



# QUALITY POLICY MANUAL FOR AEROSPACE DIVISION

FCD-0507 Quality Policy Manual Revision 11

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#### Welcome to the Quality Manual:

S.S. White has a rich history in providing quality flexible shaft assemblies and casings since 1844. It is with great pride that we make our Quality Policy Manual available to you.

If you need additional information, including procedures, work instructions or marketing material, please contact your salesperson or one of our Quality Staff members. We would be happy to supply you with whatever quality information you need.

You can also visit our website at <u>www.sswhite.net</u>.

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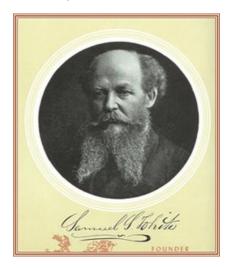
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## A Brief History of S. S. White Technologies:

Dr. Samuel Stockton White, a practicing dentist who saw a need for innovation, founded S.S. White in 1844 (before electricity!).



The company, known as S.S. White Dental Manufacturing at the time, rapidly became a pioneer in the field of dentistry with the introduction of its high-speed flexible shaft dental drills. In 1915, S.S. White found additional uses for its flex shafts as replacements for drive links in automobile speedometers. In 1931, the company published the industry's first handbook, which quickly became "the source" for all engineers interested in rotary motion. Soon the flexible shaft found use in power tools, instrumentation, motor controls, and consumer products. In 1941 (during WW II), the U.S. Military asked S.S. White to design various drive assemblies for the Aircraft Industry. It was this assignment that gave us the expertise of designing complex flexible shaft assemblies of exacting quality. By 1950, S.S. White, known for its progressive management, became the largest employer in Staten Island, New York. S.S. White was acquired in 1968 by Pennwalt Corporation a Fortune 200 Corporation. S.S. White Industrial Division relocated in 1972 to its current plant in Piscataway, New Jersey; completely severing its ties with S.S. White Dental Manufacturing.

In 1973, a young engineer, Rahul Shukla, joined the company. Shukla had obtained three engineering degrees but had never come across the term flexible shaft in all of his engineering curriculum. When he looked into it, he realized that no definitive scientific formulas to design these complex shafts ever existed; the void sparked a dream and obsession to develop this knowledge. Shukla carried out many experiments and research studies throughout the 70's. A turning point came when Adam Black III, a senior research engineer, joined the team, resulting in five years of exhaustive work. In 1987, a Doctoral degree was awarded to Dr. Black by The Stevens Institute of Technology for his breakthrough discoveries.

The very next year, 1988, Rahul Shukla took over the stewardship of S.S. White when the company was acquired from Pennwalt. Now, for the first time since the turn of the century, the company has a President / CEO whose commitment and knowledge of flexible shaft is without equal.

Today, the company operates three distinct product lines specializing in Shukla Medical which markets our own line of orthopedic extraction kits for emergency rooms, surgical instruments provided to the medical OEM market, and Flexible Shafts the heart and soul of the company. We are committed to advancing our leadership role with the development of new technologies and products. Our scientific approach to design has brought us great success in the high tech fields of Aeronautics and Medical Instruments. Our breakthrough discoveries with the mathematics governing flex shaft properties has led to the introduction of our STEADY FLEX and POWER FLEX shafts. These shafts took eight years to perfect and perform 30% better on average than current industry standards. We are continually creating new applications for flexible shafts and developing our future markets.

That's our history, setting the standards in technology and backing it up with the best quality and service in the business.

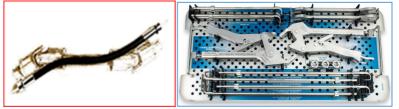
#### **Our Products:**

S.S. White is engaged in the design, manufacture and sale of the following types of products:

Rotary motion flexible shafts, casings, instruments and accessories for commercial use, for aircraft and medical
applications and use in the automotive and truck industries. These shafts convey rotary motion without the
use of universal joints or gearboxes.

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• Custom hand held surgical instruments and extraction kits for the orthopedic industry. These are sold to many OEM companies as well as to our wholly-owned subsidiary, Shukla Medical.



We are fortunate to have a market presence in many different industries- aerospace, medical, automotive, industrial, etc. and take great pride in our ability to serve many unique customers.

## **Our Quality Policy Statement:**

## "We will strive to meet and exceed customer expectations by continually improving our quality system and delivering outstanding service and quality product on-time"

#### Introduction and Scope:

The S.S. White Quality System is modeled after and compliant with the International Standard ISO 9001:2015, hereinafter referred to as the "Standard". We have included all of the requirements of AS9100:2016 Rev D and Good Manufacturing Practices, FAR 21, Subpart K. S.S. White has established the scope of its management system which takes into consideration interested parties and their requirements, external and internal issues facing the organization, as well as products supplied.

ISO9001:2015 and AS9100 Rev D Scope Statement:

#### "Design, Manufacture and Assembly of Aircraft Components and Systems"

S.S. White (SSW) is a privately held, small corporation. It is divided into two primary divisions: (1) Flexible Shaft Division, (2) Medical Products Division. This system is directed and controlled at the corporate level. The President and Chief Executive Officer of SSW has appointed the Director of Corporate Quality (who acts as the Management Representative) to manage the Corporate Quality Organization which entails the implementation, direction, and management of the SSW Total Quality System. The Director of Corporate Quality speaks for the President and CEO on matters regarding the SSW Total Quality System.

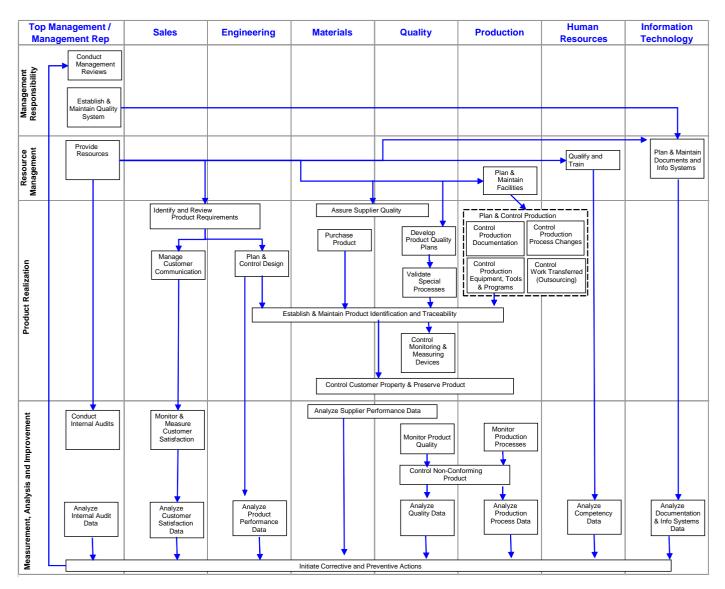
Participation in the system is company-wide. Every employee throughout the company participates in the quality system as applicable to individual requirements. The Management Policy Committee (MPC) consists at minimum of the Director of Corporate Quality; heads of IT, Finance, Engineering, Manufacturing, Human Resources, Sales; and the President/CEO. The MPC establishes quality policy objectives, develops corporate strategy, provides resources and leads by example in order to deploy improvement activities and establish the SSW quality culture. Quality activities and decisions are communicated to the organization through the Director of Corporate Quality and/or other members of the executive staff.

**Exclusion for IISO9001:2015/AS9100:2016 Rev D:** Clause 8.5.5.h. of the AS9100:2016 Rev D Standard is not applicable to S.S. White as it is not within the scope of our organization nor is it required by any of our interested parties.

Aerospace and automotive devices and instruments- design, manufacturing and assembly: ISO 9001:2015 and AS9100 Rev D

## **1. Interactional Process Flow Chart:**

This chart describes the sequence and interaction of quality system processes at S. S. White Technologies:



## 2. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 4.1 Understanding the Organization and Its Context

**PURPOSE**: The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 4 CONTEXT OF THE ORGANIZATION Element 4.1, Understanding the Organization and its Context

**RESPONSIBILITIES**: The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

#### 4.1 Understanding the organization and its context

S.S. White determines 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 quality management system. The determination is carried out on a risk-based approach.

S.S. White monitors and reviews information about these external and internal issues.

#### **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0002

# **3.** Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 4.2 Understanding the Needs and Expectations of Interested Parties

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 4 CONTEXT OF THE ORGANIZATION Element 4.2, Understanding the Needs and Expectations of Interested Parties.

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on S.S. White's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, S.S. White a) determines the interested parties that are relevant to the quality management system; b) determines the requirements of these interested parties that are relevant to the quality management system.

S.S. White monitors and reviews information about these interested parties and their relevant requirements.

#### **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0002

## 4. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 4.3 Determining the Scope of the Quality Management System

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 4 CONTEXT OF THE ORGANIZATION Element 4.3, Determining the Scope of the Quality Management System

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

4.3 Determining the scope of the quality management system

S.S. White determines the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, S.S. White a) considers the external and internal issues referred to in 4.1; b) considers the requirements of relevant interested parties referred to in 4.2; c) considers the products and services of the organization.

S.S. White applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of S.S. White's quality management system is available and is maintained as documented information. The scope states the types of products and services covered, and provides justification for any requirement of this International Standard that S.S. White determines is not applicable to the scope of its quality management system.

## **REFERENCE DOCUMENTATION:**

SOP-0002; SOP-00020

## 5. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 4.4 Quality Management System and Its Processes

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 4 CONTEXT OF THE ORGANIZATION Element 4.4, Quality Management System and Its Processes

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

#### 4.4 Quality management and its processes

4.4.1. S.S. White establishes, documents, implements, maintains and continually improve a quality management system, including the processes needed and their interactions in accordance with the requirements of this International Standard. S.S. White determines the processes needed for the quality management system and their application throughout the organization and:

a) determines the inputs required and the outputs expected from these processes;

b) determines the sequence and interaction of these processes;

c) determines and apply criteria and methods needed to ensure that both the operation and control of these processes are effective;

d) determines the resources needed for these processes and ensures their availability;

e) assigns the responsibilities and authorities for these processes;

f) addresses the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;

h) improves and processes and the quality management system

These processes are managed by the organization in accordance with the requirements of this International Standard. Where S.S. White chooses to outsource any process that affects product conformity with requirements, we ensure control over such processes. Control of such outsourced processes is identified within the quality management system.

4.4.2 To the extent necessary, S.S. White 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. S.S. White has established and maintains documented information that includes: (AS9100)

- a general description of relevant interested parties (AS9100)

- the scope of the quality management system, including boundaries and applicability (AS9100)

- a description of the processes needed for the quality management system and their application throughout the organization (AS9100)

- the sequence and interaction of these processes (AS9100)
- assignment of the responsibilities and authorities for these processes (AS9100)

## **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0002

## 6. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 5.1 Leadership and Commitment

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev d Standard: Section 5 LEADERSHIP Element 5.1, Leadership and Commitment

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

5.1 Leadership and commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization

c) ensuring the integration of the quality management system requirements into the organization's business processes

d) promoting the use of the process approach and risk-based thinking

e) ensuring that the resources needed for the quality management system are available

f) communicating the importance of effective quality management and of conforming to the quality management system requirements

g) ensuring that the quality management system achieves its intended results

h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management

system

i) promoting improvement

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable 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. (AS9100)

## **REFERENCE DOCUMENTATION:**

SOP-0001

## 7. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 5.2 Policy

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 5 LEADERSHIP Element 5.2, Policy

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

5.2 Policy
5.2.1 Establishing the quality policy
Top management establishes, implements, and maintains a quality policy that:
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a) is appropriate to the purpose and context of the organization 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 quality management system

5.2.2 Communicating the quality policy

The quality policy is:

- a) available and maintained as documented information
- b) communicated, understood, and applied within the organization
- c) available to relevant interested parties, as appropriate

#### **REFERENCE DOCUMENTATION:**

SOP-0001; FCD-0507

# 8. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 5.3 Organizational Roles, Responsibilities and Authorities

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 5 LEADERSHIP Element 5.3, Organizational Roles, Responsibilities and Authorities

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the President / CEO with the guidance and direction of the Management Representative and Management Policy Committee.

## **DESCRIPTION:**

5.3 Organizational roles, responsibilities and authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.

Top management assigns the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of this International Standard
- b) ensuring that the processes are delivering their intended outputs

c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to the management

- in particular to top management
- d) ensuring the promotion of customer focus throughout the organization
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Top management appoints a specific member of the organization's management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements. (AS9100)

The management representative has the organizational freedom and unrestricted access to top management to resolve quality management issues. (AS9100)

## **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0033

#### 9. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 6.1 Actions to Address Risks and Opportunities

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 6 PLANNING Element 6.1, Actions to Address Risks and Opportunities

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the President / CEO with the guidance and direction of the Management Representative and Management Policy Committee.

#### **DESCRIPTION:**

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, S.S. White considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determines the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended results;

b) enhance desirable effects

c) prevent, or reduce, undesirable effects

d) achieve improvement.

6.1.2

S.S. White plans:

a) actions to address these risks and opportunities;

b) how to:

- 1. integrate and implement the actions into its quality management system processes
- 2. evaluate the effectiveness of these actions

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

## **REFERENCE DOCUMENTATION:**

SOP-0001

## 10. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 6.2 Quality Objectives and Planning to Achieve Them

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 6 PLANNING Element 6.2, Quality Objectives and Planning to Achieve Them

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the President / CEO with the guidance and direction of the Management Representative and Management Policy Committee.

#### **DESCRIPTION:**

6.2 Quality objectives and planning to achieve them

6.2.1 S.S. White establishes quality objectives at relevant functions, levels, and processes needed for the quality management system. The quality objectives are:

a) consistent with the quality policy

- b) measurable
- c) take into account applicable requirements
- d) relevant to conformity of products and services and enhance customer satisfaction
- e) monitored
- f) communicated
- g) updated, as appropriate

S.S. White maintains documented information on the quality objectives

#### 6.2.2 When planning how to achieve its quality objectives, S.S. White determines:

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.

#### **REFERENCE DOCUMENTATION:**

SOP-0001

## 11. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 6.3 Planning of Changes

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 6 PLANNING Element 6.3, Planning of Changes

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the President / CEO with the guidance and direction of the Management Representative and Management Policy Committee.

## **DESCRIPTION:**

6.3 Planning of changes

When S.S. White determines the need for changes to the quality management system, the changes are carried out in a planned manner. S.S. white considers:

- a) the purpose of the changes and their potential consequences
- b) the integrity of the quality management system
- c) the availability of resources
- d) the allocation of reallocation of responsibilities and authorities

## **REFERENCE DOCUMENTATION:**

SOP-0001

## 12. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 7.1 Resources

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 7 SUPPORT Element 7.1, Resources

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Policy Committee

#### **DESCRIPTION:**

7.1 Resources

7.1.1 General

S.S. White determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system. S.S. White considers:

a) the capabilities of, and constraints on, existing internal resources

b) what needs to be obtained from external providers.

#### 7.1.2 People

S.S. White determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

#### 7.1.3 Infrastructure

S.S. White determines, provides and maintains 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

S.S. White determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

## 7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

S.S. White determines and provides 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. S.S. White ensures that the resources provided:

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a) are suitable for the specific type of monitoring and measurement activities being undertaken FCD-0507 Quality Policy Manual Revision 11 Copyright ©2020, S. S. White Technologies. All rights reserved.

b) are maintained to ensure their continuing fitness for their purpose.

S.S. White retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

## 7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by S.S. White to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used 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.

The organization establishes, implements, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification. (AS9100)

The organization maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria. (AS9100)

Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions. (AS9100)

S.S. White determines if the validity of previous measurement results have been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

7.1.6 Organizational knowledge

S.S. White determines the knowledge necessary for the operation of its processes and achieves conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, S.S. White considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

## **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0009; SOP-00014; SOP-00016; SOP-00021; SOP-00022

## 13. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 7.2 Competence

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 7 SUPPORT Element 7.2 Competence

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Human Resource Manager with the guidance and direction of the Management Policy Committee

## **DESCRIPTION:**

7.2 Competence

S.S. White:

a) determines the necessary competence of persons doing work under its control that affects the performance and effectiveness of the quality management system

b) ensures that these persons are competent on the basis of appropriate education, training, or experience

c) where applicable, takes actions to acquire the necessary competence, and evaluates the effectiveness of the actions taken

d) retains appropriate documented information as evidence of competence

#### **REFERENCE DOCUMENTATION:**

SOP-0022

## 14. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 7.3 Awareness

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 7 SUPPORT Element 7.3 Awareness

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Human Resource Manager with the guidance and direction of the Management Policy Committee

#### **DESCRIPTION:**

#### 7.3 Awareness

S.S. White ensures that persons doing work under its control are aware of:

a) the quality policy

b) relevant quality objectives

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance

- d) the implications of not conforming with the quality management system requirements
- e) relevant quality management system documented information and changes thereto (AS9100)
- f) their contribution to product or service conformity (AS9100)
- g) their contribution to product safety (AS9100)
- h) the importance of ethical behavior. (AS9100)

#### **REFERENCE DOCUMENTATION:**

SOP-0022

#### 15. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 7.4 Communication

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 7 SUPPORT Element 7.4 Communication

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the President/CEO with the guidance and direction of the Management Representative and Management Policy Committee

#### **DESCRIPTION:**

7.4 Communication

S.S. White determines the internal and external communications relevant to the quality management system including:

- a) on what it will communicate
- b) when to communicate
- c) with whom to communicate
- d) how to communicate
- e) who communicates

#### **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0033

## 16. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 7.5 Documented Information

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 7 SUPPORT Element 7.5, Documented Information

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

FCD-0507 Quality Policy Manual Revision 11

## **DESCRIPTION:**

#### 7.5 Documented Information

7.5.1 General

S.S. White's quality management system includes:

a) documented information required by this International Standard

b) documented information determined by S.S. White as being necessary for the effectiveness of the quality management system.

#### 7.5.2 Creating and Updating

When creating and updating documented information, S.S. White ensures appropriate

- a) identification and description (e.g. a title, date, author, or reference number)
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic)
- c) review and approval for suitability and adequacy.

## 7.5.3 Control of documented information

7.5.3.1

Documented information required by the quality management system and by this International Standard are controlled to ensure:

a) it is available and suitable for use, where and when it is needed

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2

For the control of documented information, S.S. White addresses the following activities, as applicable:

a) distribution, access, retrieval, and use

- b) storage and preservation, including preservation of legibility
- c) control of changes e.g. 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. (AS9100)

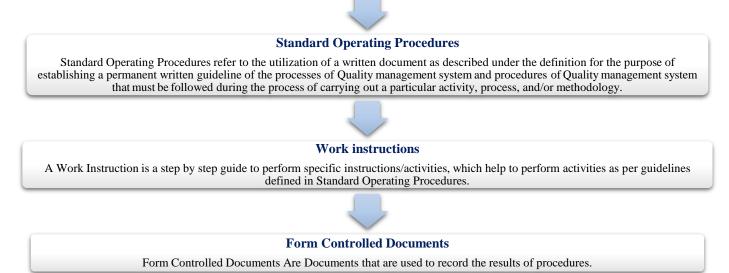
Documented information of external origin determined by S.S. White to be necessary for the planning and operation of the quality management system is identified as appropriate, and is controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

When documented information is managed electronically, data protection processes are defined (e.g. protection from loss, unauthorized changes, unintended alteration, corruption, physical damage) (AS9100). The document structure in SSW is represented below.

#### **Quality Policy Manual**

A quality manual is a document that states the Organization's intentions for operating the processes within the quality management system. It can include policies for all areas of the business that affect Organization's ability to make high quality products and meet our customers' and ISO9001:2015/AS9100:2016 Rev D's requirements.



S. S. White Technologies Pvt. Ltd. Document Structure

#### **REFERENCE DOCUMENTATION:**

SOP-0002; SOP-0020

#### 17. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.1 Operational Planning and Control

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION Element 8.1, Operational Planning and Control

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Operations with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

8.1 Operational planning and control

S.S. White plans, implements and controls the processes needed to meet the requirements for the provision of products and services, and implements the actions determined in clause 6, by:

- a) determining the requirements for the products and services
- b) establishing the criteria for:
  - 1. the processes
  - 2. the acceptance of 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 (AS9100)

d) implementing control of the processes in accordance with the criteria

e) determining, maintaining, and retaining documented information to the extent necessary;

1. to have confidence that the processes have been carried our as planned

2. 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 (AS9100)

g) engaging representatives of affected organization functions for operational planning and control (AS9100)

h) determining the process and resources to support the use and maintenance of the products and services (AS9100)

i) determining the products and services to be obtained from external providers (AS9100)

j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer. (AS9100)

As appropriate to the organization, customer requirements, and products and services, S.S. White plans and manages product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resources and schedule constraints. (AS9100) The output of this planning shall be suitable for S.S. White's operations.

S.S. White controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

We ensure that outsourced processes are controlled.

We establish, Implement, and maintain 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 ensures that work transfer impacts and risks are managed. (AS9100)

## 8.1.1 Operational Risk Management (AS9100)

S.S. White plans, implements, and controls a process for managing operational risks to the achievement of applicable requirements, which Includes as appropriate to its organization and the products and services (AS9100)

- a) assignment of responsibilities for operational risk management (AS9100)
- b) definition of risk assessment criteria (e.g.1 likelihood, consequences, risk acceptance) (AS9100)

c) identification, assessment, and communication of risks throughout operations (AS9100)

d) identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria (AS9100)

e) acceptance of risks remaining after implementation of mitigating actions. (AS9100)

## 8.1.2 Configuration Management (AS9100)

S.S. White plans, implements, and controls a process for configuration management as appropriate to its organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process: (AS9100)

a) controls product identity and traceability to requirements, including the implementation of identified changes (AS9100)

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. (AS9100)

#### 8.1.3 Product Safety (AS9100)

S.S. White plans, implements and controls processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product. (AS9100)

#### 8.1.4 Prevention of Counterfeit Parts (AS9100)

S.S. White plans, implements and controls processes, appropriate to its organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products delivered to the customer. (AS9100)

#### **REFERENCE DOCUMENTATION:**

SOP-0007; SOP-0008; SOP-0009; SOP-0010; SOP-0011; SOP-0012; SOP-0024; SOP-0036

## 18. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.2 Requirements for Products and Services

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION Element 8.2, Requirements for Products and Services

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Sales and Marketing with the guidance and direction of the Director of Operations and the Management Policy Committee.

## **DESCRIPTION:**

8.2 Requirements for products and services

## 8.2.1 Customer Communication

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 for products and services

When determining the requirements for the products and services to be offered to customers, S.S. White ensures that: a) the requirements for the products and services are defined, including:

- 1. any applicable statutory and regulatory requirements
  - 2. those considered necessary by the organization
- b) S.S. White meets the claims for the products and services it offers
- c) special requirements of the products and services are determined (AS9100)

d) operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified. (AS9100)

## 8.2.3 Review of the requirements for products and services

8.2.3.1 S.S. White ensures that it has the ability to meet the requirements for products and services to be offered lo customers. S.S. White conducts a review before committing to supply products and services to the customer, to include:

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 S.S White
- d) statutory and regulatory requirements applicable to the products and services
- e) contract or order requirements differing from those previously expressed.

This review shall be coordinated with applicable functions of the organization. (AS9100)

If upon review S.S White determines that some customer requirements cannot be met or can only partially be met, S.S. White negotiates a mutually acceptable requirement with the customer. (AS9100)

S.S. White ensures that contract or order requirements differing from those previously defined are resolved.

The customer requirements are confirmed by S.S. White before acceptance, when the customer does not provide a documented statement of their requirements.

S.S. White 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 the requirements for products and services

S.S. White ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

## **REFERENCE DOCUMENTATION:**

SOP-0003; SOP-0006

## 19. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.3 Design and Development of Products and Services

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION Element 8.3, Design and Development of Products and Services

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Operations with the guidance and direction of the Director of Sales and Marketing and the Management Policy Committee.

## **DESCRIPTION:**

8.3 Design and development of products and services

8.3.1 General

S.S. White establishes, implements, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

## 8.3.2 Design and Development Planning

In determining the stages and controls for design and development. S.S. White considers:

a) the nature, duration, and complexity of the design and development activities

b) the required process stages, including applicable design and development reviews

c) the required design and development verification and validation activities

d) the responsibilities and authorities involved in the design and development process

e) the internal and external resource needs For the design and development of products and services

- f) the need to control interfaces between persons involved in the design and development process
- g) the need for involvement of customers and users in the design and development process

h) the requirements for subsequent provision of products and services

i) the level of control expected for the design and development process by customers and other relevant interested parties

j) the documented information needed to demonstrate that design and development requirements have been met.

When appropriate, S.S. White divides the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs. (AS9100)

Design and development planning considers the ability to provide, verify, test and maintain products and services. (AS9100)

## 8.3.3 Design and Development Inputs

S.S. White determines the requirements essential for the specific types of products and services to be designed and developed. S.S. White considers:

- a) functional and performance requirements
- b) information derived from previous similar design and development activities
- c) statutory and regulatory requirements
- d) standards or codes of practice that the organization 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, components, equipment, products). (AS9100)

Inputs are adequate for design and development purposes, complete, and unambiguous.

Conflicting design and development inputs are resolved.

S.S. White retains documented information on design and development inputs.

8.3.4 Design and Development Controls

S.S. White applies controls to the design and development process to ensure that:

a) the results to be achieved are defined

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements

c) verification activities are conducted to ensure that the design and development outputs meet the 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:

f) documented information of these activities is retained

g) progression to the next stage is authorized. (AS9100)

Participants in design and development reviews include representatives of functions concerned with the design and development stage(s) being reviewed. (AS9100)

8.3.4.1 When tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following: (AS9100)

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 (AS9100)
b) test procedures describe the test methods to be used, how to per-form the test, and how to record the results (AS9100)

c) the correct configuration of the test item is submitted for the test (AS9100)

d) the requirements of the test plan and the test procedures are observed (AS9100)

e) the acceptance criteria are met. (AS9100)

Monitoring and measuring devices used for testing are controlled as defined In clause 7.1.5. (AS9100) At the completion of design and development S.S. White 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. (AS9100)

## 8.3.5 Design and Development Outputs

S.S. White ensures that design and development outputs:

a) meet the input requirements

b) are adequate for the subsequent processes for the provision of products and services

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria

d) specify the characteristics of products and services that are essential for their intended purpose and their safe and proper provision

e) specify, as applicable, any critical Items, Including any key characteristics, and specific actions to be taken for these items; (AS9100)

f) are approved by authorized person(s) prior to release. (AS9100)

S.S. White defines the data required to allow the product to be identified, manufactured, verified, used, and maintained. (AS9100)

S.S. White retains documented information on design and development outputs.

8.3.6 Design and Development Changes

S.S. White identifies, reviews, and controls 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.

The organization implements a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements. (AS9100)

The organization retains documented information on:

a) design and development changes

b) the results of reviews

c) the authorization of the changes

d) the actions taken to prevent adverse impacts.

Design and development changes are controlled In accordance with the configuration management process requirements. (AS9100)

## **REFERENCE DOCUMENTATION:**

SOP-0028

# 20. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.4 Control of Externally Provided Processes, Products and Services

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION Element 8.4, Control of Externally Provided Processes, Products and Services

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Operations with the guidance and direction of the Management Policy Committee.

## DESCRIPTION:

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

S.S. White ensures that externally provided processes, products, and services conform to requirements.

S.S. White is responsible for the conformity of all externally provided processes, products, and services, Including from sources defined by the customer. (AS9100)

S.S. White ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used. (AS9100)

The organization 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. (AS9100)

The organization requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met. (AS9100)

S.S. White 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 the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

S.S. White determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. S.S. White retains documented information of these activities and any necessary actions arising from the evaluations.

## 8.4.1.1 S.S. White: (AS9100)

a) define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status (AS9100)

b) maintain 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) (AS9100)c) periodically review external provider performance including process, product and service

conformity, and on time delivery performance (AS9100)

d) define the necessary actions to take when dealing with external providers that do not meet requirements (AS9100)

e) define the requirements for controlling documented information created by  $\cdot$  and/or retained by external providers. (AS9100)

## 8.4.2 Type and Extent of Control

S.S. White ensures that externally provided processes, products, and services do not adversely affect its ability to consistently deliver conforming products and services to its customers. S.S. White:

a) ensures that externally provided processes remain within the control of its quality management system:

b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) takes into consideration:

1) the potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements

2) the effectiveness of the controls applied by the external provider

3) the results of the periodic review of external provider performance (see 8.4.1.1 c);

d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

Verification activities of externally provided processes, products, and services are performed according to the risks identified by the organization. These include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts. (AS9100)

When externally provided product Is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements. (AS9100)

When S.S White delegates verification activities to the external provider, the scope and requirements for delegation are defined and a register of delegations shall be maintained. S.S. White periodically monitors the external provider's delegated verification activities. (AS9100)

When external provider test reports are utilized to verify externally provided products, S.S. White implements 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), S.S. White implements a process to validate the accuracy of test reports. (AS9100)

#### 8.4.3 Information for External Providers

S.S. White ensures the adequacy of requirements prior to their communication to the external provider.

S.S. White 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:

1) products and services

2) methods, processes, and equipment

3) the release of products and services

c) competence, including any required qualification of persons

d) the external providers' interactions with S.S. White

e) control and monitoring of the external providers' performance to be applied by S.S. White

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;

g) design and development control (AS9100)

h) special requirements, critical items, or key characteristics (AS9100)

i) test, inspection, and verification (including production process verification) (AS9100)

j) the use of statistical techniques for product acceptance and related instructions for acceptance by S.S. White k) the need to: (AS9100)

-implement a quality management system (AS9100)

-use customer-designated or approved external providers, including process sources (e.g., special processes) (AS9100)

-notify the organization of non-conforming processes, products, or services and obtain approval for their disposition (AS9100)

-prevent the use of counterfeit parts (see 8.1.4) (AS9100)

-notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval (AS9100)

-flow down to external providers applicable requirements including customer requirements (AS9100) -provide test specimens for design approval, Inspection/verification, investigation, or auditing 9100)

(AS9100)

-retain documented information, including retention periods and disposition requirements (AS9100) I) the right of access by S.S. White, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain; (AS9100) m) ensuring that persons are aware of: (AS9100)

-their contribution to product or service conformity (AS9100)

-their contribution to product safety (AS9100)

-the importance of ethical behavior. (AS9100)

#### **REFERENCE DOCUMENTATION:**

SOP-0005; SOP-0010; SOP-0012

## 21. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.5 Production & Service Provision

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION Element 8.5, Production and Service Provision

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Operations with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

7.5 Production and service provision

7.5.1 Control of production and service provision

S.S. White implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed

2) the results to be achieved

b) the availability and use of suitable monitoring and measuring resources

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met

1) ensuring that documented information for monitoring and measurement activity for product acceptance Includes:2) the results to be achieved; (AS9100)

-criteria for acceptance and rejection (AS9100)

-where in the sequence verification operations are to be performed (AS9100)

-measurement results to be retained (at a minimum an indication of acceptance or rejection) (AS9100)

-any specific monitoring and measurement equipment required and Instructions associated with their use (AS9100)

2) 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). (AS9100)

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 actions 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) (AS9100)

j) the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product) (AS9100)

k) the control and monitoring of identified critical items, including key characteristics, In accordance with established processes (AS9100)

I) the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment (AS9100)

m) the identification of in-process Inspection/verification points when adequate verification of conformity cannot be performed at later stages (AS9100)

n) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized (AS9100)

o) the provision for the prevention, detection, and removal of foreign objects (AS9100)

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 (see 7.1.3) (AS9100)

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. (AS9100)

8.5.1.1 Control of Equipment, Tools, and Software Programs (AS9100)

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and shall be maintained. (AS9100)

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks. (AS9100)

## 8.5.1.2 Validation and Control of Special Processes (AS9100)

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, S.S. White establishes arrangements for these processes including, as applicable: (AS9100)

- a) definition of criteria for the review and approval of the processes (AS9100)
- b) determination of conditions to maintain the approval (AS9100)
- c) approval of facilities and equipment (AS9100)
- d) qualification of persons (AS9100)
- e) use of specific methods and procedures for implementation and monitoring the processes (AS9100)
- f) requirements for documented information to be retained. (AS9100)

## 8.5.1.3 Production Process Verification (AS9100)

S.S. White implements production process verification activities to ensure the production process Is able to produce products that meet requirements. (AS9100)

S.S. White 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). (AS9100)

S.S. White retains documented information on the results of production process verification.

## 8.5.2 Identification and Traceability

S.S. White uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

We maintain the Identification of the configuration of the products and services In order to identify any differences between the actual configuration and the required configuration. (AS9100)

S.S. White identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords}, S.S. White establishes controls for the media. (AS9100)

S.S. White 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 Providers

S.S. White exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

S.S. White identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or Incorporation into the products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, S.S. White reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

S.S. White preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for: (AS9100)

- a) cleaning (AS9100)
- b) prevention, detection, and removal of foreign objects (AS9100)
- c) special handling and storage for sensitive products (AS9100)
- d) marking and labeling, including safety warnings and cautions (AS9100)
- e) shelf life control and stock rotation (AS9100)
- f) special handling and storage for hazardous materials. (AS9100)

8.5.5 Post-Delivery Activities: This section is specifically excluded.

8.5.6 Control of Changes

S.S. White reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

S.S. White 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.

#### **REFERENCE DOCUMENTATION:**

SOP-0006; SOP-0007; SOP-0008; SOP-0009; SOP-0019; SOP-0026

## 22. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.6 Release of Products and Services

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION Element 8.6, Release of Products and Services

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

8.6 Release of products and services

S.S. White implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met

The release of products and services to tile customer do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

S.S. White retains documented information on the release of products and services. The documented information includes:

a) evidence of conformity with the acceptance criteria

b) traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, S.S. White ensures that retained documented information provides evidence that the products and services meet the defined requirements. (AS9100) S.S. White ensures that all documented information required to accompany the products and services are present at delivery. (AS9100)

## **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0010; SOP-0011; SOP-0012; SOP-0017; SOP-0021

#### 23. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.7 Control of Nonconforming Outputs

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 8 OPERATION, Element 8.7 Control of Nonconforming Outputs.

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

8.7 Control of nonconforming outputs

8.7.1

S.S. White ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

S.S. White takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

S.S. White's nonconformity control process shall be maintained as documented information including the provisions for: (AS9100)

-defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions (AS9100)

-taking actions necessary to contain the effect of the nonconformity on other processes, products, or services (AS9100)

-timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties (AS9100)

-defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts. (AS9100)

S.S. White deals with nonconforming outputs in one or more of the following ways:

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, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products are only implemented:

-after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;

-after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap are conspicuously and permanently marked, or positively controlled, until physically rendered unusable. (AS9100)

Counterfeit or suspect counterfeit, parts are controlled to prevent reentry into the supply chain. (AS9100) Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2 S.S. White 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.

#### **REFERENCE DOCUMENTATION:**

SOP-0016

## 24. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 9.1 Monitoring, Measurement, Analysis and Evaluation

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 9 PERFORMANCE EVALUATION Element 9.1 Monitoring, Measurement, Analysis and Evaluation

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality and the Director of Operations with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

- S.S. White determines:
  - 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.

S.S. White evaluates the performance and the effectiveness of the quality management system.

S.S. White retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

S.S. White monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. S.S. White determines the methods for obtaining, monitoring, and reviewing this information.

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. S.S. White develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. (AS9100)

#### 9.1.3 Analysis and Evaluation

S.S. White analyzes and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate:

- a) conformity of products and services
- b) the degree of customer satisfaction
- c) the performance and effectiveness of the quality management system
- d) if planning has been implemented effectively
- e) the effectiveness of actions taken to address risks and opportunities
- f) the performance of external providers
- g) the need for improvements to the quality management system

#### **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0009; SOP-0010; SOP-0011; SOP-0012; SOP-0017; SOP-0021; SOP-0024; SOP-0033

## 25. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 9.2 Internal Audit

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 9 PERFORMANCE EVALUATION Element 9.2 Internal Audit

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

9.2 Internal Audit

9.2.1

S.S. White conducts internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) S.S. White's own requirements for its quality management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2. S.S. White:

a) plans, establishes, implements, and maintains 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 the organization, and the results of previous audits

b) defines the audit criteria and scope for each audit

c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process

d) ensures that the results of the audits are reported to relevant management

e) takes appropriate correction and corrective actions without undue delay

f) retains documented information as evidence of the implementation of the audit program and the audit results.

## **REFERENCE DOCUMENTATION:**

SOP-0001; SOP-0010; SOP-0011; SOP-0012; SOP-0017; SOP-0021

## 26. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 9.3 Management Review

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 9 PERFORMANCE EVALUATION Element 9.3 Management Review

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Management Representative with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

9.3 Management review

9.3.1 General

Top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

#### 9.3.2 Management Review Inputs

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 quality management system
- c) information on the performance and effectiveness of the quality management system, including trends in:
- 1) customer satisfaction and feedback from relevant interested parties
- 2) the extent lo which quality objectives have been met
- 3) process performance and conformity of products and services
- 4) nonconformities and corrective actions
- 5) monitoring and measurement results
- 6) audit results
- 7) the performance of external providers
- 8) on-time delivery performance; (AS9100)

- d) the adequacy of resources
- e) the effectiveness of actions taken to address risks and opportunities (see 6. 1):
- f) opportunities for Improvement.

## 9.3.3 Management Review Outputs

The outputs of the management review shall include decisions and actions related to: a. opportunities for improvement:

- a) opportunities for improvement
- b) any need for changes to the quality management system
- c) resource needs
- d) risks Identified. (AS9100)

S.S. White retains documented information as evidence of the results of management reviews.

## **REFERENCE DOCUMENTATION:**

SOP-0001

## 27. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 10.1 General

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 10 IMPROVEMENT Element 10.1 Improvement

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

10.1 Improvement

S.S. White determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These include:

- a) improving products and services to meet requirements as well as to address future needs and expectations
- b) correcting, preventing, or reducing undesired effects
- c) improving the performance and effectiveness of the quality management system.

#### **REFERENCE DOCUMENTATION:**

SOP-0001

#### 28. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 10.2 Nonconformity and Corrective Action

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 10 IMPROVEMENT Element 10.2 Nonconformity and Corrective Action

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the S.S. White:

- a) reacts to the nonconformity and, as applicable:
  - 1) takes action to control and correct it
- 2) deals with the consequences

b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity

- 2) determining the causes of the nonconformity, including, as applicable, those related to human factors
  - 3) determining if similar nonconformities exist, or could potentially occur
- c) implements any action needed
- d) reviews the effectiveness of any corrective action taken
- e) updates risks and opportunities determined during planning, if necessary
- f) makes changes to the quality management system, if necessary

g) flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity (AS9100)

h) takes specific actions when timely and effective corrective actions are not achieved. (AS9100)

Corrective actions are appropriate to the effects of the nonconformities encountered.

S.S. White maintains documented information that defines the nonconformity and corrective action management processes. (AS9100)

10.2.2 The organization retains documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken
- b) the results of any corrective action.

## **REFERENCE DOCUMENTATION:**

SOP-0017; SOP-0033

## 29. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 10.3 Continual Improvement

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the ISO9001:2015/AS9100:2016 Rev D Standard: Section 10 IMPROVEMENT Element 10.3 Continual Improvement

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

## **DESCRIPTION:**

## 10.3 Continual improvement

S.S. White continually improves the suitability, adequacy, and effectiveness of the quality management system. The organization 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 The organization monitors the Implementation of improvement activities and evaluate the effectiveness of the results. (AS9100)

## **REFERENCE DOCUMENTATION:**

SOP-0017; SOP-0033

## 30. Policy Statement for: Code of Federal Regulations, Part 21, Subpart K—Parts Manufacturer Approvals

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirements of the FAR 21, Subpart K as amended on October 16, 2009.

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

## DESCRIPTION:

Subpart K—Parts Manufacturer Approvals § 21.301 applicability. This subpart prescribes— (a) Procedural requirements for issuing PMAs; and (b) Rules governing holders of PMAs.

§ 21.303 Application. FCD-0507 Quality Policy Manual Revision 11

(a) S.S. White apply in a form and manner prescribed by the FAA, and include the following:

(1) The identity of the product on which the article is to be installed.

(2) The name and address of the manufacturing facilities at which these articles are to be manufactured.

(3) The design of the article, which consists of—

(i) Drawings and specifications necessary to show the configuration of the article; and

(ii) Information on dimensions, materials, and processes necessary to define the structural strength of the article.

(4) Test reports and computations necessary to show that the design of the article meets the airworthiness requirements of this subchapter. The test reports and computations must be applicable to the product on which the article is to be installed, unless the applicant shows that the design of the article is identical to the design of a article that is covered under a type certificate. If the design of the article was obtained by a licensing agreement, the applicant must provide evidence of that agreement.

(5) An applicant for a PMA based on test reports and computations must provide a statement certifying that the applicant has complied with the airworthiness requirements of this subchapter.

(b) S.S. White will make all inspections and tests necessary to determine—

 (1) Compliance with the applicable airworthiness requirements;

(2) That materials conform to the specifications in the design;

(3) That the article conforms to its approved design; and

(4) That the manufacturing processes, construction, and assembly conform to those specified in the design.

#### § 21.305 Organization.

S.S. White will provide the FAA with a document describing how its organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

#### § 21.307 Quality system.

S.S. White will establish a quality system that meets the requirements of § 21.137.

#### § 21.308 Quality manual.

S.S. White will 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.

#### § 21.309 Location of or change to manufacturing facilities.

(a) An applicant may obtain a PMA for manufacturing facilities located outside of the United States if the FAA finds no undue burden in administering the applicable requirements of Title 49 U.S.C. and this subchapter.(b) S.S. White will obtain FAA approval before making any changes to the location of any of its manufacturing facilities.

(c) S.S. White will immediately notify the FAA, in writing, of any change to the manufacturing facilities that may affect the inspection, conformity, or airworthiness of its PMA article.

#### § 21.310 Inspections and tests.

(a) S.S. White will 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 this subchapter.

(b) Unless otherwise authorized by the FAA, S.S. White

(1) May not present any article to the FAA for an inspection or test unless compliance with § 21.303(b)(2) through (4) has been shown for that article; and

(2) May not make any change to an article between the time that compliance with § 21.303(b)(2) through(4) is shown for that article and the time that the article is presented to the FAA for the inspection or test.

## § 21.311 Issuance.

The FAA issues a PMA after finding that the applicant complies with the requirements of this subpart and the design complies with the requirements of this chapter applicable to the product on which the article is to be installed.

## § 21.313 Duration.

A PMA is effective until surrendered, withdrawn, or the FAA otherwise terminates it.

## § 21.314 Transferability.

S.S. White will not transfer the PMA.

## § 21.316 Responsibility of holder.

S.S. White will —

(a) Amend the document required by § 21.305 as necessary to reflect changes in the organization and provide these amendments to the FAA;

(b) Maintain the quality system in compliance with the data and procedures approved for the PMA;

(c) Ensure that each PMA article conforms to its approved design and is in a condition for safe operation;

(d) Mark the PMA article for which an approval has been issued. Marking must be in accordance with part 45 of this chapter, including any critical parts;

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

(f) Have access to design data necessary to determine conformity and airworthiness for each article produced under the PMA;

(g) Retain each document granting PMA and make it available to the FAA upon request; and

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

#### § 21.319 Design changes.

(a) Classification of design changes.

(1) A "minor change" to the design of an article produced under a PMA is one that has no appreciable effect on the approval basis.

(2) A "major change" to the design of an article produced under a PMA is any change that is not minor. (b) Approval of design changes.

(1) Minor changes to the basic design of a PMA may be approved using a method acceptable to the FAA.

(2) The PMA holder must obtain FAA approval of any major change before including it in the design of an article produced under a PMA. • ~ 21.320 Changes in quality system. After the issuance of a PMA.

(a) Each change to the quality system is subject to review by the FAA; and

(b) The holder of the PMA must immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its article.

#### § 21.320 Changes to Quality System.

After the issuance of PMA

(a) Each change to the Quality System is subject to review by the FAA; and

(b) The holder of the PMA must immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its article.

# **31.** Policy Statement for: Code of Federal Regulations, Part 21, Subpart G—Production Certificates 21.137 Quality System

**PURPOSE:** The Quality System described in this section of the Quality Policy Manual complies with the requirement of 14 CFR 21, Subpart K.

**RESPONSIBILITIES:** The overall responsibility for this procedure belongs to the Director of Corporate Quality with the guidance and direction of the Management Policy Committee.

#### **DESCRIPTION:**

As an applicant for or holder of a production certificate, S.S. White establishes and describes in writing a quality system that ensures that each product and article conforms to its approved design and is in a condition for safe operation. This quality system includes:

(a) Design data control. Procedures for controlling design data and subsequent changes to ensure that only current, correct, and approved data is used.

(b) Document control. Procedures for controlling quality system documents and data and subsequent changes to ensure that only current, correct, and approved documents and data are used.

(c) Supplier control. Procedures that—

(1) Ensure that each supplier-furnished product or article conforms to its approved design; and

(2) Require each supplier to report to the production approval holder if a product or article has been released from that supplier and subsequently found not to conform to the applicable design data.

(d) Manufacturing process control. Procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.

(e) Inspecting and testing. Procedures for inspections and tests used to ensure that each product and article conforms to its approved design. These procedures must include the following, as applicable:

(1) A flight test of each aircraft produced unless that aircraft will be exported as an unassembled aircraft. (Not applicable to S.S. White)

(2) A functional test of each aircraft engine and each propeller produced. (Not applicable to S.S. White) (f) Inspection, measuring, and test equipment control. Procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard must be traceable to a standard acceptable to the FAA.

(g) Inspection and test status. Procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.

(h) Nonconforming product and article control.

(1) Procedures to ensure that only products or articles that conform to their approved design are installed on a 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.

(2) Procedures to ensure that discarded articles are rendered unusable.

(i) Corrective and preventive actions. 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.

(j) Handling and storage. Procedures to prevent damage and deterioration of each product and article during handling, storage, preservation, and packaging.

(k) Control of quality records. Procedures for identifying, storing, protecting, retrieving, and retaining quality records. A production approval holder must retain these records for at least 5 years for the products and articles manufactured under the approval and

at least 10 years for critical components identified under Sec. 45.15(c) of this chapter.

(I) Internal audits. Procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system. The procedures must include reporting results of internal audits to the manager responsible for implementing corrective

and preventive actions.

(m) In-service feedback. 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 to—

(1) Address any in-service problem involving design changes; and

(2) Determine if any changes to the Instructions for Continued Airworthiness are necessary.

(n) Quality escapes. Procedures for identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.

## List of referenced documents

Document ID	Description
SOP-0001	MANAGEMENT RESPONSIBILITY PROCEDURE
SOP-0002	QUALITY SYSTEMS PROCEDURE
SOP-0003	CONTRACT REVIEW PROCEDURE
SOP-0005	PURCHASING PROCEDURE
SOP-0006	CONTROL OF CUSTOMER SUPPLIED PRODUCT
SOP-0007	TRACEABILITY PROCEDURE
SOP-0008	PRODUCT IDENTIFICATION PROCEDURE
SOP-0009	PROCESS CONTROL PROCEDURE
SOP-0010	INCOMING INSPECTION PROCEDURE
SOP-0011	IN-PROCESS INSPECTION PROCEDURE
SOP-0012	FINAL INSPECTION PROCEDURE
SOP-0013	USE OF AGE-SENSITIVE MATERIALS
SOP-0014	CONTROL OF INSPECTION MEASURING AND TEST EQUIPMENT PROCEDURE
SOP-0016	CONTROL OF NON-CONFORMING PRODUCT PROCEDURE
SOP-0017	CORRECTIVE AND PREVENTIVE ACTION PROCEDURE
SOP-0019	COMPONENT STOCKROOM CONTROL PROCEDURE
SOP-0020	CONTROL OF QUALITY RECORDS PROCEDURE
SOP-0021	INTERNAL AUDITING PROCEDURE
SOP-0022	TRAINING PROCEDURE
SOP-0024	Statistical Techniques Procedure
SOP-0025	WIRE AND SHAFT STOCKROOM CONTROL PROCEDURE
SOP-0026	Tooling Control Procedure
SOP-0028	DESIGN REVIEW PROCEDURE
SOP-0033	CONTINUOUS IMPROVEMENT
SOP-0035	Production Part Approval Process
SOP-0036	FOREIGN OBJECT DEBRIS (FOD) PREVENTION
SOP-17001	ACCEPTABLE USE POLICY
SOP-17002	AUDIT VULNERABILITY SCAN POLICY
SOP-17003	EMAIL USE POLICY
SOP-17004	INFORMATION SENSITIVITY POLICY
SOP-17005	APPLICATION DEVELOPMENT POLICY
SOP-17008	ONBOARDING POLICY
SOP-17012	POST MARKET SURVEILLANCE PROCEDURE
SOP-17013	PLAN OF ACTION AND MILESTONES
WI-0450	INSTRUCTION FOR EQUIPMENT AND SOFTWARE VALIDATION

## **Quality Policy Manual Revision History**

Rev	Section Changed	Page	Change Made	Date	Editor
1			Initial Issue of Document on the QSI on-line system.	6/30/98	Carolyn Ketcham
2	All Policy Manual Statements with the exception of Control of Customer Supplied Product	All except noted	Globally added requirements of AS9100, ISO-9001 and FAR 21, Subpart K; changed approvers to include just those on Quality Steering Committee (not all of MPC)	3/9/01	Carolyn Ketcham
3	4.4, 4.20		Made Design applicable to our system; changed typographical error in 4.20 (which previously referenced servicing instead of Statistical Techniques in Scope.	3/22/01	Carolyn Ketcham
4	All Policy Manual documents revised to 4; added policies for PPAP, Continuous Improvement and Manufacturing Capabilities	All	Added all of the QS9000 requirements and identified the AS9100 requirements with (AS9100). No change made except additions	12/16/02	Carolyn Ketcham
5	Cover Page, Quality Policy and Business Description		Eliminated "Technologies" and added MPI to Business Description	5/21/03	Carolyn Ketcham
6	All	All	Updated all pages to Rev 6; added ISO9000:2000 and GMP's; updated all pages to reflect ISO9000:2000 and AS9100 structure. Update	6/15/04	Carolyn Ketcham
7	All	All	Eliminated all references to the (now obsolete) QS9000 specification reducing the size of the manual by about half.	6/28/07	Carolyn Ketcham
			Added Reference Document call-outs to all ISO/AS poilcy pages (these were on the QS pages but not the ISO/AS pages).		
			Eliminated page for Organizational Chart as this is now an FCD.		
8	Add		Added independent policy statement for "Code of Federal Regulations, Part 21, Subpart K—Parts Manufacturer Approvals"	4/10/10	Carolyn Ketcham
			Removed ATM, removed Director of Human Resources from Executive Policy Team.		
	Business Description				
9 / 01	All	All	Changed to Word Format to be controlled in IQS rather than QSI. Renumbered as QP-002, new revision 01.	3/28/2011	Carolyn Ketcham
			Added Interactional Process diagram, History, Our Products		
			Added CFR, Part 21, G, 21.137 policy		
			Changed "Executive Policy Team to MPC and added Directors of Engineering and Manufacturing		
02	All Reference Documentation	6-21	Revised reference documentation back to the original SOP callouts	7/31/2011	Carolyn Ketcham
03	7.1.1, 7.1.2, 7.1.3, 7.1.4	20	Added requirements of 7.1.1, 7.1.2, , 7.1.3, and 7.1.4	12/6/2011	Carolyn Ketcham
04	Throughout		Changed all of the obsolete callouts for ISO AS	10/18/2013	Carolyn Ketcham
	Mission Statement	3	Removed. We are in the process of revising it and it is not required per the Standard		
	Scope	4	Got rid of much of the marketing fluff and included the scope as shown on the certificates. Further identified the participants on MPC. Removed discussion about the policy. Added the scope verbiage exactly from our certs.		
	Interactional Flow Chart	5	Separated 7.5.1.1 through 7.5.1.4 for clarity.		
	7.5.1.5 Servicing	15	Added language to indicate its exclusion.		
05	Exclusions	4	Changed Exclusion statement to read "S.S. White excludes section 7.5.1.4 Post-Delivery Support as it does not apply to our scope of work." On account that Para. 7.5.1.5 does not exist.	10/31/2013	Scott Daingerfield
	7 5 1 4/7 5 1 5	15	Deleted Obsolete 7.5.1.5 to align to AS9100. Added exclusion statement to 7.5.1.4 "Post-Delivery Support"		
	7.5.1.4/7.5.1.5	15		05/40/2017	lana Usina
06	All	All	Updated to include ISO9001:2015 & AS9100D Changes	05/12/2017	Joan Ikinya
07	Picture; Policy Statement; Exclusions	1, 4, 5	Replaced Company location picture. Replaced Policy statement with: We will strive to meet and exceed customer expectations by continually improving our quality system and delivering outstanding service and quality product on- time. Removed the clause numbers from the Process Flowchart	10/31/2019	Ivette Benitez

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08	Scope; Section A	5; 6	Updated to include ISO 13485:2016 to scope; Added section A for SSW Medical parts (Including Shukla Medical)	03/16/2020	Santosh Rohit Yerrabolu
09	Section A title; Section B title	5; 22	Section A title updated to "A. Medical devices and instruments - design and manufacturing: ISO 13485:2016"; Section B title updated to "B. Aerospace and automotive devices and instruments- design, manufacturing and assembly: ISO 9001:2015 and AS9100D"	03/16/2020	Santosh Rohit Yerrabolu
10	Updated title; Removed Section A; Removed references to SOP-0034 and SOP-0029; Added List of procedures;	5; 7; 7 - 33, 34	Updated document title to "Quality Policy Manual for Flexible Shaft Division" ; Removed references to SOP-0034 and SOP-0029; Added list of procedures	4/03/2020	Santosh Rohit Yerrabolu
11	17. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.1 Operational Planning and Control	17	Added SOP-0036 to 'REFERENCE DOCUMENTATION' under 17. Policy Statement for: ISO9001:2015/AS9100:2016 Rev D 8.1 Operational Planning and Control	08/04/2020	Santosh Rohit Yerrabolu