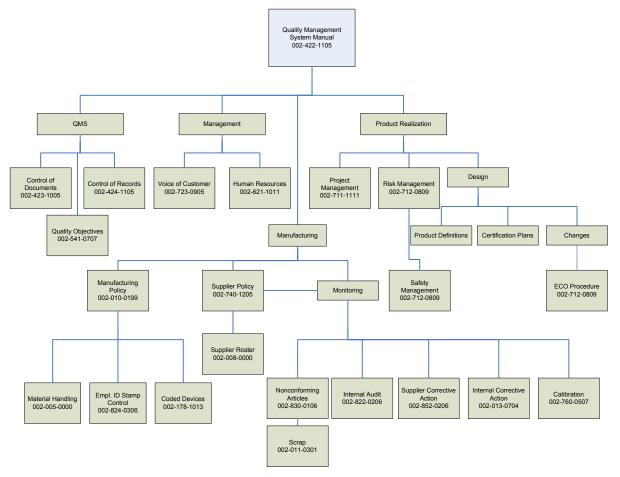
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15.0 Appendix B Document Flow Down

This section removed in Revision 11, as documents are listed in the body of the manual, and revision levels can change without being tracked in the overall quality manual revision.

A list of documents referenced herein, and their relationship to the QMS is shown:



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Revision 16 February 03, 2016 Document: 002-422-1105

16.0 Appendix D, List of Revisions

Revision 2 Dated 30 Nov 1995	5. Revised Entire Manual			
Revision 3 Dated 28 May 1997	Revised Tal Revised Sec in Appendix Revised Sec Special Man Machine) Revised Sec PMA6000 S Revised Sec PMA6000 S Revised Ap Stereo, PMA Revised Ap Serial numb	 Revised Manual Cover Revised Table of Contents Revised Section 4.0 to delete redundant forms exhibited in Appendix C Revised Section 5.0 to number the paragraphs for Special Manufacturing Process (Wave Soldering Machine) Revised Section 6.0 to add PMA6000 Stereo, PMA6000 Stereo/Marker, and PM1000II. Revised Section 8.0 to add PMA6000 Stereo, PMA6000 Stereo/Marker, and PM1000II. Revised Appendix C to add forms for PMA6000 Stereo, PMA6000 Stereo/Marker and PM1000II. Revised Appendix D to add ID tags (Box end label and Serial number) for PMA6000 Stereo, PMA6000 		
Revision 4, Dated 07 August 1	Revised Tal Revised ent Manager to Vice Preside responsibili Revised Sec with new or Revised Sec and amend to organization Added Sect Assurance Revised Sec accordance Revised Sec Manufactur technology Revised Sec	ction 1 to align personnel responsibilities ganizational chart ction 2 to add software design data control, responsibilities in accordance with new		
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Sound Quality. Sound Engineering.

	Revised Section 7 to add software coding device calibration and remove equipment specific intervals Revised Section 8 to remove unit specific test procedures Revised Section 10 to amend responsibilities in accordance with new organizational chart Revised Section 12 to add Software dependent device handling procedures Revised Section 14 to show Vice President of Engineering Revised Section 17 to add Certified Repair Station in lieu of MMF Amended Appendix A in accordance with new organization Amended Appendix B with new facility layout including new equipment
	99 Revised entire manual to bring into MS Word Format
Revised Section 1	Placed approval responsibility with Vice President of Engineering,
	Added Airworthiness determination and FAA reporting
	responsibilities to the Vice President of Engineering
	Added reporting requirements to Vice President of Engineering
	and MRB responsibilities and control of non-conforming material
	to the Quality Assurance Manager's responsibilities. Added ECO coordination responsibilities and FAA Airworthiness
	Determination and Coordination to the Vice President of
	Technical Services responsibilities.
	Added material handling responsibilities to the Manufacturing manager's responsibilities.
	Modified receiving inspection to clarify the responsibilities of
	non-conforming parts.
	Shifted responsibility of received parts logging and inspection
	from receiving to the purchasing department.
Revised Section 2:	Clarify major and minor change and responsibility.
	Clarified Change form contents Minor grammatical corrections
Revised Section 4:	Added reference to specific work instructions
	Clarified responsibility for documentation
	Clarify responsibility for non-conforming material
	Minor grammatical corrections

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ENGINE	ERING ®	Quality Sy	stems	Revision 16
INCORPO		Manu		February 03, 2016
Sound Quality. Sound Eng	ineering.	FAA-Approved TS	-	Document: 002-422-1105
		TAA-Appioved 15		
Revised Section 5	Re	moved references t	o Special Ma	nufacturing Processes, all
			-	ering are within the definition
		normal procedures		
Revised Section 8				tification of final inspector,
	no	ted in QA Manual.		
Revised Section 10	Ad	lded defined Non-C	Conforming M	Iaterial Procedure and
	ref	ferences thereto.		
	Ad	lded defined Suppli	er Survey Fo	rm and references thereto
		arify applications of	-	
	Cl	arify responsibilitie	s of Quality A	Assurance manager regardin
	no	n-conforming parts	segregation	
	Ad	lded reference to we	ork instructio	ons
	Ch	anged "buyer" to "	purchasing d	epartment"
Revised Section 11	Ad	lded Reference to N	Jon-conformi	ing Material Procedure, and
	de	leted the specifics f	rom the QA l	Manual.
	Cl	arify responsibilitie	s of Quality A	Assurance manager regardir
	no	n-conforming parts	segregation	
	Ad	lded reference to we	ork instructio	ons
	Ad	lded responsibilities	s for FAA Co	ontacts in the event of
	un	airworthy condition	IS.	
Revised Section 12	Ad	lded Reference to S	hipping Proc	edure as work instructions
	Ac	lded reference to ot	her work inst	ructions
	Ac	lded reference to No	on Conformi	ng Material procedure
	Ac	lded reference to E0	CO procedure	5
	Ac	lded procedure for l	life-limited m	naterials
Revised Section 13	Ac	lded reference to fin	nal inspectior	n tags
	Ac	lded more compreh	ensive proces	ss for Airworthiness
	de	termination, process	ses and respo	nsibilities for FAA liaison a
	co	ordination of Airwo	orthiness Dire	ectives.
Revised Section 14	Cl	arify responsibilitie	s for tracking	g service difficulties
	Cl	arify responsibilitie	s for FAA Co	ontacts
Revised Section 15	Cl	Clarify the persons responsible for performing audit to give		
		signments to others.		
	Cl	arify internal feedba	ack and respo	onsibility for corrective action
Davision (. Data 101	Norres	$h_{0} = 2001$		
Revision 6: Dated 01	inovem	Uei 2001.		
Revised Cover Revised Section III	Change	d FAA manual halda	r Cony 5 from	Nashville MISO to Atlanta
Reviseu Section III				Production Test Manager.
Revised Section IV		Revision 6 history	nuer, copy /,	r rougenon rest wiallager.
Revised Table of conte				
Revised Section 1				
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Service Calls is deleted, President doesn't have responsibility for routine Section 1.1.4 calls. Section 1.1.5 through 1.1.7 Removed the statement "when necessary." Section 1.2.1 Added text regarding coordination of test procedures with Production Test Manager. Section 1.2.2 Vice President has given SQC (Statistical Process Control) to Manufacturing Manager, but is responsible for reviewing reports and implementing necessary design changes. Section 1.2.6 through 1.2.10, Deleted, moved adjustment of inspection points to OC Manager and Manufacturing manager. SPC has been moved to manufacturing manager. Moved Inspection adjustments to QA manger. Section 1.2.12, Changed text to clarify Major/Minor determination and reporting every 6 Section 1.2.14 months. Deleted, VP Engr. Doesn't handle routine support calls Section 1.2.17 Removed specific form reference. Section 1.2.18 Section 1.2.23 Added, Vice President of Engineering is responsible for training on new designs, products, or processes. Section 1.3.14 Removed specific reference to Appendix C Forms Section 1.3.16 QA Manager trains the inspectors, but manufacturing manager is responsible to see that assembly workers are trained. Section 1.3.17 Removed specific reference to Appendix C Forms Section 1.3.18 Grammar change. Section 1.3.25 Added review of inspection points Section 1.4.6 Manufacturing Manger now responsible for workplace safety. Section 1.4.16 Added service history feedback into manufacturing and quality which had been assigned to Vice President Engineering. Section 1.5.1 and 1.5.2 Clarified that the Manufacturing Manager can delegate task, but not responsibility. Also production test training moved to Production Test Manager. Section 1.5.7 Removed "Periodic" test equipment calibration inspection, surveillance is constant. Manufacturing Manager no longer reports to Vice President of Engineering. Section 1.5.9 Manufacturing Manager does not need to take technical service calls. Section 1.15.11 Section 1.5.16 through 1.5.22, Added Statistical Process Control (SPC) responsibility. Section 1.7.1, Added "Inspection orders" to technical Staff responsibilities Section 1.7.3, Added Production Test Manager Section 1.7.5. Added Production Test Manager Section 1.7.11, Added responsibility for understanding inspection practices. Section 1.8, Changed title from "Purchasing" to "Inventory Control" as a better job title. Section 1.9, Added Production Test Manager, and all duties and responsibilities shown. Revised Section 2.1.8 Removed specific reference to Appendix C tags.

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Revised Section 2.1.9 Removed specific reference to Appendix C forms.

Revised Section 2.1.1 Changed. to show minor changes submitted on 6-month schedule.

FAA-Approved TSOA and PMA

- Revised Section 2.2 Removed specific reference to Appendix C forms.
- Revised Section 3.5, Minor word change, dropped "if necessary."
- Revised Section 6.1 Statistical Quality Control tracking moved to Manufacturing Manager.
- Revised Section 6.2 Removed specific reference to Appendix C forms.
- Revised Section 8.6 Added text to clarify that any non-conforming items are corrected and 100% retested before being issued Final Inspection tags and put into finished goods.
- Revised Section 10.7 Parts inspection increased to 100% of non-surveyed suppliers.
- Revised Section 10.12Clarified the purchase order text and defined surveillance frequency.
- Revised Section 11.10Changed airworthiness notification description
- Revised Appendix A Modified organizational chart to reflect changes in structure covered in Section 1
- Revised Appendix B Layout changed
- Revised Appendix C Removed tags and moved to separate document.
- List of changes in Revision 7 (Oct. 28, 2002):
- Revised Section II Added 14 CFR 21.303(h) FAA-PMA Manufacturing Changed FAA manual holder Copy 4 from Manufacturing Manager to Executive Vice President.
- Revised Section IV Added Revision 7 history
- 6 Updated table of contents
- Revised Section 1.1.3 Defines selection of MRB
- Section 1.1.8, Added Executive Vice President responsibility.
- Section 1.2.1 Change Manufacturing Manager to Executive Vice President
- Section 1.2.2 Change Manufacturing Manager to Quality Manager, with SQC responsibilities
- Section 1.3.14 Added as necessary, because not all calls require Service Documentation, and the QA manager doesn't answer many service calls.
- Sections 1.3.26 thru 1.3.29, SQC responsibility moved to Quality Manager
- Title of Manufacturing Manager changed to Executive Vice President.
- Section 1.6.18 & 19, SQC moved to Quality Manager
- Section 4.0 Changed references from Manufacturing Manager to Executive Vice President.
- Section 6.0 Changed references from Manufacturing Manager to Quality Manger, as responsibility changed.
- Section 7.0 Changed references from Manufacturing Manager to Quality Manger, as responsibility changed.
- Section 8.0 Changed final inspection to include issuance of 8130-3.
- Section 10.5 Changed references from Manufacturing Manager to Executive Vice President.
- Section 10.19 Changed Manufacturing Manager to Executive Vice President.

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Section 11.7 Changed Manufacturing Manager to Executive Vice President.

Section 12.6 Changed Manufacturing Manager to Executive Vice President.

Section 12.10 Changed Manufacturing Manager to Executive Vice President.

Section 13.1 Changed final inspection to include issuance of 8130-3, and FAA-PMA.

Section 14.1 Changed Manufacturing Manager to Executive Vice President.

Section 14.2 Changed Manufacturing Manager to Executive Vice President.

Appendix A Changed title Manufacturing Manager to Executive Vice President.

Appendix B. Modified layout for new office locations.

List of changes Revision 8

Revised table of contents

Moved revision history from front to Appendix

Moved organizational chart from Appendix to Section 1

Revised manual to reflect new company organization, modify subsystem layout for more concise implementation. Clarified document relationships Appendix C.

Added annual QA manual review.

Added FAA designee responsibilities.

Removed Executive Vice President, and added the Manufacturing & Test Manager, revised Duties & responsibilities appropriately.

Added Internal Audit to Duties and responsibilities (Section 1), and changed text to show independence and reporting responsibility.

Added Paragraph 4.15.4, showing traceability of finished goods to customer.

Divided suppliers into priority and non-priority.

Divided nonconformance severity into major and minor.

List of changes in Revision 9

Changed Manual Part number to correlate with SAE AS9100

Renumbered Sections for conformity with SAE AS9100

Revised table of contents.

Changed term "Vendor" to "Supplier for consistency.

Section 7.5.1.2, Record retention extended to 3 years to be consistent with EASA requirements.

Section 8.2.2, Changed internal audit to include acceptance of results of external audits.

Added cross-reference (Appendix E) between this AS9100 Quality System and FAA Order 8100.7B, Appendix 6. Standardized evaluation criteria for PAH and associate facilities

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List of changes in Revision 10

Added approval block for management signoff.

§ 2, Removed manual review tied to scheduled management review.

§ 4.1 Added "quality" to PS Engineering Policy, and reference to Section 5.3.

§ 4.3 Added configuration management standard.

§ 5.4.1 Added reference to the Quality Objective Document

§ 5.5.1.3 (s) clarified training responsibilities

§ 5.5.1.4, Removed technical training and manufacturing responsibility from General Manager (Manufacturing and test Manager responsibility). Removed SPC (none in use).

§ 5.5.1.5 (d) Added training responsibility.

§ 5.6.1 Changed Management Review schedule from specific months to quarters to allow greater scheduling flexibility.

§ 7.5.2 Changed "Monthly" to "periodic defect reporting.

Added §7.5.2.1 "Special Process Standards" to define those in use at PS Engineering.

§8.2.4.1 Added "as necessary" to contents of work instructions.

List of changes in Revision 11

§ 1,	Updated reference to FAA Order 8100.7C, Appendix 5 Grammar corrections
§ 3	Grammar Correction
§ 4.2.1.1	Added electronic distribution option for work instructions
§ 4.2.4	Added "required" to records retained
§ 4.3	Change configuration management reference from EIA-649 to ISO 10007- 3003
§ 5.4.2	Add FAA approval to QAM prior to implementation
§ 5.5.1.3(o)	Change to allow others to add items to MRB, and only Qualit Manager can <i>remove</i> items.
§ 5.5.1.4	Grammar Correction

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§ 5.5.1.7(b)	Removed vague location reference § 5.5.1.7(c) Grammar Correction		
§ 5.5.3.1	Change from email routing to online document collaboration		
§ 6.4	Grammar Correction		
§ 7.2.2	Add document reference		
§ 7.3.5	Add definition of verification		
§ 7.3.6	Add definition of validation		
§ 7.4.2.2	Relocate requirements to supplier policy document		
§ 7.4.3.2.1	Removed "electronic format" as a stamp is used on the packing list, which is retained.		
§ 7.5.1	Document number corrected		
§ 7.5.3	Changed responsibility for packaging review from engineering to quality		
§ 7.6	Add "certificates' to calibration data filed		
§ 8.2.2	Removed form number and changed wording. PS Engineering will use an AS9100 audit form developed by Honeywell until internal form is developed.		
§ 8.3	Removed purchasing and manufacturing as options for MRB Grammar Correction Corrected from number		
§ 10.1	Added heading as logical break in section		
§ 11	Corrected section references, added optical media as storage		
§ 13	Updated facility to show main Finished Goods location.		
§ 14	Deleted Appendix C, as this section is redundant with documents listed in the manual, and revision levels cannot be kept current as sub-tier documents, otherwise included by reference and linked to this document, are revised.		

Summary of Changes in Revision 12

Revised Sections 1 through 8 to align with SAE AS9100C Standard.

Added § 7.1.1, Project Management, § 7.1.2 Risk Management, § 7.1.3 Configuration Management, and relocated Control Of Work Done by Outside Contractors to § 7.1.4.

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Changed *Vice President of Engineering* to **Engineering Manager**, and *Vice President of Quality Systems* to **Quality Manager** to make duties generic to individuals appointed by management, instead of specific titles.

Summary of Changes in Revision 13

Updated manual for changes in 14 CFR Part 21,—*Certification Procedures For Products and Parts,* Amendment(s) published October 16, 2009, in 74 FR 53384.

Table of Contents and subheadings; Added cross reference to sections in 14 CFR Part 21.

§ 1 – Scope: Changed references to relevant sections in 14 CFR Part 21.

§ 4, Quality Management System: Changed revision on AS9100: Revision from B to C

Added §4.1.1 Changes affecting the Quality System (§21.320, §21.620)

§ 7.5.2.1, Special Process Standards: Changed IPC-610: to Revision E

Added new §7.5.3.1 Inspection and Test Status (§21.137(g)) and §7.5.3.2 Marking of articles (§45.15)

§8.3 Control of Nonconforming Articles: Added quality escape information.

Added specific sections: §9.1Reporting of failures, malfunctions, and defects. (§21.3), §9.2 Changes to manufacturing facilities (§21.309, §21.609), and §9.3 FAA Inspections

and tests (§21.310).

Summary of Changes in Revision 14

Updated after internal/customer audit. Added SMS language.

§1 Changed references in Order 8100:7E

§3.1 Added SMS definitions

- §4.1 Added SMS in 4.1 (i) and (j), QMS relationship diagram, Figure 4-1
- §4.2.1 Added references
- §4.2.2 Added references
- §5 Updated organization chart (Fig 5-1) to add support positions
- §5.1 Added SMS to Management Commitment
- §5.2 Added references
- §5.4.1 added SMS to objectives planning

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- \$5.5.1 Removed individual job descriptions, duties and responsibilities to a new document, 002-621-1011, *Human Resources, Competence and Training.*
- §5.5.2 Restructured to match standard, and added (e), SMS reference
- §5.5.3 Added SMS reference
- §5.6.1 Added SMS reference
- §5.6.2 Added SMS reference
- §6.1 Added SMS reference

§6.2.1 Added reference to new document, 002-621-1011, *Human Resources, Competence and Training*

§6.2.1 Added SMS competence reference

§7.1 Added SMS and end of life references

§7.1.1 Relocated some details of Project management to a new procedure, 007-711-1105, *Project Management Policy*.

- §7.2.2 (e) Added SMS reference
- § 7.4.3.1 Added customer access to suppliers as Purchase Order option
- §7.5.2 Added hand soldering as special process
- §8.2.2 Added SMS reference
- §8.4 Added SMS reference
- §8.5.2 Renumbered to conform to Standard, added (g) to match AS9100:C

§ 8.5.3 Added SMS input. Relocated production manager specific task for number of ICAR to the Quality Objectives policy.

§ 11 renamed as *Programmed Devices*, as Software is not always correct term, and modified Obsolesce process

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Summary of Changes in Revision 15

§1.0	Updated references to FAA Order 8120.23, RTCA DO-178C, and included AS9006.		
§3.1	Added definitions for software and safety related activities		
§4.0	Added FAA reference		
§5.4.1	Added software reference		
§5.5.3	Added software reference		
§6.6.2	Added software reference for competence		
§6.3.2.1	Added software considerations in manufacturing capacity		
§6.4	Added software considerations in work environment		
§7.1	Added software life cycle to planning activities		
§7.1.3	Added software configuration management		
§7.2.2	Added software requirements review		
§7.3.1(f)	Added software to planning process		
§7.3.3	Added software to planning process		
§7.3.5	Added software to verification process		
§7.3.6	Added software to validation process		
§7.4.2	Added software considerations in purchasing process		
§7.4.3.1	Added procedure document number		
§7.4.3.2	Added procedure document number		
§7.4.3.4	Added procedure document number		
§7.5.1(a)	Added software production process		
§8.5.2	Added procedure document number		
§9.4	Added section on Responsibility of Production Approval Holders, in accordance with 14 CFR §21.316 and 21.616.		
§11.0	Updated section with reference to DO-178C		
§15.0	Added block diagram for document flow down		
§16.0	Added list of revisions for Revision 15		
§17.0	§17.0 Added Elements 101 – 119 for organizational management and 301 – 309 for software quality assurance		

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Summary of Changes in Revision 16

<u>§5.0:</u>	Amended organizational chart to add accountable manager
<u>§5.5:</u>	Added §5.5.1.1 Accountable manager description and name
<u>§5.5.1.2:</u>	Specified designees for issuing Authorized Release Documents
<u>§6.2.3:</u>	Added delegation information for Accountable Manager
<u>§6.3.2.5:</u>	Added reference to 14 CFR 21 Subparts and 14 CFR Part 145 applicable
<u>§7.2.4(g)</u>	Added supplier escape notification
<u>§7.4.4</u>	Added supplier escape notification
§8.2.2	Added audit schedule publishing
<u>§8.4:</u>	Added reference to in-service feedback and procedure information.
<u>§9.1:</u>	Added subsection 9.1.1 for responses to Quality Escapes and Recalls
§11.0:	Deleted out of date information found in other procedures.
Appendix A:	Facility Layout: revised

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17.0 Appendix E – Cross reference to Order 8120.23 Appendix H Elements

Element	QA Manual	Sub Section	Other Document	Element	QA Manual	Sub Section	Other Document
101	<u>9.4</u>		PMA Supplements	420	<u>7.5.3</u>		
102	<u>9.4</u>			421	7.5.3		
103	9.4			422	7.5.5		
104	No longer appl	icable	-	423			002-005-0000
105	2			424			002-005-0000
106	2			425	<u>7.5.3</u> .1		
107	4.2.4		002-424-1105	426	7.5.5		002-005-0000
108	4.2.4		002-424-1105	427	<u>7.5.3</u> .2		
109	9.2			428	<u>7.5.3</u> .2		
110	<u>9.1</u>			429	No longer applicable		
111	<u>9.1</u>			430	<u>12</u>		
112	<u>9.1</u>	8.2.4		431	<u>12</u>		
113	<u>9.1</u>			432	<u>12</u>		
114	<u>9.0</u>			507	<u>7.6</u>		
115	<u>5.5.1</u>		002-621-1011	508	<u>7.6</u>		
116	<u>8.2.2</u>		002-822-0206	509	<u>7.6</u>		
117	8.2.2		002-822-0206	<u>7.6</u>			
118	<u>8.5</u>			511	<u>8.2.3</u>		
119	<u>8.3</u>		002-830-0106	512	Not applicable		
201	4.2.3		002-423-1005	513	4.2.3		Work Instructions
202	4.2.3		002-423-1005	514	<u>5.5.1</u>	<u>7.5.1 8.2.4</u>	
203			002-423-1005	515	<u>8.2.4</u>		
204	No longer applicable		510	516	Not applicable		
205		7.3.7	-				
206	<u>10</u>			528	Not applicable		
207	<u>10</u>			529		<u>8.3</u>	002-830-0106
208	<u>9.1</u>			530	<u>8.3</u>		002-830-0106
209			Installation Manuals	531	<u>7.3.7</u>		002-830-0106
210	<u>9.1</u>			532	<u>8.4</u>		
211	Not Applicable		8.4	533		<u>8.4</u>	

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Quality Systems

Manual FAA-Approved TSOA and PMA

Element	QA Manual	Sub Section	Other Document	Element	QA Manual	Sub Section	Other Document
301			002-710-0000	534			8.5.2
302	11	<u>1.0.c</u>	002-022-0000	601			002-740-1205
303	11		002-002-0000	602	7.4.2.1		002-740-1205
304	11		002-002-0000	603	<u>1.4.2.1</u>		002-740-1205
305	11		002-002-0000		Not applicab	<u>م</u>	002-140-1200
306	11		002-002-0000		Not applicabl		
307	11		002-178-1013	606	4.2		002-740-1205
308	11		002-178-1013		Not applicab		002 1 10 1200
309	11		002-178-1013		Not applicab		
000			002-170-1010	000			
		610		609	Not applicab	e	
310-315	Not applicable			610	7.4		002-740-1205
401	4.2.3		002-423-1005		7.4		
402	7.5.2			612	7.4	1	002-740-1205
403	7.5.1.2		-	613			002-740-1205
404	6.2.2			614	<u>7.4.2</u> .1		002-740-1205
405	4.2.4			615	<u>7.4.2</u> (g)	1	
406	7.6	<u>7.5.1.3</u>		616	Not applicable		
407	8.2.3			617		7.4.2	
408	No longer applicable		Work Instructions flow requirements		Not applicable		002-740-1205 §4.1.3
409	<u>7.5.1.1</u>			619	Not applicab	e	
410	7.5.3	7.5.1.1					
411	8.2.4.2						
412	<u>6.4</u>		002-005-0000				
413	7.4.3.2		002-005-0000				
414	<u>7.4.3.2</u> .1						
415	<u>7.4.3.3</u>						
416	<u>7.4.3.3</u>						
417	<u>7.4.3.3</u>						
418	Not applicable						
419	Not applicable						

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