

## AS9100 / ISO 13485 QUALITY MANUAL

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Approved by:

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This document has been issued to: ASC QMS ERP

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## Introduction

American Standard Circuits (ASC) is located at 475 Industrial Drive in West Chicago, Illinois, and is a Total Solutions Provider for the PCB Industry, capable of delivering advanced technology to virtually every industry sector in quantities ranging from quick prototypes to large volume production.

ASC has developed and implemented a Quality Management System (QMS) to document ASC's best practices, improve customer satisfaction and drive overall organizational improvement. Considerations in the development of the QMS includes organizational environment and associated risks, ASC's needs and objectives, products provided, processes utilized, and the organizational structure.

The Quality Management System addresses the overall operations and production of company product with a focus on satisfying the requirements and expectations of our customers. This manual also discusses the processes required to meet requirements of MIL-PRF-31032, ASC's military certification.

## Purpose

This manual serves as the parent source for all processes and other materials that pertain to ASC's QMS. It also may be used by customers and both internal and external audit teams to gain an overview of the QMS. Unless otherwise stated, this manual establishes the links necessary to:

- Identify, document, implement, maintain and improve the processes needed for the quality system and their application throughout ASC.
- Delineates authorities & responsibilities of personnel responsible for performing within the system.
- Determine sequences and interactions of these processes.
- Determine criteria and methods needed to ensure the operation and controls of these processes are effective.
- Ensure availability of resources and information necessary to support, measure, analyze and monitor these processes.
- Implement actions necessary to achieve planned results and improvements of these processes.

## Quality Management System Scope

**Scope:** The supply of custom rigid and flexible PCB's and bonded RF thermal packages, including interconnect electronic circuits for military, aerospace, medical, communications and other high-tech markets.

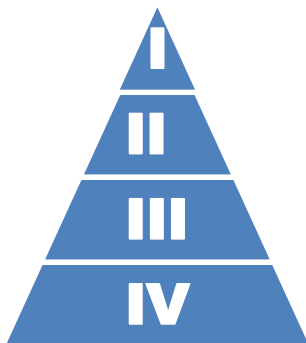
The Quality Management System of ASC is structured to be compliant with the international standard **SAE AS9100 Rev D and ISO 13485 2016** (referred as AS9100, ISO, QMS or equivalent in the documented information) and meets all the applicable requirements of the standard. ASC determines that the following clause is **not applicable** to the products and services provided.

- Clause 8.3 AS9100/7.3 ISO 13485 Design and Development – ASC manufactures custom, build-to-print product per customer supplied designs and specifications, generally supplied in the form of electronic Gerber files/3D CAD models. ASC does not have design ownership and therefore requirements of the referenced clauses have no application for our business.
- Clauses 7.5.3 Installation Activities, 7.5.4 Servicing Activities, 7.5.5 Particular Requirements for Sterile Medical Devices, 7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems, 8.2.2 ISO 13485 Reporting to Regulatory Authorities – ASC does not manufacture medical devices.

ASC is also qualified to the following military certifications:

- MIL-PRF-31032C Amendment 1

## QMS Documentation Structure



<i>Level I</i>
Quality Manual
<i>Level II</i>
Supporting QMS Documents
<i>Level III</i>
Work Instructions
<i>Level IV</i>
Forms & Records

**Documented Information:** Processes flow through the top-level Quality Management System procedures referenced throughout this manual. This means that any sub-processes, forms, checklists, etc. will be subordinate to the top-level documented information.

## Process Approach

ASC has applied the process approach Plan-Do-Check-Act (PDCA) cycle to the quality management system, reference QMS-001A AS9100 Document Structure (PDCA).

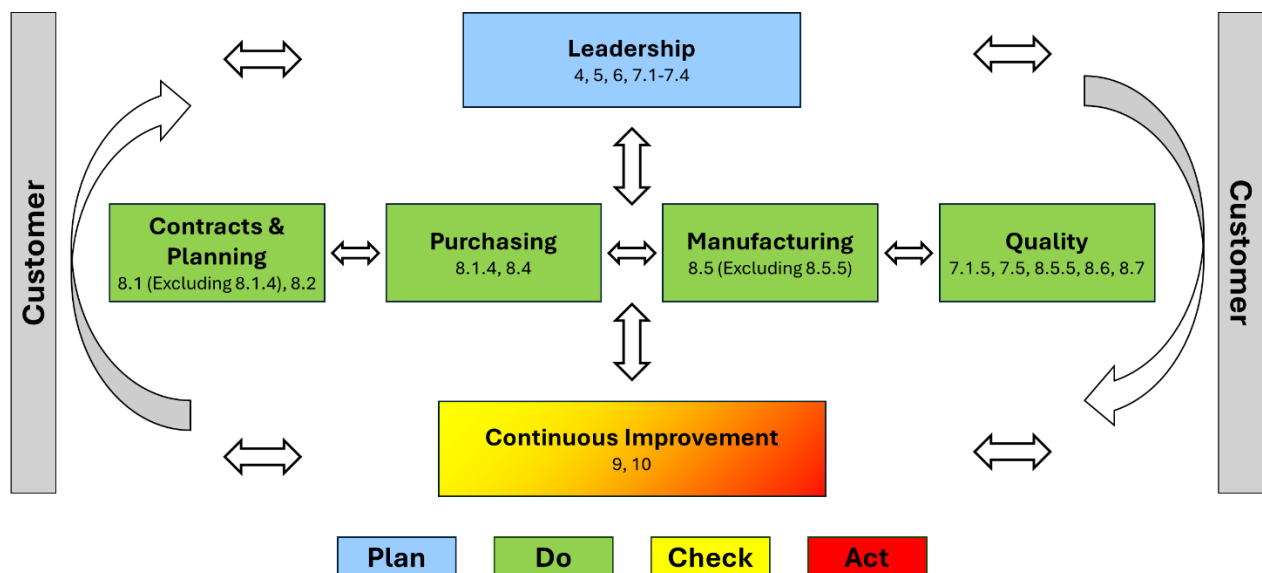
PDCA cycle enables ASC to assure that processes are adequately resourced and managed and that opportunities for improvement are determined and acted on.

## Core Processes

Core Processes are categorized into seven interactive groups:

- **Leadership Process** - 4 Context of the Organization, 5 Leadership, 6 Planning, 7.1 Resources, 7.2 Competence, 7.3 Awareness, 7.4 Communication
- **Contracts and Planning Processes** - 8.1 Operational Planning and Control (Excluding 8.1.4), 8.2 Requirements for products and services
- **Purchasing Process** - 8.4 Control of Externally Provided Processes, Product and Services, 8.1.4 Prevention of Counterfeit Parts
- **Manufacturing Processes** - 8.5 Production and Service Provision (Excluding 8.5.5)
- **Quality** - 7.1.5 Monitoring & Measuring Resources, 7.5 Documented Information, 8.5.5 Post-Delivery Activities, 8.6 Release of Products and Services, 8.7 Control of Non-Conforming Output
- **Continuous Improvement** - 9 Performance Evaluation, 10 Improvement

Note: Clause numbers/names are different for ISO 13485



## Context of the Organization

ASC determines the external and internal issues relevant to the purpose and the strategic direction of the organization, understands the needs and expectations of its interested parties, determines the scope of the quality management system and establishes, implement, maintain, and continually improves the quality management system including the processes needed and their interactions.

Documented Information: 

- QMS-020 Context of the Organization

## Leadership

Top management has been actively involved in implementing the quality management system, and is committed to:

- Demonstrate leadership and commitment with respect to the QMS
- Enhance customer satisfaction by determining and addressing the risks and opportunities
- Establishing and communicating the quality policy
- Assign, communicate organizational roles, responsibilities and authorities
- Appoint management representative with the responsibility and authority for the oversight of the QMS

Documented Information: 

- QMS-013 Leadership
- QMS-013A Quality Policy

## Planning

When planning the quality management systems, ASC addresses the risks and opportunities to give assurance that the quality management system can achieve its intended results, enhance desirable effects, prevent or reduce undesirable effects, and achieve improvement.

Quality objectives are established to support our organization’s efforts in achieving our quality policy and continual improvement of the quality management system and are compatible with the context and strategic direction of the organization.

When ASC determines the need for changes to the quality management system, it considers the purpose for changes and their potential consequences, maintain integrity of the QMS, provide resources, and allocate or reallocate responsibilities and authorities.

Documented Information: 

- Management Review Records

Risk and Opportunities Document: 

- QMS-001C\_Risk & Opportunities Register

QMS Change Documents: 

- DLA-FC120B TRB PF
- Weekly TRB Meetings

## Support

ASC determines the resources needed to establish, implement, maintenance, and continually improve the quality management system, and considers capabilities and constraints of existing resources and what shall be obtained from external providers.

Documented Information: 

- Management Review Records

## Infrastructure and Environment

ASC provides and maintains the necessary infrastructure and environment for the operation of the processes and to achieve the conformity of the product.

Documented Information: 

- QMS-018 Infrastructure

## Measuring and Resources

ASC provides the resources needed to assure valid and reliable results when monitoring and measuring to verify the conformity of the product and services to requirements.

Documented Information: 

- QMS-006 Measurement Traceability

## Organizational Knowledge

ASC determines the knowledge, competence, awareness necessary for the operation of the processes and the conformance of the products and services, including the internal and external communications relevant to the quality management system.

Documented Information: 

- QMS-019 Competence, Awareness & Comm.

## Documented Information

ASC establishes and controls the documented information required by the AS9100 international standard, military specifications, and documented information determined by ASC as being necessary for the effectiveness of the quality management system.

Documented Information: 

- QMS-003 Documented Information

## Operation

Quality planning is required before new products or processes are implemented. During this planning, ASC manages operational risk, configuration and product safety.

Documented Information: 

- QMS-014 Configuration Management

## Requirements for Products and Services

ASC identifies and reviews the requirement for the products, to assure that ASC has the ability to meet customer requirements.

Documented Information: 

- QMS-015 Customer Related Processes

## Control of External Provided Processes, Products and Services

ASC has established a process to assure that externally provided processes, products and services conform to the requirements, and to assure that do not adversely affect ASC' ability to consistently deliver conforming products to our customers. ASC assures that customer requirements are flowed down to the external provider.

Documented Information: 

- QMS-017 Purchasing

## Production and Service Provision

ASC, Inc. plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

- Control of Equipment, Tools and Software Programs
- Validation and Control of Special Processes
- Production Process Verification
- Identification and Traceability
- Property Belonging to Customer and External Providers
- Preservation
- Post Delivery Activities
- Control of Changes
- Release of Products and Services
- FOD Prevention

Documented Information: 

- QMS-016 ID & Traceability
- QMS-009 Engineering Change Request
- ASC Traveler

## Control of Nonconforming Outputs

ASC assures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The term “nonconforming outputs” includes nonconforming product or service generated, received from an external provider, or identified from a customer.

Documented Information: 

- QMS-005 Control of Nonconforming Outputs

## PERFORMANCE EVALUATION

### Monitoring, Measurement, Analysis and Evaluation

ASC has determined what shall be monitored and measured, when and how will be measured, and how the results shall be analyzed and evaluated.

ASC monitors customers’ perception through customer satisfaction questionnaires, satisfaction questioners are not part of what we currently do, and score cards are our soul customer satisfaction indicators, meetings with customers, customer satisfaction score cards.

Documented Information: 

- QMS-006 Measurement Traceability

### Internal Audit

ASC has established and, implements and maintains an internal audit program to assure the quality management system conforms to AS9100 International Standard requirements and to the quality management requirements established internally.

Documented Information: 

- QMS-004 Internal Audit

### Management Review

Management reviews the QMS annually. This review assesses continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes.

Documented Information: 

- Management Review Records

## Improvement, Nonconformity & Corrective Action

ASC determines and selects opportunities to continually improve the effectiveness of the quality management system using the quality policy, quality objectives, audit results, analysis of data, corrective actions and management review, and implements any necessary actions to meet and enhance customer requirements customer satisfaction. Corrective actions are appropriate to the effects of the nonconformities encountered; and actions shall be taken to eliminate the cause of nonconformities in order to correct, prevent and reduce undesired effects.

Documented Information:      • QMS-007 Improvement

## Regulatory Affairs

ASC has established and implemented a regulatory process to demonstrate the company's commitment to regulatory compliance, provide guidance and determine responsibilities for ensuring compliance with all applicable regulatory requirements.

Documented Information:      • QMS-022 Regulatory Affairs

## MIL-PRF 31032 Specific Requirements

Processes required to meet the requirements of MIL-PRF-31032 flow through;

- DLA-120 Quality Manual
- Verification Test and Inspection Methods

ASC has listed test methods which can be performed at ASC and those which will be performed at an approved third-party laboratory per the appropriate procedure.

- Qualification Testing

Documented process flows are established to identify the qualification process for initial certification and subsequent amending of published QML.

- Periodic Conformance Inspection

Periodic conformance testing is documented in the DLA QMS, which outlines the monitoring of quality and the reliability of the technology and processes at ASC.

- Test Optimization

Test optimization, where applicable, are appropriately documented.

## Revision History

<b>Revision</b>	<b>Date</b>	<b>Description of change(s)</b>
6	1/3/23	Updated for adding ISO 13485 Requirement in existing QMS-001
7	2/8/24	Added Revision History
8	7/9/24	Added Document in Planning Section
9	8/26/2025	Updated core process interaction diagram to correct clause responsibility per AS9100 audit finding.
10	4/3/2026	Updated to new logo. Reviewed for MR Q1 2026, no changes.