AS 9100

IN A

SMALL

BUSINESS

By Core Business Solutions
Co-Founder and President

Welcome! This guide is designed to give you a high-level overview of the AS9100 process and to briefly explain how Core Business Solutions can help you achieve AS9100 compliance.

Top management needs to demonstrate leadership and commitment to the QMS and ensure its integration into the company's business processes which AS 9100 can help your company do.

SCOTT
DAWSON

AVIATION
SPACE
DEFENSE

In the aviation, space and defense industries, quality and product safety are paramount. The major original equipment manufacturers (OEMs) work with a global supply-chain made up of manufacturers and distributors which includes thousands of small businesses. To ensure quality and safety of the millions of components, assemblies, software, etc. that make up the aircraft, vehicles and other OEM systems used in the field, the AS9100 standard has been developed.

Your company may be required to become AS9100 certified to meet a current or future customer contract. If that is the case, there are several steps needed to complete and maintain the certification. Certification is issued by a third-party auditor following a certification audit. For you to be successful, everyone in your company will need to be involved. This whitepaper explains the basics of what is needed to get certified, including steps to get started.

AN INTRODUCTION TO
AS9100

What is AS9100?

It is a global quality standard that defines minimum requirements for a company's processes to enhance safety of its products and performance for its customers. AS9100 is written for companies in the aviation, space and defense industries. It is based on the ISO 9001 standard used in other industries.

Who Wrote it?

An industry group called "IAQG" (International Aerospace Quality Group) with representatives from aviation, space and defense industries.

Who Uses it?

Manufacturing companies throughout the aviation, space and defense industries from the major OEMs throughout all levels of the supply-chain. (Note: a separate standard – AS9120 – is available for distributors).

What Are the Benefits?

Being compliant to the standard helps a company to be efficient and competitive. Being AS9100 certified allows a company to qualify for contracts that include this requirement.

Who Uses the Certificate?

An independent, third-party auditor called a "Registrar" (or certification body) conducts an initial certification audit to confirm your company is compliant to the AS9100 requirements. Following a successful audit, the Registrar issues the AS9100 certificate. To maintain certification, annual surveillance audits are conducted to confirm continued compliance and ongoing improvement.

Who Needs to be Involved?

All managers and employees must participate in preparing for AS9100 certification and maintaining the quality management system. It is everyone's job to ensure your customer receives the highest quality.

Is This the Only Certificate?

No, there are other standards available for certification. ISO 9001 is similar to AS9100 but not specifically designed for aviation, space and defense industries. AS9120 is the quality standard for parts distributors. Other common standards include ISO 14001 (environmental), ISO 45001 (health and safety) and ISO 27001 (information security).

What Requirements are Included?

Like ISO 9001 and AS9120, AS9100 requirements are organized into the following sections:

- Context of the Organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

Together, these requirements are called the Quality Management System (QMS) that are described in company documentation such as a quality manual, procedures, work instructions, records and other information. An effective QMS is one where a company follows its processes and documentation on a day-to-day basis and continually improves to perform better for its customers.

Going Beyond ISO 9001

Key additional requirements in AS9100:

1. Project/Program management
2. Risk management
3. Configuration management
4. Work transfers
5. Prevention and detection of counterfeit parts
6. Product safety
7. Key performance indicators (KPIs)
8. Planning of product life cycle
9. Control of critical items
10. Control of external processes and providers
11. Monitoring of external providers
12. Prevention and detection of foreign objects (FOD)

PROCESS
APPROACH

An understanding of the AS9100 standard starts with the process approach which refers to processes and activities in your company working together to deliver quality to your customers.

WHAT'S REQUIRED?

"The organization shall define key processes, monitor process performance and make improvements when results do not meet targets."
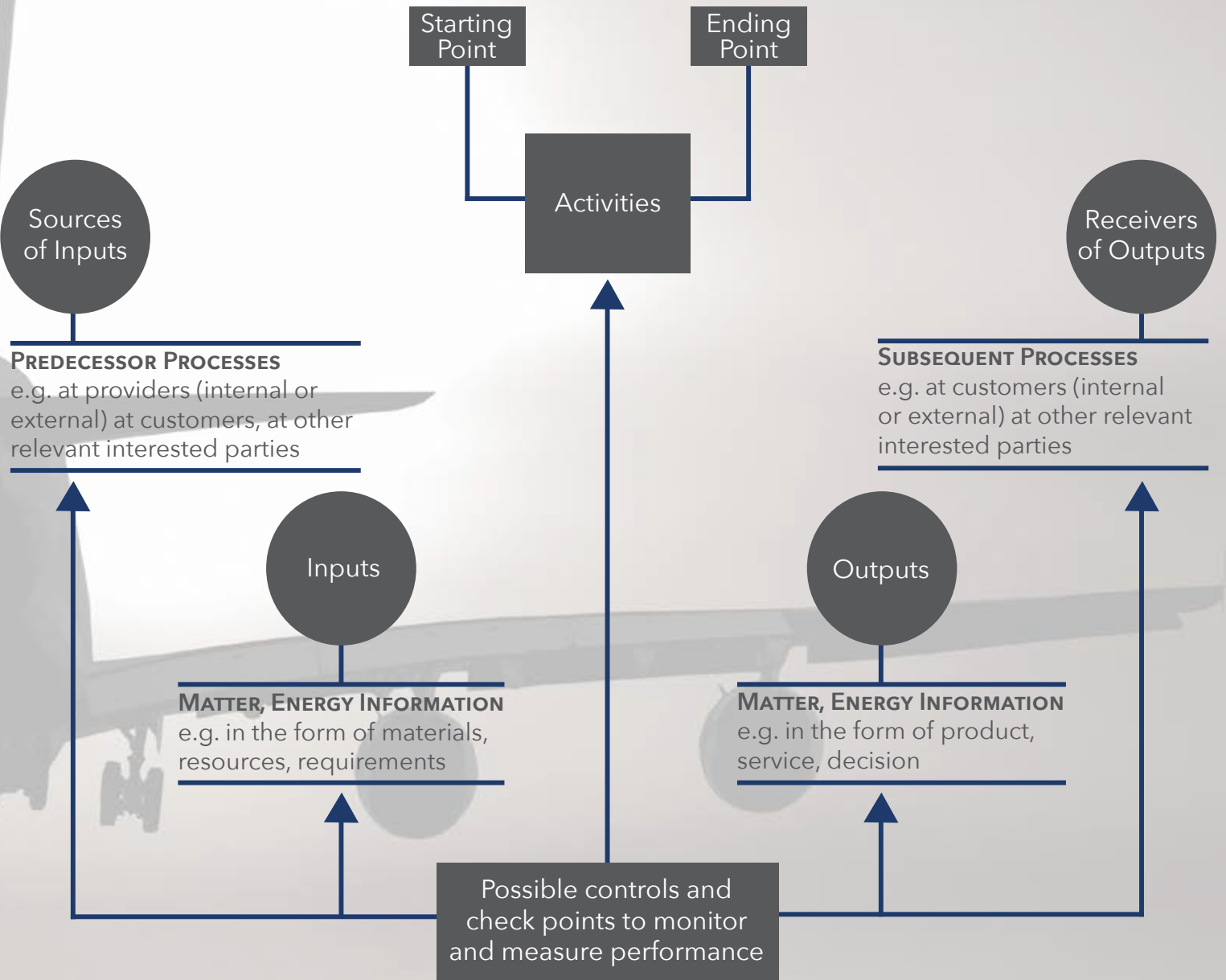
THINGS TO REMEMBER

• A process is a set of work steps that transform parts, materials or information (inputs) into a more complete form such as assemblies, products, reports, etc. with added value (outputs) based on specific requirements.
• The output of one process can be the input to another process. All of your company's processes interact and affect the final result.
• Each process is assigned a process owner who is responsible to monitor performance (objectives and KPIs) and lead improvement of the process.

AS9100D REQUIREMENTS

0.3 Process Approach
4.4 Quality Management System and Its Processes

Starting
Point

Ending
Point

Activities

Sources
of Inputs

Receivers
of Outputs

PREDECESSOR PROCESSES
e.g. at providers (internal or
external) at customers, at other
relevant interested parties

SUBSEQUENT PROCESSES
e.g. at customers (internal
or external) at other relevant
interested parties

Inputs

Outputs

MATTER, ENERGY INFORMATION
e.g. in the form of materials,
resources, requirements

MATTER, ENERGY INFORMATION
e.g. in the form of product,
service, decision

Possible controls and
check points to monitor
and measure performance

RISK
MANAGEMENT

The priorities for control and improvement of your processes and QMS should be based on risk-based thinking. This approach creates a proactive culture that seeks to prevent problems and maximize improvements by setting priorities. In your company's operations, a formal risk management process is required by AS9100.

WHAT'S REQUIRED?

"Risks and opportunities need to be identified and addressed to achieve targets you define and improve overall results. This helps to avoid negative results due to weaknesses and achieve better performance when possible."

THINGS TO REMEMBER

- Looking for risks and opportunities is everyone's responsibility and affects every company process.
- Risk-based thinking allows for better planning and improved results.
- Risk assessment is required for operational activities such as contract negotiations, program management, design and development, purchasing, work transfer, etc.

AS9100D REQUIREMENTS

0.3.3 Risk-Based Thinking
6.1 Actions to Address Risks and Opportunities
8.1.1 Operational Risk Management

CONTEXT OF THE
ORGANIZATION

A business does not operate in isolation. External factors such as the economy, industry trends, changes in technology, product obsolescence, new regulations and others have an impact on your business. Internal issues such as reorganization, expansion or change in ownership can also have a bearing. The AS9100 standard requires management to plan for such changes in the context of your organization which can introduce risk and opportunities to your business.

WHAT'S REQUIRED?

"The organization shall identify external and internal issues that impact their company and its performance and determine the requirements to comply with from interested parties. These shall be considered when determining the scope of the QMS."

THINGS TO REMEMBER

- External issues to consider include civil and military applications, specifications from aviation authorities, differing customer needs, innovative solutions compatible with mature technologies, international competition and legal environments, among others.
- Internal issues to consider include corporate requirements, company values and culture, business strategy, changes in headcount, new processes and technologies, etc.
- Relevant interested parties and their requirements to review:

  - Customers and Partners - Contractual Agreements
  - Suppliers - Contractual Agreements
  - Authorities - Regulations
  - Certification Bodies - Standards
  - Owners, Shareholders - Applicable Laws, Expectations
  - Management, Employees, Unions - Labor Laws

- The scope of the QMS defines the boundaries and applicability of the QMS requirements in your company.

AS9100D REQUIREMENTS

4.1 Understanding the Organization and Its Context
4.2 Understanding the Needs and Expectations of Interested Parties
4.3 Determining the Scope of the Quality Management System

LEADERSHIP

The QMS is first and foremost a process led by top management in order to ensure the highest product quality and delivery performance for your customers. Leadership has hands-on responsibility for making the QMS a priority in the organization. Without management involvement, the usefulness and effectiveness of the QMS will be compromised which can put AS9100 certification in jeopardy. With clear direction and direct participation from the top leadership of the organization, the QMS can provide the control and focus needed to accomplish quality objectives and improve customer satisfaction.

WHAT'S REQUIRED?

"Top management shall demonstrate leadership and commitment to the QMS and ensure its integration into the company's standard business processes."

THINGS TO REMEMBER

• Establishing a quality policy communicates the importance of quality and meeting applicable requirements.
• Defining measurable quality objectives and KPIs provides a visible yardstick of performance and improvement.
• Clarifying roles, responsibilities and authorities gives clarity for decisions, delegation and accountability.
• Being accountable for the effectiveness of the QMS involves management reviews, process reviews and document reviews by management.
• Providing resources required by the QMS includes people, equipment, infrastructure and work environment.

AS9100D REQUIREMENTS

5.0 Leadership
6.2 Quality Objectives and Planning to Achieve Them
7.1 Resources

PLANNING

Achieving higher levels of quality requires forethought and planning based on risk-based thinking; that is, identification of likely risks and opportunities from analysis of the context of the organization, customer requirements and feedback, and overall QMS performance. Measurable quality objectives define goals and monitor progress to drive improvement in your QMS process. Planning for changes to the QMS ensures potential consequences are considered and the purpose for each change is achieved.

What's Required?

"The organization shall ensure the proper planning needed to address risks, pursue opportunities, achieve objectives and manage change."

Things to Remember

- Planning should be purposeful in order to achieve intended results, enhance desirable effects, prevent, or reduce, undesired effect and achieve improvement.
- Planning is an ongoing activity that involves managers and employees who have direct responsibility for the QMS and its processes.
- Assigned actions should identify tasks to complete, resources necessary, responsibilities, dates for completion and evaluation of effectiveness.

AS9100D Requirements

6.0 Planning

SUPPORT &
RESOURCES

Processes and resources to support the QMS is foundational for effectiveness and success. Management must ensure that sufficient people, equipment and facilities are provided in an effective work environment. Documentation should remain available and up-to-date. Measurement equipment must be protected and calibrated to ensure accuracy of results. All of these activities require planning and focus to ensure the QMS can operate properly and achieve intended results.

What's Required?

"Resources shall be suitable to the organization and its activities (people, methods, tools, equipment, information systems, etc."

Things to Remember

People, competence and knowledge

• Ensure sufficient human resources are available and ensure needed levels of competency.
• Identify and maintain knowledge required by the business.

Awareness and communication

• Establish effective methods for communication.
• Ensure employee awareness of and involvement in the QMS.

Control of documents and records

• Control documented information that affect the QMS, including product quality and safety.
• Ensure employees are aware of changes in relevant documentation.

Infrastructure and work environment

• Maintain needed infrastructure such as facilities, equipment, transportation resources, information and communication technology.
• Provide a suitable working environment for people, processes, equipment and materials.

Monitoring and measuring resources

• Identify, maintain and calibrate equipment used to measure results.

AS9100D Requirements

7.1.2 People
7.1.3 Infrastructure
7.1.4 Environment for the Operation of Processes
7.1.5 Monitoring and Measuring Resources
7.1.6 Organizational Knowledge
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented Information

CUSTOMER
FOCUS

Quality of products and delivery performance are essential to customers, especially in the aviation, space and defense industries. From start-to-finish, the entire QMS, must take customer needs into account. This starts with understanding customer requirements and planning needed processes, resources and materials. Throughout your operations through delivery and support open communication with customers is essential. Measurements of quality, delivery and customer satisfaction should trigger improvement actions to achieve the highest levels of performance.

What's Required?

"The QMS is focused on customers and their needs to ensure the organization proactively meets their expectations."

Things to Remember

- Customer satisfaction starts with understanding their needs and analyzing their requirements.
- The QMS must address customer and applicable statutory and regulatory requirements.
- Top management ensures that customer satisfaction remains the focus of the QMS.
- Quality objectives and planning should support customer satisfaction.
- Operational processes should be designed to protect the customer from receiving nonconformities and late shipments.
- Processes for effective customer communication should be established.
- Customer feedback and other relevant data should be used to determine customer satisfaction and necessary actions for improvement of the QMS.

AS9100D Requirements

5.1.2 Customer focus
8.2.1 Customer communication
9.1.2 Customer satisfaction

OPERATIONS
CONTROL

In the AS9100 standard, "operations" refers to the activities starting with the review of proposed customer requirements for the project through production to shipment and post-shipment activities. In addition to controls from ISO 9001:2015, the requirements of AS9100D include additional steps to safeguard the product based on risks to operational processes. Consideration should be given to changes throughout the product life cycle, product safety, prevention of counterfeit parts and additional supplier and manufacturing controls, among others. These additional controls are vital due to the potential consequences of failure in the aviation, space and defense industries.

What's Required?

"Methodologies shall be implemented for planning and controlling operations in order to meet requirements for provision of products to customers."

Things to Remember

Configuration management

- Maintain clear identification and traceability throughout the product life cycle.
- Manage configuration during changes.
- Ensure documentation of product attributes is accurate.

Product safety

- Identify and mitigate safety risks related to the product.

Counterfeit parts prevention

- Purchase from original manufacturers, authorized distributors or other approved sources.
- Monitor parts obsolescence.
- Implement testing to detect, quarantine and report counterfeit parts.

Program/Project management

- Plan projects to address resource and schedule constraints.

Work transfers management

- Manage internal and external transfers of work to ensure continuing conformity and mitigate risk.

Special requirements, critical items, key characteristics

- Identify and control high areas of risk (e.g. new technology, capacity constraints, short lead-times, etc.).
- Apply special controls to materials that present significant risk to the product.
- Reduce variations on attributes or features of critical items.

AS9100D Requirements

8.0 Operation
8.4 Control of externally provided processes, products and services

KEY BUSINESS
PROCESSES

In order to control the quality of product throughout the product life cycle, several key business processes must be established, controlled and improved. These include product design, purchasing, manufacturing and post-delivery support. As appropriate to your organization and the nature of the products you produce, various processes, documentation and controls will be required.

What's Required?

"Processes related to the product life cycle shall be organized and controlled."

Things to Remember

Design and development

- Control product development steps including planning, reviews, verification and validation.
- Ensure product changes are managed effectively.

Control of external providers

- Ensure adequacy of requirements communicated to suppliers.
- Verify compliance of purchased products.
- Monitor and evaluate supplier performance.

Production, inspection and release

- Ensure proper planning and preparation of manufacturing.
- Conduct inspections and control quality.
- Control the release and delivery of products to customers.

Post-delivery support

- Provide customer assistance and product support according to requirements.

AS9100D Requirements

8.3 Design and development of products and services
8.4 Control of externally provided processes, products and services
8.5 Production and service provision
8.6 Release of products and services
8.7 Control of nonconforming outputs

PERFORMANCE
EVALUATION &
IMPROVEMENT

Once your AS9100D QMS is established monitoring, evaluation and improvement activities ensure that it will remain compliant with requirements and continue to meet your business needs in the future. Overall effectiveness requires continued attention and regular improvements by your top management team. Several evaluation and improvement processes are required to ensure these key activities are maintained.

What's Required?

"The organization shall evaluate its performance, address its deficiencies and pursue opportunities for improvement."

Things to Remember

Monitoring, measurement, analysis, and evaluation

• Implement appropriate monitoring and measurement methods for products, processes and services.
• Analyze the results to evaluate compliance, performance, and effectiveness.

Customer satisfaction

• Monitor and evaluate information relating to customer satisfaction including quality, delivery performance, customer complaints and requests for corrective action.

Internal audit

• Train qualified auditors.
• Develop an audit program.
• Audit compliance to requirements and effectiveness of corrective actions.

Management review

• Regularly review QMS effectiveness and alignment with strategic direction.
• Address required inputs and outputs.

Nonconforming outputs, nonconformities and corrective actions

• Establish a process for dealing with defective products, processes or service.
• Investigate nonconformities and take corrective action to eliminate the root causes.

Continual improvement

• Implement improvements by utilizing correction, corrective action, continual improvement, breakthrough change, innovation, and other appropriate methods.

AS9100D Requirements

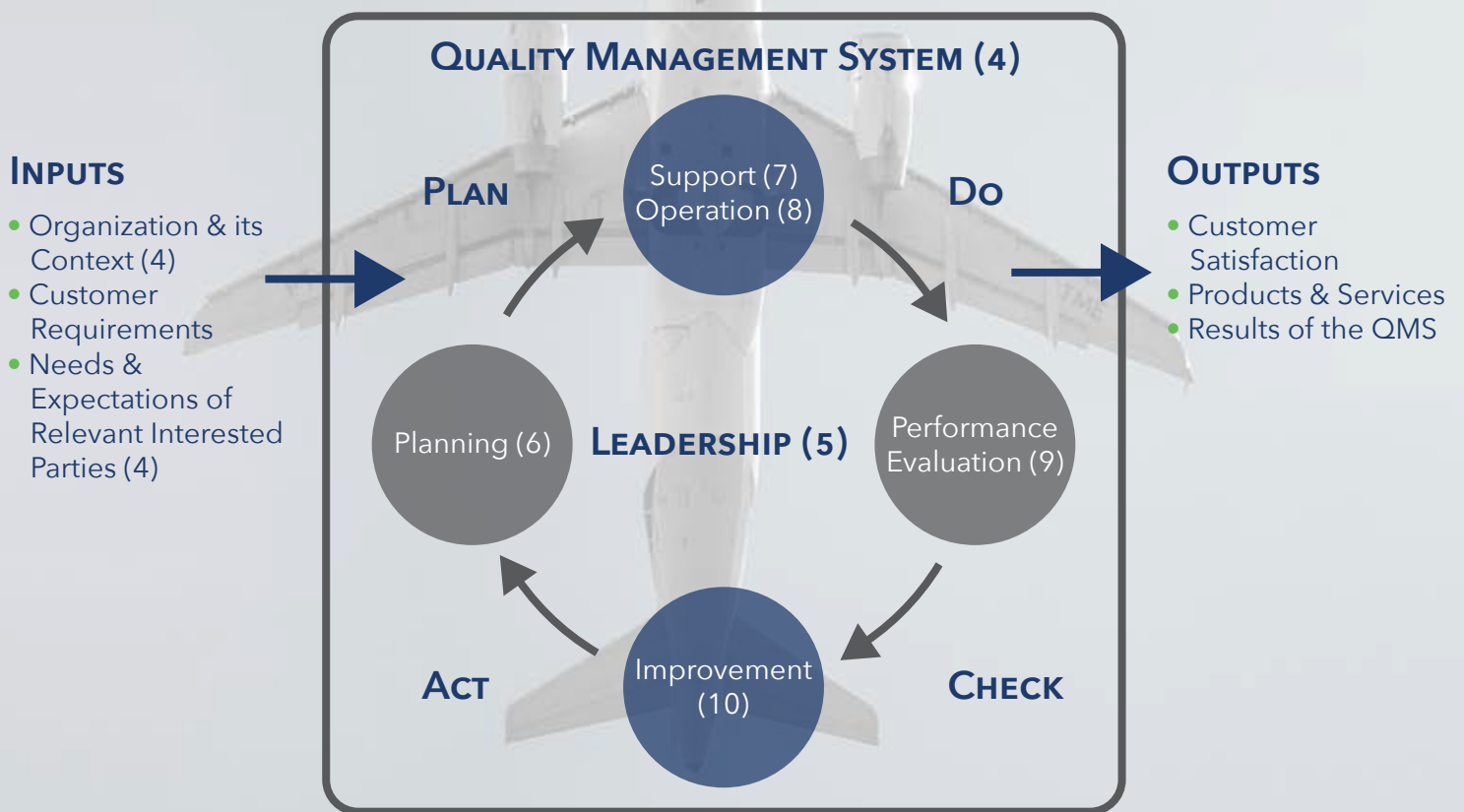0.3.2 Plan-Do-Check-Act Cycle
9.0 Performance Evaluation
10.0 Improvement

THE AS9100 STANDARD

This handbook? Outlines the basics of the AS9100D standard. The diagram below illustrates the structure of this standard and its relevant clauses.

QUALITY MANAGEMENT SYSTEM (4)

INPUTS

- Organization & its Context (4)
- Customer Requirements
- Needs & Expectations of Relevant Interested Parties (4)

PLAN

Support (7) Operation (8)

DO

OUTPUTS

- Customer Satisfaction
- Products & Services
- Results of the QMS

Planning (6)

LEADERSHIP (5)

Performance Evaluation (9)

ACT

Improvement (10)

CHECK

If you are interested in pursuing certification, contact Core Business Solutions to talk to an AS9100 consultant today!