

ASTRONAUTICS CORPORATION OF AMERICA'S

AS 9100 and FAA

QUALITY MANUAL**Proprietary Notice**

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Revision History

Revision	Date	Nature of Change(s)
J	11/25/2003	Complete rewrite of previous Quality Manual which was based on ISO-9001:1994
K	09/18/2004	Added Quality V.P to Fig. 5.5.1-1 and changed Management Review interval in 5.6.1.
L	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.
M	10/04/2006	Updated portions of the manual to ensure compliance with AS9100 standard
N	07/13/2009	Updated manual to the AS9100 revision C.
O	03/18/2010	Updated manual to include ISO9000:2008 and FAA requirements related to the applicable Title 14 Code of Federal Regulations effective April 2010.
P	03/01/2013	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.
R	03/31/2014	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.
S	08/31/2016	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.
T	09/20/2017	Complete re-write – primarily a reorganization of the document -- to reflect AS9100D and its requirements, and to delineate recent organization changes. Also implemented comments from the FAA's Manufacturing Inspection District Office (MIDO).
U	05/25/2018	Removed Figure 1: Astronautics Corporate Process Map. Placed process map into QDP 1.3 Quality Management System Second Tier Documents. In Figure 2: Astronautics Organizational Chart; updated process names to match process map. Deleted Form 2.3.1-3/3 Process Map from section 3.1 Corrected punctuation and format.
V	08/29/2019	Table 1 – removed e-mail addresses throughout Deleted Figure 2 Astronautics Organizational Chart and placed in QDP 1.3 Deleted throughout: QDP 1.3, Table 1, section 5.1.2 lists the supporting documents that identify how these requirements are implemented Deleted Vice President and Director of in section 5.3 #8 Deleted reference to Repair Station Accountable Manager is section 5.3 #8 Added #9 in section 5.3.
W	01/21/2020	Front Page – PO Box and Teutonia Ave addresses removed and replaced with Oak Creek Section 4.3 #3 Deleted: 4115 North Teutonia Avenue, Milwaukee, Wisconsin 53209 and added: 135 W Forest Hill Ave, Oak Creek, WI 53154, Updated Table 1 -Facility Addresses and Contact Numbers with above information.

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Y	06/28/2022	<p>Revision X was skipped.</p> <p>Table 1 Deleted: 1426 West National Avenue in Milwaukee, Wisconsin, 53204 133 East Washington Street, Milwaukee, Wisconsin, 53204 4.3 Determining the scope of the QMS</p> <p>Deleted</p> <p>1. If required, 133 East Washington Street, Milwaukee, Wisconsin, 53204 may be used for activities such as environmental stress screening and qualification testing.</p> <p>8.4 Control of Externally provided processes, products and services</p> <p>Added:</p> <p>1. The FAA does not issue production PMA/TSOA approvals if the manufacturing facilities (including the location of Astronautics suppliers of complex assemblies) are located outside the United States unless the FAA finds the location of the manufacturer's facilities places no undue burden on the FAA in administering the applicable requirements of Title 49 U.S.C. Astronautics shall implement and follow an undue burden policy as referenced in QDP 1.3.</p>
Z	07/06/2022	Section 5.2.2 Figure 1 Quality Policy has changed

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1.0 Abbreviations and Acronyms

ACP	Astronautics' Company Procedure
CFR	Code of Federal Regulations
CMP	Configuration Management Procedure
DAH	Design Approval Holder
D & D	Design and Development
Eng.	Engineer
ESD	Electrostatic Discharge
ESS	Environmental Stress Screening
FAA	Federal Aviation Administration
FOD	Foreign Object Debris (or Damage)
ICA	Instructions for Continued Airworthiness
MIDO	Manufacturing Inspection District Office
NCP	Nonconforming Product
PAH	Production Approval Holder
PMA	Parts Manufacturing Approval
QA	Quality Assurance
QDP	Quality Department Procedure
QMS	Quality Management System
STC	Supplemental Type Certificate
TSO	Technical Standard Order
TSOA	Technical Standard Order Authorization

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2.0 Introduction

Reference: 14 CFR §21.137, §21.307, §21.607, Quality system, §21.308, §21.608 Quality manual, and §21.310 and §21.610 Inspections and Tests

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.

1. As required in order for Astronautics to hold Parts Manufacturing Approvals (PMAs) and Technical Standard Order (TSO) authorizations, it must have a Federal Aviation Administration (FAA) approved manual. This manual contains 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.
2. This Quality Manual was written to ensure the conformity of FAA approved components and assemblies to FAA approved or accepted 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.
3. The *quality management system* is organized to comply with the requirements of the current issue of ISO9000:2015 and of AS9100D, covering design, manufacture, inspection, installation, and servicing. Detailed quality system procedures, departmental procedures, inspection instructions, work standards, specifications, and standard operating procedures have been written to support the quality management system. Quality Department Procedure (QDP) 1.3 "Quality Management System Second Tier Documents" is organized by AS9100D 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.
4. 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".
5. 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, at a minimum. 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.
6. Astronautics (as a PMA or TSO holder) 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.

3.0 Reference Documents

3.1 Astronautics Documents

QDP 1.3	Quality Management System Second Tier Documents
ACP13034	Accountable Manager for Production

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3.2 SAE International Documents

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

4. Context of Astronautics

4.1 Understanding Astronautics and its Context

1. Astronautics has determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its QMS.
2. Astronautics is monitoring and reviewing information about these external and internal issues.
3. Astronautics external and internal issues are determined, monitored, and reviewed during operation meetings, program management meetings, process improvements, and/or other similar meetings. Risks and action items are maintained and acted upon, as required.

4.2 Understanding the Needs and Expectations of Interested Parties.

1. Due to their effect, or potential effect, on Astronautics' ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Astronautics has determined:
 - a. the interested parties that are relevant to the QMS; and
 - b. the requirements of these interested parties that are relevant to the QMS.
2. Astronautics is monitoring and reviewing the information about these interested parties and their relevant requirements.
3. Interested parties are determined and their associated requirements are reviewed and monitored as identified in QDP 1.3 and as explained in 4.1 of this manual.

4.3 Determining the scope of the QMS

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

1. 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.
2. Regarding FAA requirements related to the "**Location of or change to manufacturing facilities**", Astronautics primary location of its manufacturing operations for FAA approved articles is 135 W Forest Hill Ave, Oak Creek WI. 53154. Astronautics engineering, design data control and document control are also located at the above address.
3. In addition, some engineering efforts are handled by a facility in Phoenix Arizona, at 9201 N. 25th Avenue, Suite 150, Phoenix Arizona 85021.

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Table 1 -Facility Addresses

Facility	Address
Headquarters	135 W Forest Hill Ave, Oak Creek, Wisconsin 53154
Phoenix	9201 N. 25th Ave., Suite 150, Phoenix Arizona 85021

4. 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.
5. Products and Services of Astronautics: Astronautics provides design, manufacturing and service repair of search, detection, navigation, guidance, aeronautical and nautical vehicle systems and instruments.
6. Astronautics has taken into consideration the external and internal issues referenced in section 4.1 and the requirements of relevant interested parties referred to in section 4.2 to determine the scope of our QMS.
7. Applicability: All sections of ISO9000:2015 and AS9100D are applicable to Astronautics QMS. Conformity to the international standard may only be claimed if the requirements determined as not being applicable do not affect Astronautics ability or responsibility to ensure the conformity of its product and services and the enhancement of customer satisfaction.

4.4 Quality Management System and its Processes

4.4.1 QMS and its processes

1. Astronautics has established, implemented, maintains, and is continually improving a QMS, including the processes needed and their interactions, in accordance with the requirements of this international standard. Astronautics' corporate process map is located in QDP 1.3 Quality Management System Second Tier Documents. The process owners are identified on the applicable process maps and are responsible to maintain and continually improve their processes.
2. Astronautics' QMS also addresses customer and applicable statutory and regulatory QMS requirements.
3. The Astronautics Corporate Process map identifies the processes needed for the QMS and their application throughout Astronautics. Astronautics also:
 - a. has determined the inputs required and the outputs expected from these processes and documented this information on the applicable process map;
 - b. has determined the sequence and interaction of these processes and documented this information in the corporate process map located in QDP 1.3. Outsourced processes include non-destructive testing of bare boards.
 - c. has determined and applied the criteria and methods, including monitoring, measurements and related performance indicators needed to ensure the effective operation and control of these processes;
 - d. has determined the resources needed for these processes and the process owner shall ensure their availability;

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- e. has assigned responsibilities and authorities for these processes are identified on the applicable process map or other related documented information;
- f. has addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
- g. has evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results; and
- h. has improved the processes and the QMS.

4.4.2 Support of the QMS and its processes

1. To the extent necessary Astronautics:
 - a. maintains documented information to support the operation of its processes;
 - b. retains documented information to have confidence that the processes are being carried out as planned.
2. Astronautics has established and is maintaining documented information that includes:
 - a. a general description of relevant interested parties, as identified in QDP 1.3;
 - b. The scope of the QMS, including boundaries and applicability as identified in section 4.3 of this manual;
 - c. a description of the processes needed for the QMS and their application throughout Astronautics;
 - d. the sequence and interaction of these processes.;
 - e. assignment of the responsibilities and authorities for these processes as identified on the applicable process map or other related documented information.
3. 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.
4. Astronautics has established and is maintaining a quality manual that includes:
 - a. The scope of the quality management system; including details of and justification for any exclusions as identified in section 4.3 of this manual;
 - b. Documented procedures established for the quality management system or reference to them as identified in QDP 1.3; and
 - c. A description of the interactions between the processes of the quality management system as identified in Figure 1.
5. This manual is 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.
6. 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.
7. 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.

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8. After issuance of an FAA production approval 1) each change to the quality system is subject to review by the FAA; and 2) the holder of the production approval must immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its article (refer to §21.320 and §21.620 "Changes in quality system"). This requirement does not apply to documents that are part of a project or program prior to FAA production approval, nor to documents affecting only non-FAA related production approvals.
9. Changes in design are handled by the applicable Aircraft Certification Office or design approval holder, but changes affecting the quality system are focused on production processes.
10. The control of changes to project or program documentation affecting an FAA production approval is detailed in "EDOP-1001-002 Preparing Change Orders". It is the responsibility of the process owner to ensure changes to processes, in their area of responsibility, do not adversely affect inspection, conformity, or airworthiness of our instruments and articles.
11. In the event a process change may adversely affect inspection, conformity, or airworthiness of an FAA approved article after production approval, the proposed process change must be brought to the attention of the Astronautics Quality Assurance department for guidance prior to implementation. The Quality Assurance department FAA Liaison will contact the FAA for guidance, as needed.
12. Astronautics' second tier documents are identified in QDP 1.3. To ensure the FAA has an adequate view of Astronautics' Quality Management System (QMS), including documents not requiring a review at the time of a change due to possible affects to inspection, conformity, or airworthiness, Astronautics shall provide the FAA with a copy of second-tier documents a minimum of twice a year. The second-tier documents shall be provided to the Minneapolis MIDO on a compact disc or equivalent method acceptable to the FAA.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

1. Top management demonstrates leadership and commitment with the respect to the QMS by:
 - a. taking accountability for the effectiveness of the QMS;
 - b. ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of Astronautics;
 - c. ensuring the integration of the QMS requirements into Astronautics business processes;
 - d. promoting the use of the process approach and risk-based thinking;
 - e. ensuring that the resources needed for the QMS are available;
 - f. communicating the importance of effective QM and of conforming to the QMS requirements;
 - g. ensuring that the QMS achieves its intended results;
 - h. engaging, directing and supporting persons to contribute to the effectiveness of the QMS;
 - i. promoting improvement;
 - j. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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5.1.2 Customer focus

1. Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:
 - a. customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
 - b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
 - c. the focus on enhancing customer satisfaction is maintained;
 - d. product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be achieved.

5.2 Policy

5.2.1 Establishing the quality policy

1. Top management has established, implemented, and is maintaining a quality policy. This quality policy is shown in Figure 1, and:
 - a. is appropriate to the purpose and context of Astronautics and supports its strategic direction;
 - b. provides a framework for setting quality objectives;
 - c. includes a commitment to satisfy applicable requirements;
 - d. includes a commitment to continual improvement of the QMS.

5.2.2 Communicating the quality policy

1. The quality policy is:
 - a. available and maintained as documented information;
 - b. communicated, understood and applied within Astronautics;
 - c. available to relevant interested parties, as appropriate.

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is committed to providing Best-in-Class avionics products, on time, that achieve, or exceed our customers' expectations for quality.

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will foster an environment of continuous improvement in our processes and comply with customer, regulatory, and internal requirements, policies, and procedures.

Figure 1 - Astronautics Quality Policy and Quality Objectives

5.3 Organizational Roles, Responsibilities and Authorities

Reference: 14 CFR §21.305 and 21.605 "Organization"

1. Each holder of a FAA production approval 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 QDP 1.3.
2. Quality Assurance (QA), which is an independent organization and reports directly to the President of Astronautics, has organizational freedom and authority to:
 - a. Initiate action to prevent the occurrence of any non-conformity 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.
3. 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.
4. 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' AS9100D certification.
5. Top Management ensures the responsibilities and authorities for relevant roles are assigned, communicated, and understood within Astronautics. One way to accomplish this is with the organizational chart. The organizational chart is located in QDP 1.3
6. Top management has assigned the responsibility and authority for:
 - a. ensuring the QMS conforms to the requirements of this international standard;
 - b. ensuring the processes are delivering their intended outputs;

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- c. reporting on the performance of the QMS and on the opportunities for improvement in particular to top management;
- d. ensuring the promotion of customer focus throughout Astronautics;
- e. ensuring the integrity of the QMS is maintained when changes to the QMS are planned and implemented; and
- f. Top Management has appointed a specific member of Astronautics' management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements

- 7. The management representative has the organizational freedom and unrestricted access to top management to resolve quality management issues.
- 8. The AS9100D management representative is the Director of Quality Assurance, as identified in the Astronautics Corporation of America's organizational chart.
- 9. The Production Accountable Manager for Astronautics Corporation of America is the Director of Operations, as identified in the Astronautics organizational chart, ACP13034 "Accountable Manager for Production, and as required under 14 CFR Part 21, §§ 21.305 and 21.605.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 Actions to address risks and opportunities

- 1. When planning for the QMS, Astronautics has consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:
 - a. give assurance that the QMS can achieve its intended results;
 - b. enhance desirable effects;
 - c. prevent or reduce undesired effects;
 - d. achieve improvement.

6.1.2 Astronautics has a plan:

- 1. For actions to address these risks and opportunities;
- 2. And how to:
 - a. integrate and implement the actions into its QMS processes (4.4);
 - b. evaluate the effectiveness of these actions.
- 3. To take actions to address risks and opportunities and the plan shall be proportionate to the potential impact on the conformity of product and services..

6.2 Quality Objectives and Planning To Achieve Them

6.2.1 Quality Objectives

- 1. Astronautics has established quality objectives at relevant functions, levels and processes needed for the QMS.
- 2. The quality objectives are:
 - a. consistent with the quality policy;
 - b. measureable;
 - c. take into account applicable requirements;
 - d. relevant to conformity of products and services and to enhancement of customer satisfaction;
 - e. monitored;
 - f. communicated; and
 - g. updated as appropriate.
- 3. Astronautics maintains documented information on the quality objectives.

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6.2.2 Planning For Quality Objectives

1. When planning how to achieve its quality objective, Astronautics has determined:
 - a. what will be done;
 - b. what resources will be required;
 - c. who will be responsible;
 - d. when it will be completed;
 - e. how the results will be evaluated.

6.3 Planning of changes

1. When Astronautics determines the need for changes to the QMS, the changes are carried out in a planned manner (see section 4.4)
2. Astronautics has considered:
 - a. the purpose of the changes and their potential consequences;
 - b. the integrity of the QMS;
 - c. the availability of resources;
 - d. the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

1. Astronautics has determined and provided the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS
2. Astronautics has consider:
 - a. the capabilities of, and constraints on existing internal resources;
 - b. what needs to be obtained from external providers.

7.1.2 People

1. Astronautics has determined and provided the persons necessary for the effective implementation of its QMS and for the operation and control of its processes.

7.1.3 Infrastructure

1. Astronautics has determined, provided and is maintaining the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the operation of processes

1. Astronautics has determined, provided, and is maintaining the environment necessary for the operation of its processes and to achieve conformity of products and services.

7.1.5 Monitoring and Measuring Resources

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

1. 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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7.1.5.1 General

1. Astronautics has determined and is providing the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.
2. Astronautics ensures that the resources provided:
 - a. are suitable for the specific type of monitoring and measurement activities being undertaken;
 - b. are maintained to ensure their continuing fitness for their purpose.
3. Astronautics is retaining appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

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

1. 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. Each calibration standard is traceable to a standard acceptable to the FAA.
2. When measurement traceability is a requirement, or is considered by Astronautics to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:
 - a. 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 for calibration or verification shall be retained as documented information;
 - b. identified in order to determine their status;
 - c. safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
3. Astronautics determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action, as necessary.
4. Astronautics has established, implemented, and is maintaining a process for the recall of monitoring and measurement equipment requiring calibration or verification.
5. Astronautics has a register of the monitoring and measuring equipment. The register includes equipment type, unique identification, location, and the calibration or verification method, frequency and acceptance criteria.
6. Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions.
7. Astronautics will determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action, as necessary.

7.1.6 Organizational Knowledge

1. Astronautics has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.
2. This knowledge is maintained and made available to the extent necessary.

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3. When addressing changing needs, and trends, Astronautics has considered its current knowledge and determined how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

1. Astronautics has:
 - a. determined the necessary competence of persons doing work under it's control that affects the performance and effectiveness of the QMS;
 - b. ensured that these persons are competent on the basis of appropriate education, training, or experience;
 - c. where applicable, Astronautics has taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
 - d. is retaining appropriate documented information as evidence of competence.

7.3 Awareness

1. Astronautics is ensuring that persons doing work under Astronautics control are aware of:
 - a. the quality policy;
 - b. relevant quality objectives;
 - c. their contribution to the effectiveness of the QMS, including the benefit of improved performance;
 - d. the implications of not conforming with the QMS requirements;
 - e. relevant QMS documented information and changes thereto;
 - f. their contribution to product or service conformity;
 - g. their contribution to product safety;
 - h. the importance of ethical behavior.

7.4 Communications

1. Astronautics has determined the internal and external communications relevant to the QMS including:
 - a. what it will communicate;
 - b. when to communicate;
 - c. with whom to communicate;
 - d. how to communicate; and
 - e. who communicates.

7.5 Documented Information

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

1. 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 or accepted documents and data are used.
2. 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

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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.

7.5.1 General

1. Astronautics QMS includes:
 - a. documented information required by this international standard;
 - b. documented information determined by Astronautics as being necessary for the effectiveness of the QMS.

7.5.2 Creating and updating:

1. When creating and updating documented information, Astronautics has ensured appropriate:
 - a. identification and description (title, date, author, or reference number);
 - b. format (language, software version, graphics) and media (paper, electronic);
 - c. review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

Reference: 14 CFR §21.137(b) Document Control

7.5.3.1 Documented Information

1. Documented information required by the QMS and by this International Standards shall be controlled to ensure:
 - a. its availability and suitability for use, where and when it is needed;
 - b. it is adequately protected (from loss of confidentiality, improper use or loss of integrity).

7.5.3.2 Control of Documented Information

1. For the control of documented information, Astronautics has addressed the following activities, as applicable:
 - a. distribution, access, retrieval and use;
 - b. storage and preservation, including preservation of legibility;
 - c. control of changes (version control);
 - d. retention and disposition;
 - e. Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.
2. Documented information of external origin determined by Astronautics to be necessary for the planning and operation of the QMS is identified as appropriate and controlled.
3. Documented information retained as evidence of conformity is protected from unintended alterations.
4. When documented information is managed electronically, data protection processes define protection from loss, unauthorized changes, unintended alteration, corruption, or physical damage.

8 Operations

8.1 Operational planning and Control

Reference: 14 CFR §21.137(d) Manufacturing process control.

1. Astronautics has planned, implemented and is controlling the processes needed to meet the requirements for the provision of products and services, and implement the actions determined in clause 6 by:

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- a. determining the requirements for the products and services;
- b. establishing criteria for:
 - i. the processes;
 - ii. the acceptance of the products and services;
- c. determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;
- d. implementing control of the processes in accordance with the criteria;
- e. determining, maintaining, and retaining documented information to the extent necessary:
 - i. to have confidence that the processes have been carried out as planned;
 - ii. to demonstrate the conformity of products and services to their requirements;
- f. determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
- g. engaging representatives of affected organization functions for operational planning and control;
- h. determining the process and resources to support the use and maintenance of the products and services;
- i. determining the products and services to be obtained from external providers;
- j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

- 2. As appropriate to Astronautics, customer requirements, and products and services, Astronautics is planning and managing product and service provisions in a structured and controlled manner including scheduled events performing in a planned sequence to meet requirements at acceptable risk within resource and schedule constraints.
- 3. The output of this planning is suitable for Astronautics operations.
- 4. Astronautics is controlling planned changes and reviewing the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.
- 5. Astronautics is ensuring that outsourced processes are controlled.
- 6. Astronautics has established, implemented, and is maintaining a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process does ensure that work transfer impacts and risks are managed.

8.1.1 Operational Risk Management

- 1. Astronautics has planned, implemented and is controlling a process for managing operational risks to the achievement of applicable requirements which includes as appropriate to Astronautics and products and services:
 - a. assignment of responsibilities for operational risk management;
 - b. definition of risk assessment criteria (e.g. likelihood, consequences, risk acceptance);
 - c. identification, assessment, and communication of risks throughout operations;
 - d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

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- e. acceptance of risks remaining after implementation of mitigating actions.

8.1.2 Configuration Management

1. Astronautics has planned, implemented, and is controlling a process for configuration management as appropriate to Astronautics and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle.
2. The process:
 - a. controls product identification and traceability to requirements, including the implementation of identified changes;
 - b. ensures that the documented information (e.g., requirements, design, verification, validation, and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety

1. Astronautics has planned, implemented, and is controlling the processes needed to assure product safety during the entire product life cycle, as appropriate to Astronautics and the product.

8.1.4 Prevention of Counterfeit Parts

1. Astronautics has planned, implemented, and is controlling processes appropriate to Astronautics and the product, for the prevention of counterfeit or suspect counterfeit parts use and their inclusion in products delivered to the customer.

8.2 Requirements of products and services

8.2.1 Customer Communication

1. Communication with customers includes:
 - a. providing information relating to products and services;
 - b. handling enquiries, contracts or orders, including changes;
 - c. obtaining customer feedback relating to products and services, including customer complaints;
 - d. handling or controlling customer property;
 - e. establishing specific requirements for contingency actions when relevant.

8.2.2 Determining the requirements of products or services

1. When determining the requirements for the products and services to be offered to customer, Astronautics has ensured that:
 - a. the requirements of the products and services are defined including;
 - i. any applicable statutory and regulatory requirements;
 - ii. those considered necessary by Astronautics;
 - b. Astronautics can meet the claims for the products and services it offers;
 - c. special requirements of the products and services are determined;
 - d. operational risk (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

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8.2.3 Review of the requirements for products and services

8.2.3.1 Review Before Committing

1. Astronautics ensures that it has the ability to meet the requirements for products and services to be offered to customer. Astronautics conducts a review before committing to supply products and services to a customer. That review includes:
 - 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 the specified or intended use, when known;
 - c. requirements specified by Astronautics;
 - d. statutory and regulatory requirements applicable to the products and services;
 - e. contract or order requirements differing from those previously expressed.
2. This review is coordinated with applicable functions of Astronautics.
3. If upon review Astronautics determines that some customer requirements cannot be met or can only partially be met, Astronautics negotiates mutually acceptable requirements with the customer.
4. Astronautics resolves contract or order requirements differing from those previously expressed.
5. The customer requirements are confirmed by Astronautics before acceptance, when the customer does not provide a documented statement of requirements.

8.2.3.2 Retain Documented Information

1. Astronautics retains documented information, as applicable:
 - a. on the results of the review;
 - b. on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

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

1. Astronautics' quality system includes procedures for controlling design data and subsequent changes to ensure that only current, correct and approved or accepted data is used.
2. Astronautics ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements when the requirements for the products and services change.

8.3 Design and Development of products and services

8.3.1 General

1. Astronautics has established, implemented and is maintaining a design and development process that is appropriate to ensure the subsequent provision of productions and services.

8.3.2 Design and Development (D&D) Planning

1. In determining the stages and controls for D&D, Astronautics has considered:
 - a. the nature, duration and complexity of the D&D activities;
 - b. the required process stages, including applicable D&D reviews;

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- c. the required D&D verification and validation activities;
 - d. the responsibilities and authorities involved in the D&D process;
 - e. the internal and external resources needs for the D&D of products and services;
 - f. the need to control interfaces between persons involved in the D&D process;
 - g. the need for involvement of customers and users in the D&D process;
 - h. the requirement for subsequent provision of products and services;
 - i. the level of control expected for the D&D process by customer and other relevant interested parties;
 - j. the documented information needed to demonstrate the D&D requirements have been met.
2. When appropriate, Astronautics has divided the design and development effort into distinct activities and for each activity define the tasks, necessary resources, responsibilities, design content and inputs and outputs.
 3. Design and Development planning considers the ability to provide, verify, test and maintain products and services.

8.3.3 D&D inputs

1. Astronautics has determined the requirements essential for the specific types of products and services to be designed and developed. Astronautics considers:
 - a. functional and performance requirements;
 - b. information derived from previous similar D&D activities;
 - c. statutory and regulatory requirements;
 - d. standards or codes of practice that Astronautics has committed to implement;
 - e. potential consequences of failure due to the nature of the products and services;
 - f. When applicable, the potential consequences of obsolescence (e.g. materials, processes, component, equipment, products).
2. Inputs are adequate for D&D purposes, complete and unambiguous.
3. Conflicting D&D inputs are resolved.
4. Astronautics retains documented information on design and development inputs.

8.3.4 D&D controls

1. Astronautics applies controls to the D&D process to ensure that:
 - a. the results to be achieved are defined;
 - b. reviews are conducted to evaluate the ability of the results of D&D to meet requirements;
 - c. verification activities are conducted to ensure that the D&D outputs meet the D&D input requirements;
 - d. Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
 - e. any necessary actions are taken on problems determined during the reviews or verification and validation activities;

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- f. documented information of these activities is retained;
 - g. progression to the next stage is authorized.
2. Participants in design and development reviews do include representatives of functions concerned with the design and development stages being reviewed.

8.3.4.1 Verification and Validation

1. When tests are necessary for verification and validation, these tests are planned, controlled, reviewed and documented to ensure and prove the following:
 - a. test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;
 - b. test procedures describe the test methods to be used, how to perform the test, and how to record the results;
 - c. the correct configuration of the test item is submitted for the test;
 - d. the requirements of the test plan and the test procedures are observed;
 - e. the acceptance criteria are met.
2. Monitoring and measurement devices used for testing are controlled as defined in clause 7.1.5.
3. At the completion of the design and development, Astronautics ensures that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.

8.3.5 D&D outputs

1. Astronautics ensures that D&D outputs:
 - a. meet the input requirements;
 - b. are adequate for the subsequent processes for the provision of products and services;
 - c. includes or reference monitoring and measuring requirements, as appropriate and acceptance criteria;
 - d. specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision;
 - e. specify, as applicable, any critical items, including key characteristics, and specific actions to be taken for these items;
 - f. are approved by authorized person(s) prior to release;
2. Astronautics defines the data required to allow the product to be identified, manufactured, verified, used and maintained.
3. Astronautics retains documented information for D&D outputs.

8.3.6 D&D Changes

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

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

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2. Astronautics identifies, reviews, and is controlling changes made during or subsequent to the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.
3. Astronautics has implemented a process with criteria for notifying its customer prior to implementation about changes that affect customer requirements.
4. Astronautics retains documented information on:
 - a. design and development changes;
 - b. the results of reviews;
 - c. the authorization of the changes; and
 - d. the action taken to prevent adverse effects.
5. Design and development changes are controlled in accordance with the configuration management process requirements.

8.4 Control of Externally provided processes, products and services

Reference: 14 CFR §21.137(c), Supplier Control, §21.310 (a) Inspections and tests, and §21.316 (h) Responsibility of holder. Undue Burden-14 CFR Sections 21.122(a), 21.139(a), 21.309(a), and 21.609(a).

Astronautics ensures that each supplier-provided product, article, or service conforms to the PAH requirement. Astronautics has established a supplier-reporting process for products, articles, or services that have been released from or provided by the supplier and subsequently found to not conform to the PAH requirements. Astronautics must make information available to the FAA MIDO regarding all delegation of authority to suppliers.

8.4.1 General

2. Astronautics ensures that externally provided processes, products and services conform to requirements.
3. Astronautics is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.
4. Astronautics ensures, when required, that customer-designated or approved external providers, including process sources (e.g. special processes), are used.
5. Astronautics identifies and manages the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.
6. Astronautics requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.
7. The FAA does not issue production PMA/TSOA approvals if the manufacturing facilities (including the location of Astronautics suppliers of complex assemblies) are located outside the United States unless the FAA finds the location of the manufacturer's facilities places no undue burden on the FAA in administering the applicable requirements of Title 49 U.S.C. Astronautics shall implement and follow an undue burden policy as referenced in QDP 1.3.
8. Astronautics determines the controls to be applied to externally provided processes, products and services, when:
 - a. products and services from external providers are intended for incorporation into Astronautics own products and services;

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- b. products and services are provided directly to the customer, by the external providers on behalf of Astronautics;
 - c. a process, or part of a process, is provided by an external provider as a result of a decision by Astronautics.
- 9. Astronautics determines and applies criteria for the evaluation, selection, monitoring or performance and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Astronautics retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 Control over External Providers

- 1. Astronautics:
 - a. has defined the processes, responsibilities, and authorities for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
 - b. Is maintaining a register of its external providers 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;
 - c. Is periodically reviewing external provider performance including process, product and service conformity, and on-time delivery performance;
 - d. has defined the necessary actions to take when dealing with external providers that do not meet requirements;
 - e. has defined the requirements for controlling documented information created by and/or retained by external providers.
- 2. 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.
- 3. 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.
- 4. 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.

8.4.2 Type and extent of control

- 1. Astronautics ensures that externally provided processes, products and services do not adversely affect Astronautics ability to consistently deliver conforming products and services to its customers.
- 2. Astronautics:
 - a. ensures that externally provided processes remain within the control of its QMS;

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- b. has defined both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
 - c. has taken into consideration:
 - i. the potential impact of the externally provided processes, products and services on Astronautics ability to consistently meet customer and applicable statutory and regulatory requirements;
 - ii. the effectiveness of the controls applied by the external provider;
 - iii. the results of the periodic review of external provider performance;
 - d. has determined the verification, or other activities necessary to ensure that the externally provided processes, products and services meet requirements.
3. Verification activities of externally provided processes, products and services are performed according to the risks identified by Astronautics. These shall include inspection or periodic testing, as applicable, when there is a high risk or nonconformities including counterfeit parts.
 4. When externally provided 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.
 5. When Astronautics delegates verification activities to the external provider, the scope and requirements for delegation are defined and a register of delegations maintained. Astronautics periodically monitors the external providers delegated verification activities
 6. When external provider test reports are utilized to verify externally provided products, Astronautics has implemented a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), Astronautics shall implement a process to validate the accuracy of test reports.

8.4.3 Information for external providers

1. Astronautics ensures the adequacy of requirements prior to their communication to the external provider
2. Astronautics communicates to external providers its requirements for:
 - a. the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
 - b. The approval of:
 - i. products and services;
 - ii. methods, processes and equipment;
 - iii. the release of products and services;
 - c. competence, including any required qualification of persons;
 - d. the external providers interactions with Astronautics;
 - e. control and monitoring of external providers performance to be applied by Astronautics;
 - f. verification or validation activities that Astronautics or its customer, intends to perform at the external providers premises;
 - g. design and development control;

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- h. special requirements, critical items or key characteristics;
- i. test, inspection, and verification (including product process verification;
- j. the use of statistical techniques for product acceptance and related instructions for acceptance by Astronautics;
- k. the need to:
 - i. implement a QMS;
 - ii. use customer-designated or approved external providers, including process sources (e.g., special processes);
 - iii. notify Astronautics of nonconforming processes, products or services and obtain approval for their disposition;
 - iv. prevent the use of counterfeit parts;
 - v. notify Astronautics of changes to processes, products or services, including changes of their external providers or location of manufacture, and obtain Astronautics approval;
 - vi. flow-down to external providers applicable requirements including customer requirements;
 - vii. provide test specimens for design approval, inspection/verification, investigation or auditing;
 - viii. retain documented information, including retention periods and disposition requirements;
- l. the right of access by Astronautics, their customer, and regulatory authorities to the applicable areas of the facilities and to the applicable documented information, at any level of the supply chain;
- m. ensuring that persons are aware of:
 - i. their contribution to product or service conformity;
 - ii. their contribution to product safety;
 - iii. -the importance of ethical behavior.

8.5 Production and Service Provisions

8.5.1 Control of production and Service provision

Reference: 14 CFR §21.137(d), Manufacturing Process Control, §21.137(e) Inspecting and testing, and §21.137(g) Inspection and test status.

1. Astronautics' quality system includes procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.
2. Astronautics implements product and service provision under controlled conditions. Controlled conditions shall include, as applicable:
 - a. The availability of documented information that defines:
 - i. the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - ii. the results to be achieved;
 - b. the availability and use of suitable monitoring and measuring resources;

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- c. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and the acceptance criteria for products and services have been met;
 - i. ensuring that documented information for monitoring and measurement activities for product acceptance includes:
 - 1. criteria for acceptance and rejection;
 - 2. where in the sequence verification operations are to be performed;
 - 3. measurement results to be retained (at a minimum an indication of acceptance or rejection);
 - 4. any specific monitoring and measurement equipment required and instructions associated with their use;
 - ii. ensuring that when sampling is used as a means of product acceptance, the sampling plan is 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).
- d. the use of suitable infrastructure and environment for the operation of processes;
- e. the appointment of competent persons including any required qualification;
- f. the validation and periodic revalidation of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g. the implementation of action to prevent human error;
- h. the implementation of release, delivery and post-delivery activities;
- i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
- j. the accountability for all products during production (e.g., part quantities, split orders, nonconforming product);
- k. the control and monitoring of identified critical items including key characteristics in accordance with established processes;
- l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
- m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
- n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or otherwise documented and authorized;
- o. the provision for the prevention, detection, and removal of foreign objects;
- p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements;
- q. the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

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8.5.1.1 Control of Equipment, Tools, and Software Programs

1. Equipment, tools and software programs used to automate, control, monitor or measure production processes are validated prior to final release for production and maintained.
2. Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

8.5.1.2 Validation and Control of Special Processes

1. For processes where the resulting output cannot be verified by subsequent monitoring or measurement, Astronautics has established arrangements for these processes including, as applicable:
 - a. definition of criteria for the review and approval of the processes;
 - b. determination of conditions to maintain the approval;
 - c. approval of facilities and equipment;
 - d. qualification of persons;
 - e. use of specific methods and procedures for implementation and monitoring the processes;
 - f. requirements for documented information to be retained.

8.5.1.3 Production Process Verification

1. Astronautics has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.
2. Astronautics uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity is repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).
3. Astronautics retains documented information on the results of production process verification.

8.5.2 Identification and traceability

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

1. Astronautics identifies 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 establishes appropriate controls for the media.
2. Where traceability is a requirement, Astronautics controls the unique identification of the product and maintain records.
3. 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".
4. 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.

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5. 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.
6. 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. Astronautics uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
8. Astronautics maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.
9. Astronautics identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provisions
10. When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), Astronautics has established controls for the media.
11. Astronautics controls the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external suppliers

1. Astronautics exercises care with property belonging to customers or external providers while it is under Astronautics control or being used by Astronautics.
2. Astronautics identifies, verifies, protects, and safeguards customers or external providers' property provided for use or incorporation into the products and services.
3. When property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, Astronautics reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

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

1. Astronautics' quality system includes procedures to prevent damage and deterioration of each product, part, and article during handling, storage, preservation, and packaging.
2. Astronautics preserves the outputs during production and service provision to the extent necessary to ensure conformity to requirements.
3. Preservation of outputs shall also be included, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:
 - a. cleaning;
 - b. prevention, detection and removal of foreign objects;
 - c. special handling and storage for sensitive products;
 - d. marking and labeling, including safety warnings and cautions;
 - e. shelf life control and stock rotation;
 - f. special handling and storage for hazardous materials.

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8.5.5 Post-Delivery Activities

Reference: 14 C FR §21.3 Reporting of failures, malfunctions, and defects, §21.137(m), In-service Feedback, §21.310 Inspections and Test, §21.303 Application

1. 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.
2. Astronautics meets requirements for post-delivery activities associated with the products and services.
3. Astronautics may not present any article to the FAA for an inspection or test unless compliance to §21.303.
4. In determining the extent of post-delivery activities that are required, Astronautics considers:
 - a. statutory and regulatory requirements;
 - b. the potential undesired consequences associated with its products and services (ESD/FOD/Moisture control, etc);
 - c. the nature, use and intended lifetime of its products and services;
 - d. customer requirements;
 - e. customer feedback;
 - f. collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
 - g. control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
 - h. controls required for work undertaken external to Astronautics (e.g., off-site work);
 - i. products/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).
5. When problems are detected after delivery, Astronautics takes appropriate action including investigation and reporting.

8.5.6 Control of Changes

1. Astronautics reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.
2. Astronautics retains documented information describing the results of the review of changes, the person(s) authorizing the change and any necessary actions arising from the review.
3. Persons authorized to approve production or service provision changes shall be identified.

8.6 Release of Products and Services

Reference: 14 CFR §21.137 (o) Issuing authorized release documents

1. Astronautics has procedure(s) for issuing authorized release documents. These procedures include the selection, appointment, training, management and removal of individuals authorized to issue authorized release documents. These procedures include export compliance to the aircraft.
2. Astronautics implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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3. The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a release authority, and as applicable, the customer
4. Astronautics retains documented information on the release of products and services. The documented information shall include:
 - a. evidence of conformity with the acceptance criteria
 - b. traceability to the person(s) authorizing the release
5. When required to demonstrate product qualification, Astronautics ensures that retained documented information provides evidence that the products and services meet the defined requirements.
6. Astronautics ensures that all documented information required to accompany the products and services are present at delivery.

8.7 Control of Nonconforming Product (NCP) outputs

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

1. Astronautics has 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. These procedures include the requirement to ensure that discarded articles are rendered useless.

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

2. 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.

8.7.1 Control of NCP outputs

1. Astronautics ensures that outputs not conforming to their requirements are identified and controlled to prevent their unintended use or delivery.
2. Astronautics takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services after delivery of products, during or after the provision of services.
3. Astronautics' nonconformity control process is maintained as documented information including the provisions for:
 - a. defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions
 - b. taking actions necessary to contain the effect of the nonconformity on other processes, products, or services.
 - c. timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties.
 - d. defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.
4. Astronautics deals with NCP outputs in one or more of the following ways:

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- a. correction
 - b. segregation, containment, return or suspension of provision of products and services.
 - c. informing the customer
 - d. obtaining authorization for acceptance under concession by a relevant authority and, by the customer.
5. Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:
 - a. after approval by an authorized representative of Astronautics responsible for design or by persons having delegated authority from the design organization.
 - b. after authorization by the customer, if the nonconformity results in a departure from the contract requirements.
 6. Product dispositioned for scrap are conspicuously and permanently marked, or positively controlled, until physically rendered unusable.
 7. Counterfeit, or suspect, counterfeit, parts are controlled to prevent re-entry into the supply chain.
 8. Conformity to the requirements are verified when NCP outputs are corrected.

8.7.2 NCP Documented Information

1. Astronautics retains documented information that:
 - a. describes the nonconformity;
 - b. describes the actions taken;
 - c. describes any concessions obtained;
 - d. identifies the authority deciding the action in respect of the nonconformity.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

Reference: 14 CFR §21.137 Quality system

9.1.1 General

1. Astronautics has determined:
 - a. what needs to be monitored and measured;
 - b. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
 - c. when the monitoring and measuring shall be performed;
 - d. when the results from monitoring and measurement shall be analyzed and evaluated.
2. Astronautics evaluates the performance and the effectiveness of the QMS.
3. Astronautics retains appropriate documented information as evidence of the results.
4. QDP 1.3, Table 1, section 9.1 lists the supporting documents that identify how these requirements are implemented.

9.1.2 Customer Satisfaction

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

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1. 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).
2. Astronautics monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Astronautics has determined the methods for obtaining, monitoring, and reviewing this information.
3. Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. Astronautics has developed and implemented plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

1. Astronautics analyzes and evaluates appropriate data and information arising from monitoring and measurement.
2. The results of analysis are used to evaluate:
 - a. conformity of products and services;
 - b. the degree of customer satisfaction;
 - c. the performance and effectiveness of the QMS
 - d. if planning has been implemented effectively;
 - e. the effectiveness of actions taken to address risk and opportunities;
 - f. the performance of external providers;
 - g. the need for improvements to the QMS.

9.2 Internal audits

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

1. Astronautics conducts internal audits at planned intervals to determine whether the quality management system:
 - a. Conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by Astronautics; and
 - b. Is effectively implemented and maintained.
2. 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.

9.2.1 Internal Audits

1. Astronautics conducts internal audits at planned intervals to provide information on whether the QMS:
 - a. conforms to:
 1. Astronautics own requirements for its QMS
 2. the requirements of this International Standard;
 - b. is effectively implemented and maintained.

9.2.2 Internal Audits

1. Astronautics has:

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- a. planned, established, implemented, and is maintaining an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting Astronautics, and the results of previous audits;
- b. define the audit criteria and scope for each audit;
- c. select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d. ensure that the results of the audits are reported to relevant management;
- e. take appropriate correction and corrective actions without undue delay; and
- f. retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General

Top management reviews Astronautics' QMS, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Astronautics.

9.3.2 Management Review Inputs

1. The management review is planned and carried out taking into consideration:
 - a. the status of actions from previous management reviews;
 - b. changes in external and internal issues that are relevant to the QMS;
 - c. information on the performance and effectiveness of the QMS, including trends in:
 - I. customer satisfaction and feedback from relevant interested parties;
 - II. the extent to which quality objectives have been met;
 - III. process performance and conformity of products and services;
 - IV. nonconformities and corrective actions;
 - V. monitoring and measurement results;
 - VI. audit results;
 - VII. the performance of external providers; and
 - VIII. on-time delivery performance.
 - d. the adequacy of resources;
 - e. the effectiveness of actions taken to address risks and opportunities; and
 - f. opportunities for improvement.

9.3.3 Management Review Outputs

1. The outputs of the management review include decisions and actions related to:
 - a. opportunities for improvement
 - b. any need for changes to the QMS
 - c. resource needs
 - d. risks identified

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2. Astronautics retains documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

1. Astronautics has determined and selected opportunities for improvement and implemented any necessary actions to meet customer requirements and enhance customer satisfaction.
2. These actions include, but are not limited to:
 - a. improving products services to meet requirements as well as to address future needs and expectations;
 - b. correcting, preventing, or reducing undesired effects; and
 - c. improving the performance and effectiveness of the QMS.

10.2 Nonconformity and Corrective Action

Reference: 14 CFR §21.137(i), Corrective and Preventive Actions, and 14 CFR §21.137(m), In-service Feedback

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.

10.2.1 Nonconformity and Corrective Action

1. When a nonconformity occurs, including any arising from complaints, Astronautics will:
 - a. react to the nonconformity and, as applicable:
 - i. take action to control and correct it;
 - ii. deal with the consequences;
 - b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur, or occur elsewhere by:
 - i. reviewing and analyzing the nonconformity;
 - ii. determining the causes of the nonconformity, including, as applicable, those related to human factors;
 - iii. determining if similar nonconformities exist, or could potentially occur;
 - c. implement any action needed;
 - d. review the effectiveness of any corrective action taken;
 - e. update risks and opportunities determined during planning, if necessary;
 - f. make changes to the QMS, if necessary;
 - g. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity; and
 - h. take specific actions when timely and effective corrective actions are not achieved.
2. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

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3. Astronautics maintains documented information that defines the nonconformity and corrective action management processes.

10.2.2 Documented Information

1. Astronautics retains documented information as evidence of:
 - a. the nature of the nonconformities and any subsequent actions taken;
 - b. the results of any corrective action.

10.3 Continual Improvement

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

1. 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.
2. Astronautics continually improves the suitability, adequacy, and effectiveness of the QMS.
3. Astronautics considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.
4. Astronautics monitors the implementation of improvement activities and evaluate the effectiveness of the results.