

ASTRONAUTICS CORPORATION OF AMERICA'S

AS 9100 and FAA

QUALITY MANUAL

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Revision History

Revision Date	Nature of Change(s)
11/25/2003	Complete rewrite of previous Quality Manual which was based on ISO-9001:1994
09/18/2004	Added Quality V.P to Fig. 5.5.1-1 and changed Management Review interval in 5.6.1.
03/18/2005	Section 5.5.1: added that customers will be notified of top management changes when required by contract. Updated Appendix A to reflect consolidation of QAMs into QDP. Updated the manual and added Appendix B to address Federal Aviation Administration (FAA) requirements.
10/04/2006	Updated portions of the manual to ensure compliance with AS9100 standard
07/13/2009	Revision N -- Updated manual to the AS9100 revision C.
03/18/2010	Revision O -- Updated manual to include ISO9000:2008 and FAA requirements related to the applicable Title 14 Code of Federal Regulations effective April 2010.
03/01/2013	Revision P -- The FAA required a separate quality manual for their approval instead of accepting the AS 9100 manual. As a result, FAA requirements related to the applicable Title 14 Code of Federal Regulation have been deleted from this manual. Also, in this revision, the Appendix A – AS9100 Procedure Matrix was updated, and, to bring this document in line with company policy, the initials “ACA” were replaced by “Astronautics” throughout this document.
03/31/2014	Revision R -- The cover page was updated to the current company format and lines for physical signatures were removed. With FAA Minneapolis Manufacturing Inspection District Office (MIDO) concurrence, the manual was updated to include relevant requirements for an FAA manual based on sections of Title 14 part 21 of the Code of Federal Regulations applicable to Astronautics' current <u>production</u> approvals (TSOAs and PMAs). The manual's organizational chart was updated to reflect a change in the structure of management. Content was also revised to minimize duplications due to overlaps between AS 9100 and FAA requirements, as well as to make minor corrections. In addition, Appendix A was updated to update the manual's second tier documents.
08/31/2016	Revision S -- Appendix A, the “AS9100 Procedure Matrix” listing second tier supporting procedures, was taken out of this document and made a separate document so those procedures can be updated without affecting this manual and its approvals. Also, Figure 2, “Astronautics Organizational Chart” was updated slightly to more accurately reflect the current structure.

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1.0 Scope

Reference: 14 CFR §21.137, §21.307, §21.607, Quality system, and §21.138, §21.308, §21.608 Quality manual

This manual describes the quality system in operation within the design, manufacturing and servicing of search, detection, navigation and guidance aeronautical and nautical vehicle systems and instruments in order to meet the requirements of the customer and applicable statutory and regulatory requirements for which Astronautics Corporation of America (Astronautics) conducts business.

As required in order for Astronautics to hold Parts Manufacturing Approvals (PMAs), Supplemental Type Certificates (STCs), and Technical Standard Order (TSO) authorizations, it must have a Federal Aviation Administration (FAA) *approved* manual. This manual was updated to fulfill the quality manual requirements for an FAA design approval holder (DAH) and a production approval holder (PAH) as outlined in Title 14 of the Code of Federal Regulations (14 CFR), part 21. It is written in the English language, it must be retrievable in a form acceptable to the FAA, and must be approved by the FAA Minneapolis Manufacturing Inspection District Office (MIDO), before use.

This Quality Manual was written to ensure the conformity of FAA approved components and assemblies to FAA approved design data. The PMA and TSOA programs are under the management of Astronautics, with the FAA Liaison acting as the FAA's point of contract. The management recognizes it is fully responsible for the quality of its PMA and TSOA parts, whether manufactured in-house at Astronautics or subcontracted to outside suppliers.

The *quality management system* is organized to comply with the requirements of the current issue of ISO9000:2008 and AS9100 covering design, manufacture, inspection, installation and servicing. Detailed quality system procedures, departmental procedures and inspection instructions, work standards, specification and standard operating procedures *have been written* to support the *quality management system*. *A helpful index of these can be found in the referenced document, QDP 1.3 "Quality Management System Second Tier Documents". QDP 1.3 is organized by AS9100 sections. This manual, complemented by the documents outlined in QDP 1.3, describes the documented quality assurance system called for in 14 CFR Part 21.*

At this writing, the relevant FAA requirements are found in 14 CFR Part 21, Subpart G, §21.137 "Quality system", which is the quality system requirement for both 14 CFR Part 21 Subpart K §21.307 "Quality System" and 14 CFR Part 21 Subpart O §21.607 "Quality System".

Revision of this manual is requested by those management personnel who are responsible for its implementation, with review and approval by the Director of Quality Assurance and the President of Astronautics. A controlled copy is maintained on Astronautics' internal intranet site. Uncontrolled copies may be made available, as needed, to customers and other agencies and will be marked as uncontrolled.

Astronautics must allow the FAA to inspect its quality system, facilities, technical data, and any manufactured articles and witness any tests, including any inspections or tests at a supplier facility, necessary to determine compliance with FAA regulations.

1.1 Application

Reference: 14 CFR §21.137 Quality system, §21.309, and §21.609 Location of or change to manufacturing facilities

This manual applies to all employees whose actions affect product quality. Compliance with the quality manual, procedures, and instructions developed to support it, are mandatory for all functions and personnel of Astronautics. In addition, it is used to inform Astronautics' customers what controls are implemented to assure product and process quality.

Regarding FAA requirements related to the "**Location of or change to manufacturing facilities**", Astronautics primary location of its manufacturing operations of FAA approved articles is 1426 West National Avenue in Milwaukee, Wisconsin, 53204. This building is called "Plant 4". Some quality system operations required by FAA regulations includes such things as design data control and document control, which are part

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of the activities performed in the Headquarters building located at 4115 North Teutonia Avenue, Milwaukee, Wisconsin 53209, as well as in Plant 4. Also, if required, support activities such as environmental stress screening, may also be performed at Astronautics' Plant 3 facility located at 133 East Washington Street, Milwaukee, Wisconsin, 53204.

Facility Addresses and Contact Numbers

Facility	Address	Phone & Facsimile Numbers	E-mail address
All	1426 West National Avenue Milwaukee, Wisconsin 53204	Tel - 414-671-5153 Fax -414-671-0000	Management Representative j.williams@astronautics.com
Plant 4	1426 West National Avenue Milwaukee, Wisconsin 53204	Tel - 414-671-5500 Fax -414-671-0000	Customer Service: customerservice@astronautics.com
Headquarters	4115 North Teutonia Avenue Milwaukee, Wisconsin 53209	Tel - 414-449-4000 Fax -414-447-8231	General Information: busdev@astronautics.com
Plant 3	133 East Washington Street Milwaukee, Wisconsin 53204	Tel - 414-647-9166 Fax -not applicable	General Information: busdev@astronautics.com

Also, in accordance with 14 CFR part 21 requirements related to the "**Location of or change to manufacturing facilities**", Astronautics must obtain FAA approval ***before*** making any changes to the location of any of its manufacturing facilities. Astronautics shall notify the FAA in writing immediately of *any change* to the manufacturing facilities *that may affect the inspection, conformity, or airworthiness of its products or articles* in accordance with 14 CFR part 21 requirements. For this purpose, immediately means the same business day that the Management Representative is made aware of *and has confirmed* such a change, or the following business day if it is after hours at the MIDO Office. Electronic means, such as an e-mail, will be acceptable for this purpose.

1.2 Reference Documents

1.2.1 Astronautics Documents

QDP 1.3 Quality Management System Second Tier Documents

1.2.2 SAE International Documents

AS 9100 Quality Management System - Requirements for Aviation, Space and Defense Organizations

2.0 Quality Policy and Quality Objective

Astronautics' is dedicated to a quality policy which is effectively understood, implemented and maintained at all levels of the organization. This ensures that products are supplied to achieve consistent customer satisfaction. Astronautics quality policy and quality objectives are part of Astronautics orientation and posted on the Astronautics intranet.

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3.0 Process Interface Diagram

The following diagram represents the key processes and their interrelationships within the quality management system.

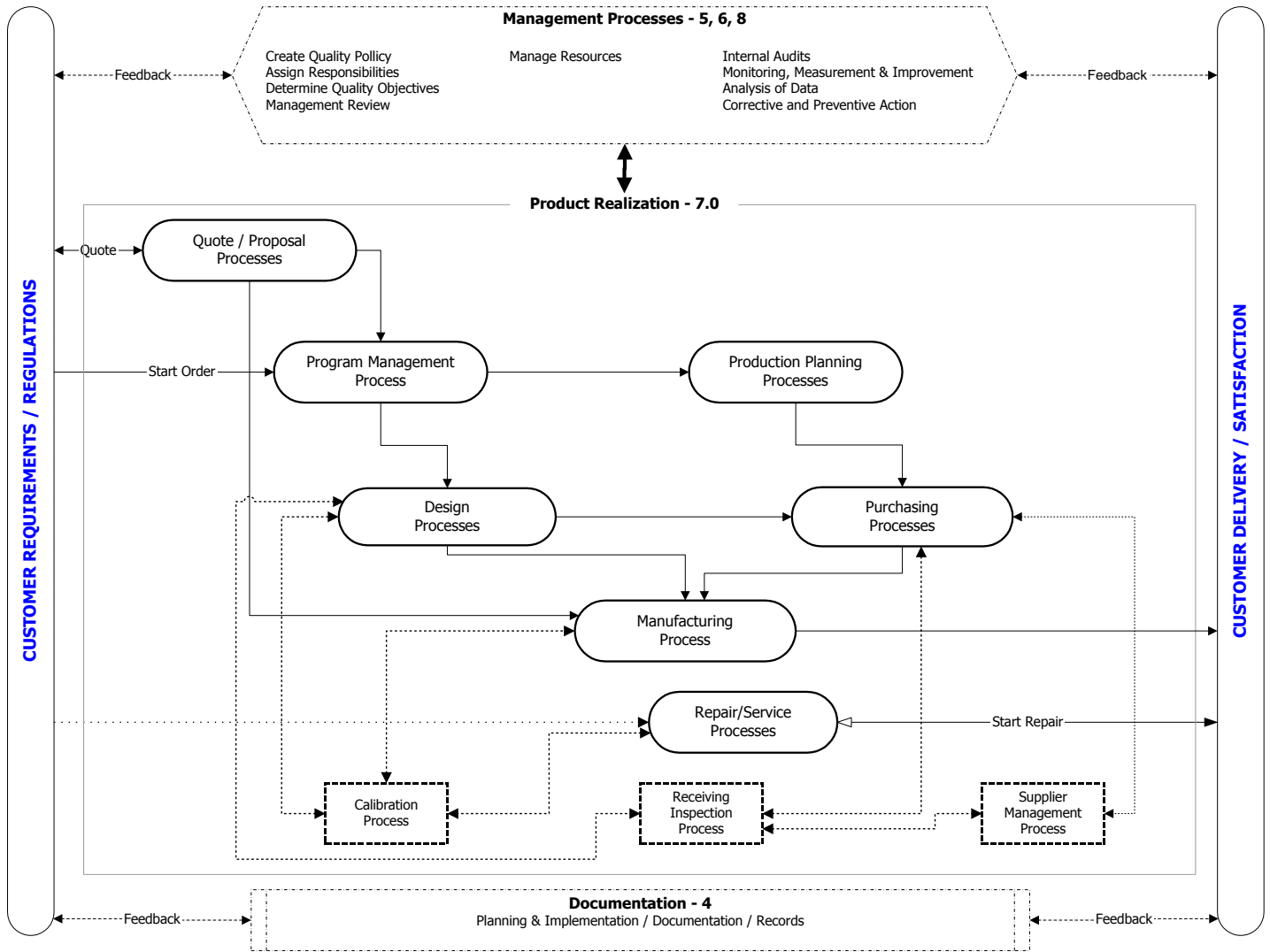


Figure 1 – Process Interface Diagram

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4.0 Quality Management System

Reference: 14 CFR §21.137, §21.307, and §21.607 Quality system

4.1 *General Requirements*

Astronautics Corporation of America (Astronautics) shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. Astronautics' quality management system shall also address customer and applicable statutory and regulatory quality management system requirements

Astronautics shall:

- a) Determine the processes needed for the quality management system and their application throughout Astronautics;
- b) Determine the sequence and interaction of these processes;
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) Monitor; measure where applicable; and analyze these processes; and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by Astronautics in accordance with the requirements of this International Standard.

Where Astronautics chooses to outsource any process that affects product conformity to requirements, Astronautics shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

4.2 *Documentation Requirements*

4.2.1 *General*

The quality management system documentation shall include:

- a) Documented statements of a quality policy and quality objectives;
- b) A quality manual;
- c) Documented procedures and records required by this International Standard; and
- d) Documents, including records, determined by Astronautics to be necessary to ensure the effective planning, operation and control of its processes.

Astronautics shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.

4.2.2 *Quality Manual*

Reference: 14 CFR §21.138, §21.308, and §21.608 Quality manual

As a holder of a PMA and a TSO authorization, Astronautics must provide a manual describing its quality system to the FAA for approval. The manual must be in the English language and retrievable in a form acceptable to the FAA.

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Astronautics shall establish and maintain a quality manual that includes:

- a) The scope of the quality management system; including details of and justification for any exclusions;
- b) Documented procedures established for the quality management system or reference to them; and
- c) A description of the interactions between the processes of the quality management system.

This manual shall be revised as necessary to ensure the current FAA requirements are addressed, and that current procedures are being followed in Astronautics manufacturer's quality system. All proposed manual revisions will be submitted to the Minneapolis MIDO, which is responsible for the production certificate oversight of Astronautics as it relates to FAA approved articles.

Applicable comments resulting from the FAA's review shall be incorporated and an updated preliminary version of the document shall then be resubmitted to the MIDO for review. The proposed revision will not be released for use by the Astronautics quality system until written documentation approving the revision has been received from the managing FAA MIDO.

Proposed updates will be submitted when considered necessary and will be submitted on an "as needed" basis. Whenever revisions to this manual are necessary, the new revision will be identified by a revision letter (e.g. A, B, C, etc.) and a revision date.

4.2.3 Control of Documents

Reference: 14 CFR §21.137(b) Document Control

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

Within Astronautics' quality system are procedures that comply with 14 CFR, Part 21, paragraph §21.137(b) for controlling quality system documents and data, as well as subsequent changes. Those procedures are in place to ensure only current, correct, and approved documents and data are used. A documented procedure shall be established to define the controls needed:

- a) To approve documents for adequacy prior to issue;
- b) To review and update as necessary and re-approve documents;
- c) To ensure that changes and the current revision status of documents are identified.
- d) To ensure that relevant revisions of applicable documents are available at points of use;
- e) To ensure that documents remain legible and readily identifiable;
- f) To ensure that documents of external origin determined by Astronautics to be necessary for the planning and operation of the quality management system are identified and their distribution controlled;
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

Astronautics shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

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Records shall remain legible, readily identifiable and retrievable.

Reference: 14 CFR §21.137(k), Control of Quality Records,.

Astronautics' quality system includes procedures for identifying, storing, protecting, retrieving and retaining quality records. As a production approval holder, Astronautics must retain these records for at least five (5) years for the products and articles manufactured under the approval. At this writing, Astronautics does not make critical components as identified under 14 CFR part 45 under its production approvals, but if such components are manufactured, the records for those must be retained for at least ten (10) years.

5.0 Management Responsibility

5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to Astronautics personnel the importance of meeting customer as well as statutory and regulatory requirements;
- b) Establishing the quality policy;
- c) Ensuring that quality objectives are established;
- d) Conducting management reviews; and
- e) Ensuring the availability of resources.

5.2 Customer Focus

Top Management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

Top Management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.

Astronautics' quality system includes a procedure for notifying a customer, customers, or a regulatory agency when the location of, or a change to, manufacturing facilities occurs that may affect the inspection, conformity, or airworthiness of its product or article.

5.3 Quality Policy

Top management shall ensure that the quality policy:

- a) Is appropriate to the purpose of Astronautics;
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- c) Provides a framework for establishing and reviewing quality objectives;
- d) Is communicated and understood within Astronautics; and
- e) Is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product are established a relevant functions and levels within Astronautics. The quality objectives shall be measureable and consistent with the quality policy.

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5.4.2 Quality Management System Planning

Top management shall ensure that:

- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

Reference: 14 CFR §21.135 Organization

Each holder of an FAA production certificate must provide the FAA with a document describing how its organization will ensure compliance with the provisions of 14 CFR part 21. This manual describes the assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components. Refer to Figure 2 below.

5.5.1 Responsibility and Authority

Top management shall ensure responsibilities and authorities are defined and communicated within Astronautics.

Quality Assurance (QA), which is an independent organization and reports directly to the President of Astronautics, has the organizational freedom and authority to:

- a) Initiate action to prevent the occurrence of any non-conformities related to product, process, and quality systems;
- b) Identify and record any product, process, and/or quality system problems;
- c) Initiate, recommend, or provide solutions through designated channels;
- d) Verify the implementation of solutions; and
- e) Control further processing, delivery, or installation of non-conforming product until the deficiency or unsatisfactory condition has been corrected.

The Astronautics organization is shown in the organizational chart, Figure 2. All departments are independent and are responsible for the quality of the work they perform. Specific responsibilities include initiation action to prevent the occurrence of any nonconformities, identifying and recording any problems relating to the product, process and quality system, initiating, recommending or providing solution through designated channels relating to product, process, and the quality system, also, each department verifies the implementation of solutions and controls further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

Each departmental vice president, director, and manager has the responsibility to ensure that the stated Quality Policy is implemented throughout their respective departments. Each departmental vice president, director or manager must ensure compliance with the paragraphs assigned to them, making sure they are both understood and implemented.

When required by contract or by regulation, customer or regulatory agencies or both will be notified of top management changes or changes in the status of Astronautics' AS9100 certification.

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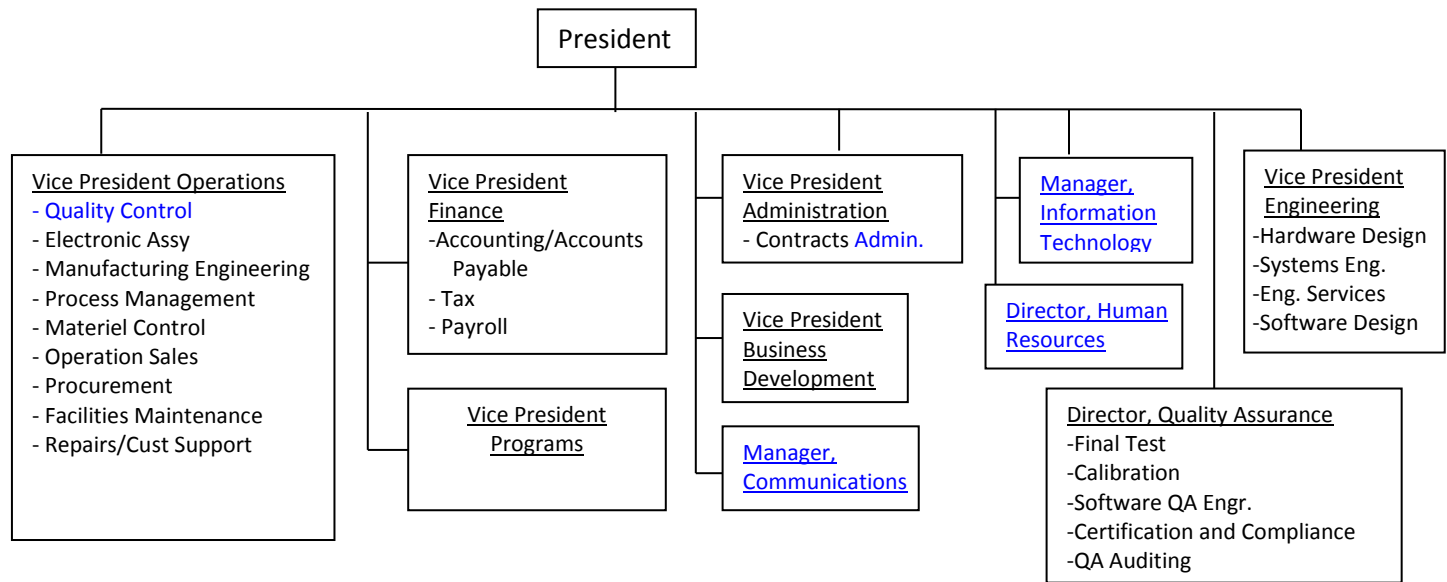


Figure 2 – Astronautics Organizational Chart

5.5.2 Management Representative

Top management shall appoint a member of Astronautics' management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- Ensuring that processes needed for the quality management system are established, implemented and maintained;
- Reporting to top management on the performance of the quality management system and any need for improvement;
- Ensuring the promotion of awareness of customer requirements throughout Astronautics; and
- The organizational freedom and unrestricted access to top management to resolve quality management issues.

5.5.3 Internal Communication

Top management shall ensure that appropriate communication processes are established within Astronautics and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Top management shall review Astronautics' quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review Input

The input to management review shall include information on:

- Results of audits;
- Customer feedback;

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- c) Process performance and product conformity;
- d) Status of preventive and corrective actions;
- e) Follow-up actions from previous management reviews;
- f) Changed that could affect the quality management system; and
- g) Recommendations for improvement.

5.6.3 Review Output

The output from the management review shall include any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes;
- b) Improvement of product related to customer requirements; and
- c) Resource needs.

6.0 Resource Management

6.1 Provision of Resources

Astronautics shall determine and provide the resources needed:

- a) To implement and maintain the quality management system and continually improve its effectiveness; and
- b) To enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Training and Awareness

Astronautics shall:

- a) Determine the necessary competence for personnel performing work affecting conformity to product requirements;
- b) Where applicable, provide training or take other actions to achieve the necessary competence;
- c) Evaluate the effectiveness of the actions taken;
- d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and
- e) Maintain appropriate records of education, training, skills and experience.

6.3 Infrastructure

Astronautics shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) Buildings, workplace and associated utilities;
- b) Process equipment (both hardware and software); and
- c) Supporting services (such as transportation, communication or information systems).

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6.4 Work Environment

Astronautics shall determine and manage the work environment needed to achieve conformity to product requirements.

7.0 Product Realization

7.1 Planning of Product Realization

Reference: 14 CFR §21.137(d) Manufacturing process control, §21.137(e) Inspecting and testing, and Subpart L §21.327 Export airworthiness approvals

As required by 14 CFR, Part 21, Astronautics' quality management system contains procedures for manufacturing process control, inspections and tests, ensuring calibration and control of inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design, and for documenting inspection and test status.

Astronautics may apply for an FAA export airworthiness approval, and to do so, must apply in a form and manner prescribed by the FAA. Unless directed otherwise, an 8130-1 application will be completed, and will be presented to the FAA or FAA designee along with sufficient additional documentation to show compliance.

Astronautics shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization, Astronautics shall determine the following, as appropriate:

- a) Quality objectives and requirements for the product;
- b) The need to establish processes and documents, and to provide resources specific to the product;
- c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements;
- e) Configuration management appropriate to the product; and
- f) Resources to support the use and maintenance of the product.

The output of this planning shall be in a form suitable to Astronautics' method of operations.

7.1.1 Project Management

As appropriate to Astronautics and the product, Astronautics shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

Astronautics shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements that include, as appropriate, the Astronautics and the product:

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

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7.1.3 Configuration Management

Astronautics shall establish, implement and maintain a configuration management process that includes, as appropriate to the product:

- a) Configuration management planning;
- b) Configuration identification;
- c) Change control;
- d) Configuration status accounting; and
- e) Configuration audit.

7.1.4 Control of Work Transfers

Astronautics shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g. from one Astronautics facility to another, from Astronautics to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Astronautics shall determine:

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) Requirements not stated by the customer, but necessary for specified or intended use, where known;
- c) Statutory and regulatory requirement applicable to the product; and
- d) Any additional requirements considered necessary by Astronautics.

7.2.2 Review of Requirements Related to the Product

Astronautics shall review the requirements related to the product. This review shall be conducted prior to Astronautics' 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 defined;
- b) Contract or order requirements differ from those previously expressed are resolved;
- c) Astronautics has the ability to meet the defined requirements;
- d) Special requirements of the product are determined; and
- e) Risks (e.g. new technology, short delivery time frame) have been identified.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by Astronautics prior to acceptance.

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

7.2.3 Customer Communication

Astronautics shall determine and implement effective arrangements for communicating with customers in relation to:

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- a) Product requirements;
- b) Enquiries, contracts or order handling, including amendments; and
- c) Customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

Astronautics shall plan and control the design and development of product.

During the design and development planning, Astronautics shall determine:

- a) The design and development stages;
- 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.

Where appropriate, Astronautics shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.

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.

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

Astronautics shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements shall be determined and records maintained. These inputs shall include:

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

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous, and not in conflict with each other.

7.3.3 Design and Development Outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

- a) Meet the input requirements for design and development;
- b) Provide appropriate information for purchasing, production and service provision;
- c) Contain or reference product acceptance criteria;
- d) Specify the characteristics of the product that are essential for its safe and proper use; and
- e) Specify, as applicable, any critical items, including any key characteristics, and specific action to be taken for these items.

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Astronautics shall define the data required to allow the product to be identified, manufactured, inspected, used, and maintained, including, for example:

- The drawings, part lists and specifications necessary to define the configuration and the design features of the product, and
- The material, process, manufacturing and assembly data needed to ensure conformity of the product.

7.3.4 Design and Development Review

At suitable stages, systemic reviews of design and development shall be performed in accordance with planned arrangements:

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

Participants in such reviews shall include representatives of functions concerned with the design and development stages being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and Development Validation

Design and Development validation shall be performed in accordance with planned arrangement to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Whenever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.6.1 Design and Development Verification and Validation Testing

Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed and documented to ensure and prove the following:

- a) Test plans or specifications identify the product being tested and the resources being used, define test objective 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 of the product is submitted for the test;
- d) The requirements of the test plan and the test procedures are observed; and
- e) The acceptance criteria are met.

7.3.6.2 Design and Development Verification and Validation Documentation

At the completion of design and/or development, Astronautics shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

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7.3.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

Design and development changes shall be controlled in accordance with the configuration management process.

Reference: 14 CFR §21.137(a), Design Data Control

Astronautics' quality system includes procedures for controlling design data and subsequent changes to ensure that only current, correct and approved data is used.

7.4 Purchasing

7.4.1 Purchasing Process

Reference: 14 CFR §21.137(c), Supplier Control, §21.310 (a) Inspections and tests, and §21.316 (h) Responsibility of holder.

Astronautics shall ensure that each supplier-furnished product, part, or article conforms to specified purchase and approved design data requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. Astronautics shall require each supplier to report to Astronautics - the production approval holder - if a part, product, or article has been released from that supplier and has subsequently been found not to conform to the applicable design data.

Astronautics shall be responsible for the conformity of all product purchased from suppliers, including parts and assemblies from sources defined by the customer. Astronautics must make information available to the FAA MIDO regarding all delegation of authority to suppliers.

Astronautics shall evaluate and select suppliers based on their ability to supply product in accordance with Astronautics' requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

Astronautics shall:

- a) Maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family), and will provide the approved supplier list to the FAA MIDO in a method and a manner acceptable to the FAA;
- b) Periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented;
- c) Define the necessary actions to take when dealing with suppliers that do not meet requirements;
- d) Ensure where required that both Astronautics and all suppliers use customer-approved special process sources;
- e) Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status; and
- f) Determine and manage the risk when selecting and using suppliers.

In addition, Astronautics must allow the FAA to inspect its quality system, facilities, technical data, and any manufactured articles and witness any tests, including any inspections or tests at a supplier facility, necessary to determine compliance with the FAA regulations.

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Unless otherwise authorized by the FAA, Astronautics or its supplier may not present any article to the FAA for an inspection or test unless compliance with the following has been shown for that article. Astronautics or its supplier must make all inspections and tests necessary to determine:

- a) that materials conform to the specifications in the design;
- b) that the article conforms to its approved design; and
- c) that the manufacturing processes, construction, and assembly conform to those specified in the design.

No change may be made to an article between the time compliance with these items is shown for that article and the time that the article is presented to the FAA for the inspection or test.

7.4.2 Purchasing Information

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

- a) Requirements for approval of product, procedures, processes and equipment;
- 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 statistical techniques for product acceptance, and related instructions for acceptance by Astronautics, and as applicable critical items including key characteristics;
- f) Requirements for test specimens (e.g. production method, number, storage conditions) for design approval, inspection/verification, investigating or auditing;
- g) Requirements regarding the need for the supplier to:
 - 1. Notify Astronautics of nonconforming product including those products found nonconforming after shipment,
 - 2. Obtain Astronautics approval for nonconforming product disposition,
 - 3. Notify Astronautics of changes in product and/or process, changes of supplier, changes of manufacturing facility location and, where required, obtain Astronautics approval, and
 - 4. Flow-down to the supply chain the applicable requirements including customer requirements;
- h) Records retention requirements; and
- i) Right of access by Astronautics, their 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.

Astronautics shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

Astronautics shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where Astronautics delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

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Where Astronautics or its customer intends to perform verification at the supplier's premises, Astronautics shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service provision

Reference: 14 CFR §21.137(d), Manufacturing Process Control

Astronautics' quality system includes procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.

Astronautics shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- a) The availability of information that describes the characteristics of the product;
- b) The availability of work instructions, as necessary;
- c) The use of suitable equipment;
- d) The availability and use of monitoring and measuring equipment;
- e) The implementation of monitoring and measurement;
- f) The implementation of product release, delivery and post-delivery activities;
- g) Accountability for all product during production (e.g. parts quantities, split orders, nonconforming product);
- h) Evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- i) Provision for the prevention, detection and removal of foreign objects;
- j) Monitoring and control utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements; and
- k) Criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Planning shall consider, as appropriate:

- Establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
- Designing, manufacturing and using tooling to measure variable data,
- Identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and
- Special processes

7.5.1.1 Production Process Verification

Astronautics shall use a representative item from the first production run of a new part of assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes shall be identified.

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Astronautics shall control and document changes affecting processes, production equipment, tools or software programs.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage.

7.5.1.4 Post-Delivery Support

Reference: 14 CFR §21.3 Reporting of failures, malfunctions, and defects, and §21.137(m), In-service Feedback

Astronautics must have procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures must include a process for assisting the design approval holder, whether that is Astronautics or not, to address any in-service problem involving design changes; and to determine if any changes to the Instructions for Continued Airworthiness (ICA) are necessary.

Post-delivery support shall provide as applicable for the:

- a) Collection and analysis of in-service data;
- b) Actions to be taken, including investigation and reporting, when problems are detected after delivery;
- c) Control and updating of technical documentation;
- d) Approval, control and use of repair schemes; and
- e) Controls required for off-site work (e.g. work undertaken by Astronautics at the customer's facilities).

7.5.2 Validation of Process for Production and Service Provision

Astronautics' shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

Astronautics shall establish arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes;
- b) Approval of equipment and qualification of personnel;
- c) Use of specific methods and procedures;
- d) Requirements for records; and
- e) Revalidation.

7.5.3 Identification and Traceability

Reference: 14 CFR §21.137(g), Inspection and Test Status, and 14 CFR §45.15(c), Marking requirements for PMA articles, TSO articles, and Critical parts.

Where appropriate, Astronautics shall identify the product by suitable means throughout product realization.

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Astronautics shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Astronautics shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Astronautics' quality system includes procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design data. When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), Astronautics shall establish appropriate controls for the media.

Where traceability is a requirement, Astronautics shall control the unique identification of the product and maintain records.

For articles manufactured as replacement or modification PMA articles, each PMA article must be permanently and legibly marked with the Astronautics' name, trademark, symbol, or other FAA approved identification and part number; and the letters "FAA-PMA".

For articles manufactured as TSO (or TSOA) articles, each TSO article must be permanently and legibly marked with the Astronautics' name, trademark, symbol, or other FAA approved identification and part number; and -- unless otherwise specified in the applicable TSO -- must be marked with the TSO number or numbers and letter(s) of designation, as well as all markings specifically required by the applicable TSO or TSOs, and either the serial number or the date of manufacture of the article or both.

If an article is manufactured that meets the definition of an FAA "critical part", which a replacement time, inspection interval, or related procedure is specified in the Airworthiness Limitations section of a manufacturer's maintenance manual or Instructions for Continued Airworthiness, that article must be permanently and legibly marked with a serial number (or equivalent) unique to that article in addition to the other applicable requirements.

Note: If *the FAA* finds a part or article made by Astronautics is too small or otherwise impractical to mark with any of the required information, Astronautics must attach that information to the part or its container.

7.5.4 Customer Property

Astronautics shall exercise care with customer property while it is under Astronautics' control or being used by Astronautics. Astronautics shall identify, verify, protect and safeguard customer property provided for use of incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, Astronautics shall report this to the customer and maintain records.

7.5.5 Preservation of Product

Reference: 14 CFR §21.137(j), Handling and Storage

Astronautics shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Preservation of product shall also include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for:

- a) Cleaning;
- b) Prevention, detection and removal of foreign objects;
- c) Special handling for sensitive products;
- d) Marking and labeling including safety warnings;
- e) Shelf life control and stock rotation; and
- f) Special handling for hazardous materials.

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Astronautics' quality system includes procedures to prevent damage and deterioration of each product, part, and article during handling, storage, preservation, and packaging.

7.6 Control of Monitoring and Measuring Equipment

Reference: 14 CFR §21.137(f) Inspection, measuring, and test equipment control

Astronautics shall maintain procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard must be traceable to a standard acceptable to the FAA.

Astronautics shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Astronautics shall maintain a register of the monitoring and measuring equipment and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, checking method, and acceptance criteria.

Astronautics shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Astronautics shall ensure that environmental conditions are suitable for the calibration, inspection, measurement, and testing being carried out.

Where necessary to ensure valid results, measuring equipment shall:

- a) Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) Be adjusted or re-adjusted as necessary;
- c) Have identification in order to determine its calibration status;
- d) Be safeguarded from adjustments that would invalidate the measurement results; and
- e) Be protected from damage and deterioration during handling, maintenance and storage.

Astronautics shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, Astronautics shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Astronautics shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Astronautics' quality system includes procedures to ensure the calibration and control of all inspection, measuring, and test equipment that is used in determining conformity of each product and article to its approved design data.

8.0 Measurement, Analysis and Improvement

8.1 General

Astronautics shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

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- a) To demonstrate conformity to product requirements;
- b) To ensure conformity of the quality management system; and
- c) To continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, Astronautics shall monitor information relating to customer perception as to whether Astronautics has met customer requirements. The methods for obtaining and using this information shall be determined.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Astronautics shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Reference: 14 CFR §21.137(m) In-service feedback

Astronautics' quality system includes a Customer Corrective Action Procedure as a means of processing customer complaints and corrective action requests. The Customer Corrective Action Procedure meets the requirements of 14 CFR Part 21, paragraph §21.137(m).

8.2.2 Internal Audit

Reference: 14 CFR §21.137(l), Internal Audits

Astronautics shall conduct internal audits at planned intervals to determine whether the quality management system:

- Conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by Astronautics; and
- Is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

Astronautics' quality system includes a procedure for planning, conducting, and documenting internal audits ensure compliance with the approved quality system, and reporting results of internal audits to the manager/supervisor responsible for implementing corrective and preventive actions.

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8.2.3 Monitoring and Measurement of Processes

Reference: *14 CFR §21.137 Quality system, §21.137(d) Manufacturing process control, and §21.137(h) Nonconforming product and article control*

Astronautics shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

In the event of process nonconformity, Astronautics shall:

- Take appropriate action to correct the nonconforming process;
- Evaluate whether the process nonconformity has resulted in product nonconformity;
- Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products; and
- Identify and control any nonconforming product.

8.2.4 Monitoring and Measurement of Product

Reference: *14 CFR §21.137(d) Manufacturing process control, §21.137(e) Inspecting and testing, §21.137 (f) Inspection, measuring, and test equipment control, and §21.137(g) Inspection and test status.*

Astronautics shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.

Measurement requirements for product acceptance shall be documented and shall include:

- a) Criteria for acceptance and/or rejection;
- b) Where in the sequence measurement and testing operations are to be performed;
- c) Required records of the measurement results (at a minimum, indication of acceptance or rejection); and
- d) Any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including *key characteristics*, have been identified, Astronautics shall ensure they are controlled and monitored in accordance with the established processes.

When Astronautics uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records shall indicate the person(s) authorizing release of the product for delivery to the customer.

Where required to demonstrate product qualification, Astronautics shall ensure that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Astronautics shall ensure that all documents required to accompany the product are present at delivery.

Astronautics' quality system includes procedures for inspections and tests used to ensure that each product and article conforms to its approved design.

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8.3 Control of Nonconforming Product

Reference: 14 CFR §21.137(h), *Nonconforming product and article control*

Astronautics shall have procedures to ensure that only products or articles that conform to their approved design are installed on an FAA type-certificated product. These procedures must provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming products and articles. Only authorized individuals may make disposition determinations.

Astronautics shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Astronautics' documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable, Astronautics shall deal with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity;
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) By taking action to preclude its original intended use or application;
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

Astronautics' nonconforming product control process shall provide for timely reporting of delivered nonconforming product (a.k.a. articles) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of Astronautics responsible for design.

Astronautics shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Product (part or article) that is dispositioned as scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

Astronautics' quality system provides for the identification, documentation, evaluation, segregation, and disposition of nonconforming products and articles. Only authorized individuals may make disposition determinations.

Reference: 14 CFR §21.137(n), Quality Escapes

Astronautics' quality system includes procedures for identifying, analyzing, and initiating appropriate corrective action for products, parts, or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.

8.4 Analysis of Data

Astronautics shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

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The analysis of data shall provide information related to:

- a) Customer satisfaction;
- b) Conformity to product requirements;
- c) Characteristics and trends of processes and products, including opportunities for preventive action; and
- d) Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

Reference: 14 CFR §21.137(i), Corrective and Preventive Actions

Astronautics shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Astronautics shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

Astronautics has procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the FAA approved design or noncompliance with the approved quality systems, as required by 14 CFR, Part 21.

8.5.2 Corrective Action

Reference: 14 CFR §21.137(i), Corrective and Preventive Actions, and 14 CFR §21.137(m), In-service Feedback (also see this manual's sections 7.5.1.4 "Post-Delivery Support" and 8.2.1 "Customer Satisfaction" above)

Astronautics shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for:

- 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 results of action taken;
- 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

Astronautics' quality system includes procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system.

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8.5.3 Preventive Action

Astronautics shall 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.

A documented procedure shall be established to define requirements for:

- a) Determining 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; and
- e) Reviewing the effectiveness of the preventive action taken.