



Quality Manual

President Titanium, CO. Inc.  
243 Franklin Street  
Hanson, MA. 02341  
Tel. 781-294-0000  
Fax 781-293-3753  
[www.presidenttitanium.com](http://www.presidenttitanium.com)

**Notice:** Information in this document may not be disclosed to any third party without specific authorization from President Titanium.

Approval	Approval	Revision/Date	Reason for Change
<i>Shawn MacLeod</i>	<i>John Toler</i>	00 -- 03/16/2018	Complete Rewrite

## Table of Contents

<b>Sections</b>	<b>Page #</b>
<b>Forward</b>	3
<b>Introduction</b>	3
<b>1. Scope</b>	4
<b>2. Normative References</b>	5
<b>3. Terms and Definitions</b>	5
<b>4. Context of President Titanium</b>	6
4.1 Understanding President Titanium and its context	6
4.2 Understanding the needs and expectations of interested parties	6
4.3 Determining the scope of the quality management system	6
4.4 Quality management system and its processes	7
<b>5. Leadership</b>	7
5.1 Leadership and commitment	7
5.1.1 General	7
5.1.2 Customer focus	7
5.2 Policy	7
5.2.1 Establishing the quality policy	7
5.2.2 Communicating the quality policy	8
5.3 Organizational roles, responsibilities and authorities	8
<b>6. Planning</b>	9
6.1 Actions to address risks and opportunities	9
6.2 Quality objectives and planning to achieve them	9
6.3 Planning of changes	9
<b>7. Support</b>	10
7.1 Resources	10
7.1.1 General	10
7.1.2 People	10
7.1.3 Infrastructure	10
7.1.4 Environment for the operation of processes	10
7.1.5 Monitoring and measuring resources	10
7.1.6 Organizational knowledge.	11
7.2 Competence	11
7.3 Awareness	11
7.4 Communication	12
7.5 Documented Information	12
7.5.1 General	12
7.5.2 Creating and Updating	12
7.5.3 Control of Documented Information	12
<b>8. Operation</b>	13
8.1 Operational Planning and Control	13
8.1.1 Operational Risk Management (Not Used)	14
8.1.2 Configuration Management	14
8.1.3 Product Safety	15
8.1.4 Prevention of Counterfeit (Not Used)	15
8.2 Requirements for products and services	15
8.2.1 Customer Communication	15
8.2.2 Determining the requirements for products and services	15
8.2.3 Review of the requirements for products and services	15
8.2.4 Changes to requirements for products and services	16
8.3 Design and development of products and services N/A	16

## Table of Contents continued

Sections	Page #
8.4 Control of externally provided processes, products and services	16
8.4.1 General	16
8.4.2 Type and extent of control	17
8.4.3 Information for external providers.	18
8.5 Production and service provision	18
8.5.1 Control of production and service provision	18
8.5.2 Identification and traceability	19
8.5.3 Property belonging to customers or external providers	20
8.5.4 Preservation	20
8.5.5 Post-delivery activities	21
8.5.6 Control of changes	21
8.6 Release of products and services	21
8.7 Control of nonconforming outputs	21
9. Performance Evaluation	22
9.1 Monitoring, measurement, analysis and evaluation	22
9.1.1 General	22
9.1.2 Customer satisfaction	23
9.1.3 Analysis and evaluation	23
9.2 Internal audit	23
9.3 Management review	24
9.3.1 General	24
9.3.2 Management review inputs	24
9.3.3 Management review outputs	24
10. Improvement	24
10.1 General	24
10.2 Nonconformity and Corrective Action	24
10.3 Continual Improvement	25
Appendix	26

## FOREWORD

***This Quality Manual includes ISO 9001:2015<sup>1</sup>/AS9120 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes as shown in bold, italic text.***

## Introduction

This Quality Manual describes the policies and company-wide control system of President Titanium's Quality Management System. This Quality Management System addresses the requirements of the ISO (International Organization for Standardization) Quality Standards as defined in ISO-9001-2015 and SAE (Society of Automotive Engineers) AS9100 / 9120 Aerospace Standard. The Quality Assurance Procedures and Work Instructions of President Titanium are proprietary. All unauthorized use is prohibited.

This Manual is intended as a general, all encompassing, Quality Policy statement appropriate to all customers, but supplemented by detailed Operating Procedures and Work Instructions.

<sup>1</sup> With the permission of the International Organization for Standardization (ISO). The complete ISO 9001 standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit [www.iso.org](http://www.iso.org). Copyright remains with ISO.

**Approvals / Revision Control:**

This Quality Policy Manual has been approved in its entirety prior to issue by the Vice President Operations (OPS VP) and Quality Manager (QM). The Approval Box also maintains Revision History. The OPS VP and QM is authorized to approve the Quality Management System, in its entirety, with electronic signatures that are controlled through an electronic database.

All subsequent revisions shall be approved by OPS VP and QM. The initial release of a section shall be labeled "00." Subsequent revisions shall be numerically indexed and dated.

President Titanium reserves the right to make improvements of the Operating Procedures and Work Instructions without necessarily revising the Quality Manual. This Manual will receive a general review on an annual basis and will be revised as needed.

The participation of all President Titanium's employees in the development and approval of the Standard Operating Procedures and Work Instructions is encouraged.

All copies issued outside of President Titanium shall be considered "uncontrolled" unless specifically requested by customers or outside 3rd parties.

**QUALITY MANAGEMENT SYSTEM — REQUIREMENTS**

**1 SCOPE - The distributor of domestic-made 6AL/4V Grade5, 6AL/4V ELI and CP-Grade 4, titanium bar, sheet and plate serving the aerospace and medical industries.**

**This standard includes ISO 9001:2015<sup>2</sup> quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.**

***It is emphasized that the requirements specified in this standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.***

***If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.***

This quality management system specifies requirements that meet ISO 9001-2015/AS9120 for President Titanium when they:

- a) Need to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) Aim to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1: In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.

---

<sup>2</sup> With the permission of the International Organization for Standardization (ISO). The complete ISO 9001 standard can be obtained from any ISO member or from the ISO Central Secretariat: 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, SWITZERLAND, or visit [www.iso.org](http://www.iso.org). Copyright remains with ISO.

## 2. NORMATIVE REFERENCES

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

**9100:2016 Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations**

ISO 9000:2015 Quality management systems – Fundamentals and vocabulary

**ISO 9001:2015 Quality management systems – Requirements**

## 3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 *and the following apply*.

*Within this standard, the term manufacturer is intentionally used to clearly delineate the relationship between the product creator and the organization. The terms external provider and original manufacturer can be synonymous.*

**external provider** → **organization** → **customer**  
*(manufacturer / provider)*

### 3.1 Article

*Material, part, component, assembly, or appliance which is listed by the design organization as eligible for installation in/on the product or included in the design data approved by the authority.*

### 3.2 Authorized Release Certificate

*Document attesting that a product is released for use (e.g., release or return to service) and certifying that the activities performed, and the results achieved, conform to established organization, regulatory, and customer requirements.*

### 3.3 Certificate of Conformity (commonly referred to as a 'Certificate of Conformance')

*Documented information that attests to product conformity; conformance to defined process, design, and specification requirements.*

### 3.4 Counterfeit Part

*An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.*

*NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.*

### 3.5 Distributor

*An organization carrying out the purchase, storage, splitting, or sale of products without affecting product conformity. The term 'organization' in the context of this standard means a distributor.*

### 3.6 Product Safety

*Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.*

### 3.7 Splitting

*The division of product either physically or by batch quantity, without affecting the product characteristics or conformity.*

**3.8 Suspected Unapproved Part**

*A part for which there is objective and credible evidence indicating that the part is likely an unapproved or counterfeit part.*

*NOTE: This includes: articles shipped to an end user by a supplier who does not have direct delivery authorization from the approved production organization; new articles that do not conform to the approved design/data; articles that have not been manufactured or maintained by an approved source; articles that have been intentionally misrepresented, including counterfeit parts; and articles with incomplete or inappropriate documentation.*

**3.9 Test Report**

*Documented information that shows objective evidence provided by either the manufacturer or a certified testing facility that the product conforms with specific design requirements, product or performance characteristics.*

**3.10 Unapproved Part**

*A part that was not produced or maintained in accordance with approved or acceptable data and applicable statutory, regulatory, and customer requirements.*

---

**4 CONTEXT OF PRESIDENT TITANIUM -- (Refer to SOP 4)****4.1 Understanding President Titanium and its context**

President Titanium shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

President Titanium shall monitor and review information about these external and internal issues during management review (refer to SOP 9).

The internal and external issues are documented in the interested party and risk assessment form (QF 4.2-1).

**4.2 Understanding the needs and expectations of interested parties**

Due to their effect or potential effect on President Titanium's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, President Titanium shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

President Titanium shall monitor and review information about these interested parties and their relevant requirements.

**4.3 Determining the scope of the quality management system**

President Titanium shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, President Titanium shall consider:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services of President Titanium.

President Titanium shall apply all the requirements of ISO 9001 if they are applicable within the determined scope of its quality management system.

The scope of President Titanium's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered and provide justification

for any requirement of ISO 9001 that President Titanium determines is not applicable to the scope of its quality management system.

Conformity to ISO 9001 may only be claimed if the requirements determined as not being applicable do not affect President Titanium's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

#### **4.4 Quality management system and its processes (See Appendix)**

**4.4.1** President Titanium shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001.

***The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.***

President Titanium shall determine the processes needed for the quality management system and their application throughout President Titanium, and shall:

- a) determine the inputs required and the outputs expected from these processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

**4.4.2** To the extent necessary, President Titanium shall:

- a) maintain documented information to support the operation of its processes;
- b) retain documented information to have confidence that the processes are being carried out as planned.

***The organization shall establish and maintain documented information that includes:***

- ***a general description of relevant interested parties (see 4.2 a);***
- ***the scope of the quality management system, including boundaries and applicability (see 4.3);***
- ***a description of the processes needed for the quality management system and their application throughout the organization;***
- ***the sequence and interaction of these processes;***
- ***assignment of the responsibilities and authorities for these processes.***  
***(See organization chart and refer to the job descriptions for the assignment of the responsibilities and authorities of the processes outlined above).***

***NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.***

---

## **5 LEADERSHIP -- (Refer to SOP 5)**

### **5.1 Leadership and commitment**

#### **5.1.1 General**

Top management shall demonstrate 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 President Titanium;

- c) ensuring the integration of the quality management system requirements into President Titanium'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.

NOTE: Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit, or not for profit.

### 5.1.2 Customer focus

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

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

## 5.2 Policy

### 5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

- a) is appropriate to the purpose and context of President Titanium 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 shall:

- a) be available and be maintained as documented information;
- b) be communicated, understood and applied within President Titanium;
- c) be available to relevant interested parties, as appropriate.

### 5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within President Titanium.

Top management shall assign the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of ISO 9001;
- 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 (see 10.1), in particular to top management;
- d) ensuring the promotion of customer focus throughout President Titanium;
- 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 shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements. (See Appendix)***

***The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.***

**NOTE:** The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

---

## **6 PLANNING -- (Refer to SOP 6)**

### **6.1 Actions to address risks and opportunities**

**6.1.1** When planning for the quality management system, President Titanium shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

**6.1.2** President Titanium shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
  - 1) integrate and implement the actions into its quality management system processes (see 4.4);
  - 2) evaluate the effectiveness of these actions.

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

NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address President Titanium's or its customers' needs.

### **6.2 Quality objectives and planning to achieve them**

**6.2.1** President Titanium shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

President Titanium shall maintain documented information on the quality objectives.

**6.2.2** When planning how to achieve its quality objectives, President Titanium shall determine:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

### 6.3 Planning of changes

When President Titanium determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

President Titanium shall consider:

- 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 or reallocation of responsibilities and authorities.
- 

## 7 SUPPORT -- (Refer to SOP 7)

### 7.1 Resources

#### 7.1.1 General

President Titanium shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

President Titanium shall consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

#### 7.1.2 People

President Titanium shall determine and provide 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

President Titanium shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE: Infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

#### 7.1.4 Environment for the operation of processes

President Titanium shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE: A suitable environment can be a combination of human and physical factors, such as:

- a) social (e.g. non-discriminatory, calm, non-confrontational);
- b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
- c) physical (e.g. temperature, heat, humidity, light, air flow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

### 7.1.5 Monitoring and measuring resources

#### 7.1.5.1 General

President Titanium shall determine and provide 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.

President Titanium shall ensure that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

President Titanium shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

**7.1.5.2 Measurement traceability (Refer to WI 7.1.5)**

When measurement traceability is a requirement, or is considered by President Titanium 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 shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.***

***The organization shall maintain a register of the monitoring and measuring equipment. The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.***

**NOTE:** Monitoring and measuring equipment can include, but are not limited to, personally owned and customer supplied equipment used to provide evidence of product and service conformity.

***Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).***

President Titanium shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and shall take appropriate action as necessary.

**7.1.6 Organizational knowledge**

President Titanium shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, President Titanium shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

**NOTE 1:** Organizational knowledge is knowledge specific to President Titanium; it is generally gained by experience. It is information that is used and shared to achieve President Titanium's objectives.

**NOTE 2:** Organizational knowledge can be based on:

- a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
- b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

**7.2 Competence**

President Titanium shall:

- a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensure that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retain appropriate documented information as evidence of competence.

**NOTE: Consideration should be given for the periodic review of the necessary competence.**

NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

### 7.3 Awareness

President Titanium shall ensure that persons doing work under President Titanium's 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;**
- f) their contribution to product or service conformity;**
- g) their contribution to product safety;**
- h) the importance of ethical behavior.**

### 7.4 Communication

President Titanium shall determine 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.

**NOTE: Communication should include internal and external feedback relevant to the quality management system.**

### 7.5 Documented information (Refer to WI 7.5)

#### 7.5.1 General

ECI's quality management system shall include:

- a) documented information required by ISO 9001;
- b) documented information determined by President Titanium as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

#### 7.5.2 Creating and updating

When creating and updating documented information, President Titanium shall ensure 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.

**NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.**

#### 7.5.3 Control of documented information

**7.5.3.1** Documented information required by the quality management system and by ISO 9001 shall be 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, President Titanium shall address 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.**

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

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

**When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).**

**Documented information that provides evidence of product origin, conformity, and shipment shall be retained.**

**NOTE: Examples of documented information that is retained may include, but is not limited to:**

- **manufacturer, distributor, and repair station test and inspection reports;**
- **purchase orders/contracts;**
- **certificates of conformity (manufacturer, sub-tier distributor), copies of authorized release certificates;**
- **nonconformance, concession, and corrective actions;**
- **documented information of lot or batch traceability;**
- **documented information of storage, preservation, or shelf life condition (e.g., time, temperature, humidity).**

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

## **8 OPERATION - (Refer to SOP 8)**

### **8.1 Operational planning and control**

President Titanium shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) determining the requirements for the products and services;

**NOTE: Determination of requirements for the products and services should include consideration of:**

- **personal and product safety;**
- **availability and inspectability;**
- **product obsolescence;**
- **prevention, detection, and removal of foreign objects;**
- **handling, packaging, and preservation;**
- **recycling or final disposal of the product at the end of its life.**

- b) establishing criteria for:

- 1) the processes;
- 2) the acceptance of products and services;

**NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:**

- *process control*;
  - *process capability measurements*;
  - *statistical process control*;
  - *design of experiments*;
  - *verification*;
- c) determining the resources needed to achieve conformity to the product and service requirements **and to meet on-time delivery of products and services**;
- d) implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary:
- 1) to have confidence that the processes have been carried out as planned;
  - 2) to demonstrate the conformity of products and services to their requirements.
- f) engaging representatives of affected organization functions for operational planning and control;**
- g) determining the products and services to be obtained from external providers;**
- h) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.**

**NOTE: One method to achieve operational planning and control can be through using integrated phased processes.**

**As appropriate to the organization, customer requirements, and products and services, the organization shall plan and manage 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 resource and schedule constraints.**

**NOTE: This activity is generally referred to as project planning, project management, or program management.**

The output of this planning shall be suitable for President Titanium's operations.

**NOTE: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.**

President Titanium shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

President Titanium shall ensure that outsourced processes are controlled (see 8.4).

**The organization shall 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 shall ensure that work transfer impacts and risks are managed.**

**NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.**

#### **8.1.1 (Not Used)**

#### **8.1.2 Configuration Management**

**The organization shall plan, implement, and control a process for configuration management as appropriate to the 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 shall:**

- a) control product identity and traceability to requirements, including the implementation of identified changes;**
- b) ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.**

**8.1.3 (Not Used)****8.1.4 Prevention of Counterfeit Parts**

*The organization shall plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.*

**NOTE: Counterfeit part prevention processes should consider:**

- *training of appropriate persons in the awareness and prevention of counterfeit parts;*
- *application of a parts obsolescence monitoring program;*
- *controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;*
- *requirements for assuring traceability of parts and components to their original or authorized manufacturers;*
- *verification and test methodologies to detect counterfeit parts;*
- *monitoring of counterfeit parts reporting from external sources;*
- *quarantine and reporting of suspect or detected counterfeit parts.*

**8.1.5 Prevention of Suspected Unapproved Parts (Refer to WI 8.1.5)**

*The organization shall plan, implement, and control a process appropriate to the organization and the product that identifies and prevents the release of unapproved and suspected unapproved parts.*

**NOTE: Suspected unapproved parts prevention processes should consider:**

- *training of appropriate persons in the awareness and identification of suspected unapproved parts;*
- *requirements for assuring traceability of parts and components to an authorized source;*
- *inspection processes to detect suspected unapproved parts;*
- *monitoring of suspected unapproved parts reporting from external sources;*
- *quarantine and reporting of suspected unapproved parts in accordance with applicable requirements from the competent authority or customers, as required.*

**8.2 Requirements for products and services (Refer to WI 8.2)****8.2.1 Customer communication**

Communication with customers shall include:

- 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, President Titanium shall ensure that:

- a) the requirements for the products and services are defined, including:
  - 1) any applicable statutory and regulatory requirements;
  - 2) those considered necessary by President Titanium;
- b) President Titanium can meet the claims for the products and services it offers.

**8.2.3 Review of the requirements for products and services**

**8.2.3.1** President Titanium shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. President Titanium shall conduct a review before committing to supply products and services to a 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 President Titanium;
- 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 President Titanium.***

***If upon review President Titanium determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.***

**8.2.3.2** President Titanium shall retain documented information, as applicable:

- a) on the results of the review;
- b) on any new requirements for the products and services.

#### **8.2.4 Changes to requirements for products and services**

President Titanium shall ensure 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.

### **8.3 Design and Development of Products and Services, is NOT APPLICABLE.**

The scope of the QMS does not include Clause 8.3 Design and Development of Products and Services, because the organization works to customer requirements and specifications and has no design responsibility.

### **8.4 Control of externally provided processes, products and services (Refer to WI 8.4)**

#### **8.4.1 General**

President Titanium shall ensure that externally provided processes, products and services conform to requirements.

***The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.***

***The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.***

***The organization shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.***

***The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.***

President Titanium shall determine 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 President Titanium's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of President Titanium;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

President Titanium shall determine and apply 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. President Titanium shall retain documented information of these activities and any necessary actions arising from the evaluations.

***NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited***

*quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.*

**8.4.1.1 The organization shall:**

- 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;**
- 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);**
- c) periodically review external provider performance including process, product and service conformity, and on-time delivery performance;**
- d) define the necessary actions to take when dealing with external providers that do not meet requirements;**
- e) define the requirements for controlling documented information created by and/or retained by external providers.**

**8.4.2 Type and extent of control**

President Titanium shall ensure that externally provided processes, products and services do not adversely affect President Titanium's ability to consistently deliver conforming products and services to its customers.

President Titanium shall:

- a) ensure that externally provided processes remain within the control of its quality management system;
- b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) take 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) determine 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 shall be performed according to the risks identified by the organization. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.***

***NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.***

***NOTE 2: Verification activities can include:***

- *review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);*
- *inspection and audit at the external provider's premises;*
- *review of the required documentation;*
- *review of production part approval process data;*
- *inspection of products or verification of services upon receipt;*

***When external provider test reports are utilized to verify externally provided products, the organization shall implement 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 risk, the organization shall implement a process to validate the accuracy of test reports.***

**8.4.3 Information for external providers**

President Titanium shall ensure the adequacy of requirements prior to their communication to the external provider. President Titanium shall communicate 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 President Titanium;

e) control and monitoring of the external providers' performance to be applied by President Titanium;

f) verification or validation activities that President Titanium, or its customer, intends to perform at the external providers' premises.

***g) test, inspection, and verification;***

***h) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;***

***i) the need to:***

- ***implement a quality management system;***
- ***use customer-designated or approved external providers, including process sources (e.g., special processes);***
- ***notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;***
- ***prevent the use of counterfeit parts (see 8.1.4 and 8.1.5);***
- ***notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture;***
- ***flow down to external providers applicable requirements including customer requirements;***
- ***provide a certificate of conformity, test reports, or authorized release certificate, as applicable;***
- ***retain documented information, including retention periods and disposition requirements;***

***j) the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;***

***k) ensuring that persons are aware of:***

- ***their contribution to product or service conformity;***
- ***their contribution to product safety;***
- ***the importance of ethical behavior.***

**8.5 Production and service provision (Refer to SOP 8 and WI 8.5.4)****8.5.1 Control of production and service provision**

President Titanium shall implement production and service provision under controlled conditions. Controlled conditions shall 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;

***NOTE 1: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.***

***NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.***

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:***

- *criteria for acceptance and rejection;*
- *where in the sequence verification operations are to be performed;*
- *measurement results to be retained (at a minimum an indication of acceptance or rejection);*
- *any specific monitoring and measurement equipment required, and instructions associated with their use;*

**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.**

d) the use of suitable infrastructure and environment for the operation of processes;

**NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.**

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);**

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

**k) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;**

**l) the provision for the prevention, detection, and removal of foreign objects;**

**m) 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);**

**n) the consequences of obsolescence (e.g., materials, components, equipment, products).**

#### **8.5.1.1 Control of Equipment, Tools, and Software Programs**

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

**Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.**

#### **8.5.2 Identification and traceability**

President Titanium shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

**The organization shall 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.**

President Titanium shall identify 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), the organization shall establish controls for the media.**

President Titanium shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

**Unserviceable product shall be controlled and physically segregated from serviceable product.**

**NOTE: Traceability requirements can include:**

- *the identification to be maintained throughout the product life;*
- *the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);*

- *for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;*
- *the identification of the product's condition in inventory (e.g., new, overhauled, repaired, altered, rebuilt).*

***The organization shall maintain product identification and traceability by suitable means (e.g., labels, bar codes) from receipt; during splitting, storage, packaging, and preservation operations and until delivery. This includes handling or packing operations outsourced to external providers.***

***When delivering split product, the following information shall be retained:***

- *amount delivered relative to amount received from external provider,*
- *purchase order number(s),*
- *customer's name(s).*

### **8.5.3 Property belonging to customers or external providers**

President Titanium shall exercise care with property belonging to customers or external providers while it is under President Titanium's control or being used by President Titanium.

President Titanium shall identify, verify, protect and safeguard 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, President Titanium shall report this to the customer or external provider and retain documented information on what has occurred.

### **8.5.4 Preservation**

President Titanium shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

***Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:***

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

### **8.5.5 Post-delivery activities**

The scope is limited in its application of Clause 8.5.5 Post-Delivery Activities, because the organization does not provide post-delivery support other than for the return of nonconforming product after delivery to customers. The organization will take appropriate action including investigation and reporting on returned product.

The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use, and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback;
- f) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).***

***When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.***

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

#### **8.5.6 Control of changes**

President Titanium shall review and control 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 shall be identified.***

***NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.***

President Titanium shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

#### **8.6 Release of products and services (Refer to WI 8.5.4)**

President Titanium shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

President Titanium shall retain documented information on the release of products and services. The documented information shall include:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

***The organization shall ensure that all documented information required to accompany the products and services are present at delivery.***

***NOTE: Where there is a formal agreement with the customer, the organization can deliver a certifying statement created by the organization that references the original manufacturer's certificate of conformity and documented information that is retained and traceable by the organization. The certifying statement indicates that defined requirements have been met throughout the organization's processes.***

#### **8.7 Control of nonconforming outputs**

**8.7.1** President Titanium shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

***NOTE: The term "nonconforming outputs" includes suspected unapproved, unapproved, counterfeit, and nonconforming product or service generated internally, received from an external provider, or identified by a customer.***

President Titanium shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

***The organization's nonconformity control process shall be maintained as documented information including the provisions for:***

- ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***
- ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***
- ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***

- **defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).**

**NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.**

President Titanium shall deal 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.

**Dispositions of nonconforming product shall be limited to:**

- **scrap;**
- **rejection for return to the external provider;**
- **rejection for revalidation by the manufacturer;**
- **submittal to either the customer or design authority for use-as-is disposition, as applicable.**

**Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.**

**Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.**

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

**8.7.2 President Titanium shall retain documented information that:**

- a) describes the nonconformity;
  - b) describes the actions taken;
  - c) describes any concessions obtained;
  - d) identifies the authority deciding the action in respect of the nonconformity.
- 

## **9 PERFORMANCE EVALUATION - (Refer to SOP 9)**

### **9.1 Monitoring, measurement, analysis and evaluation**

#### **9.1.1 General**

President Titanium shall determine:

- 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.

President Titanium shall evaluate the performance and the effectiveness of the quality management system.

President Titanium shall retain appropriate documented information as evidence of the results.

#### **9.1.2 Customer satisfaction**

President Titanium shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. President Titanium shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

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

### 9.1.3 Analysis and evaluation

President Titanium shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

**NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).**

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.

NOTE Methods to analyze data can include statistical techniques.

## 9.2 Internal audit

**9.2.1** President Titanium shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

- 1) President Titanium's own requirements for its quality management system;

**NOTE: The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements.**

- 2) the requirements of ISO 9001;

b) is effectively implemented and maintained.

**NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.**

**9.2.2** President Titanium shall:

- a) plan, establish, implement and maintain 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 President Titanium, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit program and the audit results.

## 9.3 Management review

### 9.3.1 General

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

### 9.3.2 Management review inputs

The management review shall be 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 to 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;**
- 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;
- b) any need for changes to the quality management system;
- c) resource needs.
- d) risks identified**

President Titanium shall retain documented information as evidence of the results of management reviews.

---

## 10 IMPROVEMENT -- (Refer to SOP 10)

### 10.1 General

President Titanium shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall 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.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

### 10.2 Nonconformity and corrective action

**10.2.1** When a nonconformity occurs, including any arising from complaints, President Titanium shall:

- a) react to the nonconformity and, as applicable:
  - 1) take action to control and correct it;
  - 2) deal with the consequences;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 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) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

- g) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;*
- h) take specific actions when timely and effective corrective actions are not achieved.*

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

***The organization shall maintain documented information that defines the nonconformity and corrective action management processes.***

**10.2.2** President Titanium shall retain documented information as evidence of:

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

### **10.3 Continual improvement**

President Titanium shall continually improve the suitability, adequacy and effectiveness of the quality management system.

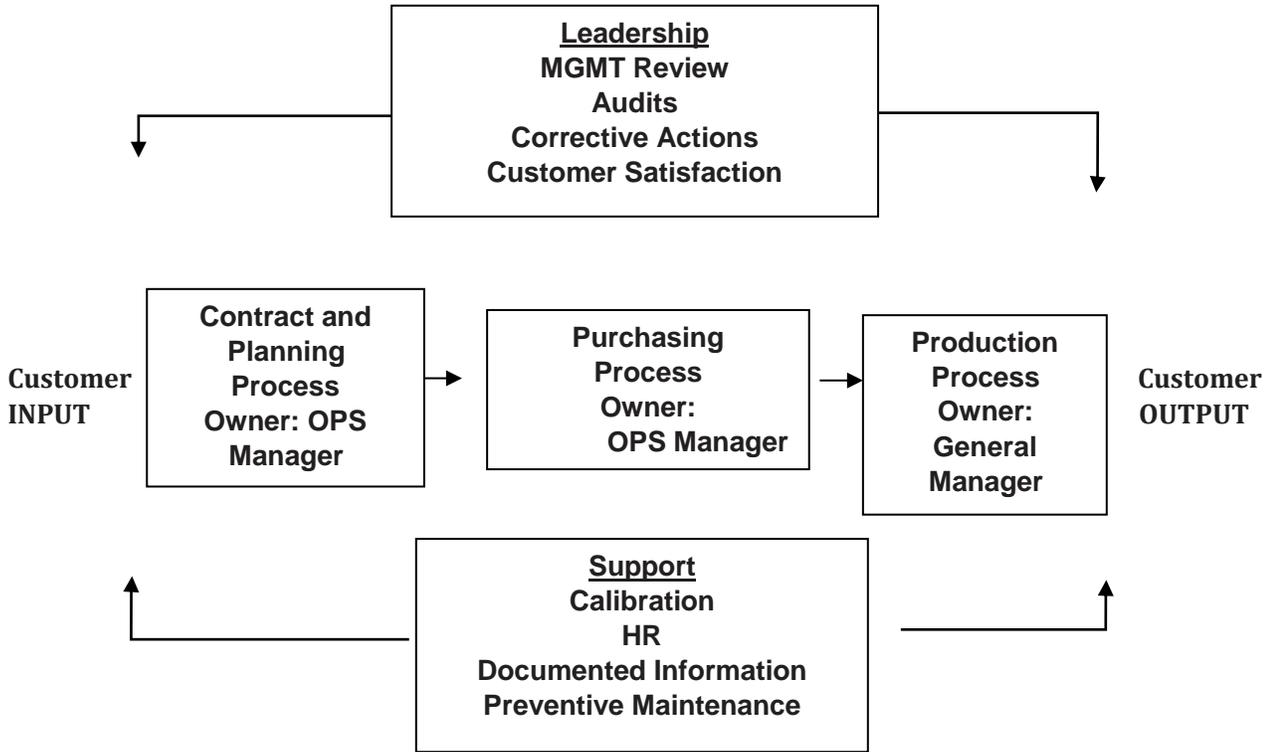
President Titanium shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

***The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.***

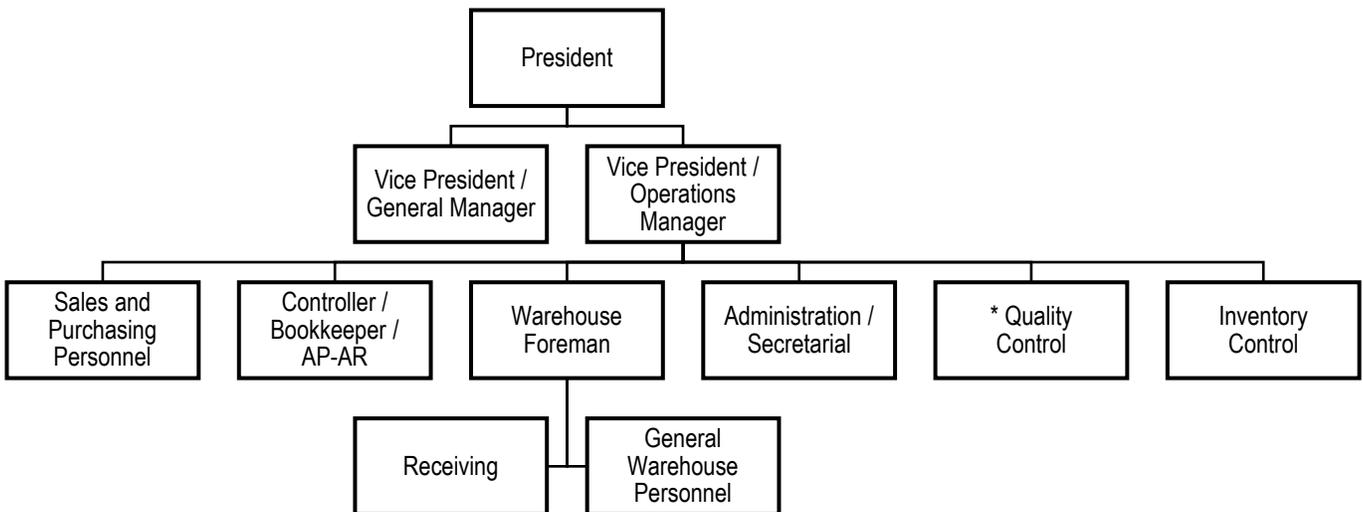
***NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.***

Appendix

President Titanium Process Flow Diagram and Processes



Organizational Chart



\*QMS Management Representative