Quality Management System Manual

Conforms to ISO 9001; ISO 13485; AS9100

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0.0 Revision History and Approval

Rev.	Nature of changes	Approval	Date
22	Original release in new format	Frank Meiland	03/21/2018
23	Revised to incorporate changes due to AS9100D	Frank Meiland	04/30/2018
24	Revised to remove Appendix B1, B2, and B3 and to remove references to the revisions of the standards (AS9100 rev C, ISO 9001 rev 2015, and ISO 13485 rev 2016) and changed scope of the QMS (ref. QAM section 4.3) from “contract manufacturer of precision swiss screw machine components” to “contract manufacturer of precision machined components”. Additionally, reviewed to ensure compliance to standards AS9100 rev D, ISO 9001 rev 2015, and ISO 13485 rev 2016.	Frank Meiland	05/08/2019
25	Revised section 4.3 to remove the terms not responsible and exclusion.	Frank Meiland	07/29/2019
26	Added justification for not applicable standard elements (Exclusions).	Jay Longbottom	08/14/2020
27	Updated verbiage from section 9.1.2 to new Customer Satisfaction tracking.	Mike Ledestich	4/18/2022
28	Updated section 9.3 Management Review	Mike Ledestich	6/14/2022
29	Updated manual to add new procedure numbers.	Mike Ledestich	4/13/2023
30	Updated to include exceptions and exclusions clauses in scope.	Mike Ledestich	08/11/2023
31	Edited to add correct exceptions and remove clause 8.3	Mike Ledestich	02/09/2023
32	Updated 4.3 to clarify exemption to standard clauses; Updated 4.4 interaction of processes; added Quality and Updated Appendix A	Mike Ledestich	02/20/24
33	Added Organizational Chart. 8.5.5 Updated to add Customer Complaint handling, and Customer notification.	Mike Ledestich	9/30/24

1.0 Welcome to Swiss-Tech, LLC

Since our inception in 1965, Swiss-Tech has supplied the medical, aerospace, hydraulic, electronic, and other industries with exceptional quality components produced on Swiss-style screw machines.

Swiss-Tech has been able to invest in the latest technology, automation, and an expansion of our state of-the-art facility. Leading-edge technology, combined with a highly skilled and dedicated workforce, and a carefully selected supplier base for special processes, enables us to provide complex, ready to use parts to our customers. We believe in continuous improvement in products, processes, and people. We consistently strive to exceed our customers' expectations.

The facility is located at:

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Delavan, WI 53115

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2.0 About the Swiss-Tech Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001, ISO 13485, and AS9100 international standards, as well as to demonstrate how the company complies with those standards.

This manual is not aligned with the clause numbering schemes of QMS [Quality Management System, specifically ISO 9001, ISO 13485, and AS9100].

This manual presents "Notes" which are used to define how Swiss-Tech, LLC has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in the relevant QMS. *Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is referenced in this manual, these are indicated by *bold italics*.

3.0 Terms and Definitions

Swiss-Tech, LLC adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in ***ISO 9000: Quality Management – Fundamentals and Vocabulary***. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, that definition will supersede those provided for in this Quality Manual or ISO 9000.

General Terminology

S-T, ST, or SWISS-TECH – Swiss-Tech, LLC

Document – written information used to describe how an activity is done.

Record – captured evidence of an activity having been done.

Risk-Based Thinking Terminology

Risk – Negative effect of uncertainty

Opportunity – Positive effect of uncertainty

Uncertainty - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

Nonconforming Product Terminology

Rework: Efforts to bring nonconforming product into conformance through additional operations that *do not* alter the original design of the product.

Scrap: The discard of nonconforming product in lieu of rework or repair.

4.0 Context of the Organization

4.1 Understanding the Organization and Its Context

Swiss-Tech, LLC. has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to Swiss-Tec and its interested parties (per 4.2 below); the interested parties are identified per SOP-QA-002 (Context of the Organization).

Such issues are monitored and updated as appropriate and are discussed as part of management reviews.

4.2 Understanding the Needs and Expectations of Interested Parties

The issues determined per 4.1 above are identified through an analysis of risks facing Swiss-Tech, LLC. and its interested parties. “Interested parties” are those stakeholders who receive our precision Swiss screw machined components, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified per SOP-QA-002 (Context of the Organization)**.**

This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the Scope of the Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Swiss-Tech, LLC has determined the scope of the management system as follows:

Swiss-Tech is a contract manufacturer of precision machined components.

The following are not applicable to Swiss-Tech, LLC.:

AS-9100 ISO-9001	ISO-13485	Requirement	Justification
8.3	7.3	Product Design, design control, distribution, or the use of these components	Swiss-Tech is a contract Manufacturer of Customer Designed precision machined components
8.5.5	N/A	Post-Delivery Activities: f) collection and analysis of in-service data (e.g., performance, reliability, lessons learned); g) control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul; h) controls required for work undertaken external to the organization (e.g., off-site work);	Swiss-Tech Delivers Precision Machined Components and does not perform Service, work external to the organization, or provide Technical Documentation.
N/A	7.5.3 7.5.4	Installation Activities Servicing Activities	Swiss-Tech does not Install or Service the precision machined components
N/A	7.5.5 7.5.7	Particular requirements for sterile medical devices Particular requirements for validation of processes for sterilization and sterile barrier systems	Swiss-Tech does not produce products that require sterilization.

4.4 Quality Management System and Its Processes

4.4.1 Process Identification

Swiss-Tech has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discreetly, this reduces the potential for nonconforming components discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

Note: not all activities are considered "processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

The following top-level processes have been identified for Swiss-Tech:

- Management,
- Customer Service, Sales/Marketing,
- Purchasing,
- Production

- Quality

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has a sub-Processes which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources.
- criteria and methods employed to ensure the effectiveness of the process.

The sequence of interaction of these processes is illustrated in Appendix A.

Note: Appendix A represents the typical sequence of processes and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.

4.4.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it's impact on Products or Services provided, and associated risks.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, who present this data to Swiss-Tech management. The data is then analyzed by Swiss-Tech Management in order that Swiss-Tech Management may set goals and adjust for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the minutes of Management Review, per section 9.3.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

4.4.3 Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in QMS System Procedure SOP-OPS-001 (Control of Purchasing).

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the purchasing contract requirements.

5.0 Leadership

5.1 Leadership & Commitment

5.1.1 General

Executive leadership team of Swiss-Tech, LLC provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the management system

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

c) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note)

d) promoting awareness of the process approach

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

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

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

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

i) promoting continual improvement

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

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

5.1.2 Customer focus

The management of Swiss-Tech, LLC adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements, and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

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.

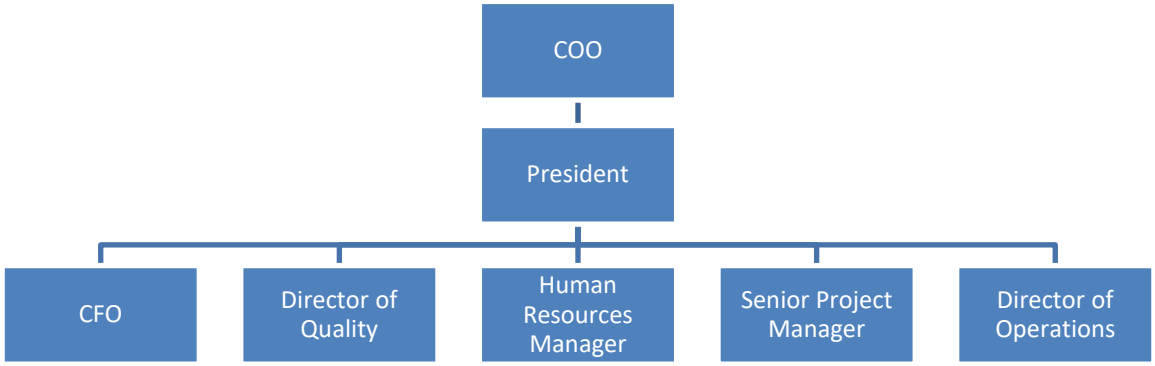
d) product and service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy

Management has developed the Quality Policy, defined in this section, that governs day-to-day operations to ensure quality.

The Quality Policy was released as a standalone document SF005 Quality Policy and is communicated and implemented throughout the organization.

5.3 Organizational Roles Responsibilities and Authorities



Org Chart 9/30/24

Executive Leadership has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through SF 158 Responsibilities and Authorities Table.

In addition, the following overall QMS responsibilities and authorities are assigned as follows:

Responsibility	Assigned To
Ensuring that the management system conforms to applicable standards	Executive Leadership
Ensuring that the processes are delivering their intended outputs	Applicable process owner
Reporting on the performance of the management system and providing opportunities for improvement for the management system	Quality Manager
Ensuring the promotion of customer focus throughout the organization	Executive Leadership
Ensuring that the integrity of the management system is maintained when changes are planned and implemented	Executive Leadership

The Quality Manager is appointed as the management representative with responsibility and authority for oversight of the above requirements. The management representative has organizational freedom and unrestricted access to top management to resolve quality management issues. Further, the Quality Manager has been assigned the role of single point of contact to represent the Swiss-Tech quality system where it is useful or required by customer or regulations. Other duties of the Quality Manager may be defined herein or within other documented procedures.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

Note: Swiss-Tech deviates slightly from the approach towards risk and opportunity presented in ISO 9001. Instead, Swiss-Tech views "uncertainty" as neutral, but defines "risk" as a potential negative effect of uncertainty, and "opportunity" as a potential positive effect of uncertainty. Swiss-Tech has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment, and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.

Swiss-Tech considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the "Context of the Organization Exercise" defined in SOP-QA-002 (Context of the Organization), as well as throughout all other activities of the QMS.

Risks and opportunities are managed in accordance with the document SOP-QA-016 (Risk and Opportunity). This procedure defines how risks are managed to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

6.2 Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, Swiss-Tech utilizes its process objectives, as discussed in 4.4 above, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work instructions or customer requirements.

The process objectives have been developed in consideration that they:

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.

Process quality objectives are defined in the minutes of management review per section 9.3 below.

6.2.2 Quality Objectives and Planning to Achieve Them

When planning how to achieve its quality objectives, the organization 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

Changes to the quality management system and its processes are being carried out in a planned manner per the procedure SOP-QA-010 (Management Review).

7.0 Support

7.1 Resources

7.1.1 General

Swiss-Tech determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness.

b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

7.1.2 People

The organization shall determine and provide the people necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

Swiss-Tech determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace, and associated facilities

b) process equipment, hardware, and software

c) supporting services such as transport

d) information and communication technology.

Equipment is validated per the procedure SOP-QA-013 (Process Validation) and maintained per the procedure SOP-OPS-008 (Preventive Maintenance).

7.1.4 Environment for the Operation of Processes

Swiss-Tech provides a clean, safe, and well-lit working environment. The Management of Swiss-Tech manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 7.1.3 above.

Human factors are considered to the extent that they directly impact on the quality of product requirements.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

7.1.5 Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see the procedure SOP-QA-001 (Calibration).

Note: Calibration and measurement traceability are not employed for all measurement devices. Instead, Swiss-Tech determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.

7.1.6 Organizational Knowledge

Swiss-Tech also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property.

b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

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

When addressing changing needs and trends, Swiss-Tech shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2 Competence

Staff members performing work affecting product quality are competent based on appropriate education, training, skills and experience. The documented procedure SOP-HR-001 (Training) defines these activities in detail.

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.3 Awareness

Training and subsequent communication ensure that staff are aware of:

a) the quality policy

b) relevant quality objectives

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

d) the implications of not conforming with the management system requirements.

7.4 Communication

Management of Swiss-Tech, LLC ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement

b) use of the results of analysis of data

c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS.

d) use of the results of the internal audit process

e) regular company meetings with all employees

f) internal emails

g) memos to employees

h) Swiss-Tech, LLC's "open door" policy which allows any employee access to management for discussions on improving the quality system.

7.5 Documented Information

The management system documentation includes both documents and records.

Note: the ISO 9001 standard uses the term "documented information"; Swiss-Tech, LLC does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined per section 3.0 above. Documents and records undergo different controls as defined herein.

The extent of the management system documentation has been developed based on the following:

- The size of Swiss-Tech, LLC
- Complexity and interaction of the processes
- Risks and opportunities
- Competence of personnel

Documents required for the management system are controlled in accordance with procedure SOP-QA-003 (Control of Documents). The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information.

All documented procedures are established, documented, implemented, and maintained.

A documented procedure SOP-QA-003 (Control of Documents) has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of component requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

8.0 Operation

8.1 Operational Planning and Control

Swiss-Tech plans and develops the processes needed for realization of its precision machined components. Planning of product realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization (see section 4.0 above), current resources and capabilities, (see section 6.0 above) as well as product requirements.

Such planning is accomplished through:

a) determining the requirements for the product

b) establishing criteria for the processes and the acceptance of the product

c) determining the resources needed to achieve conformity to the product requirements.

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

e) determining, maintaining, and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products to their requirements.

Changes to operational processes are made in accordance with the procedure SOP-ENG-005 (Job Change Request).

Outsourced processes and how Swiss-Tech controls them are defined in the documented procedure SOP-OPS-001 (Control of Purchasing).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Swiss-Tech has implemented effective communication with customers in relation to:

a) providing information relating to product requirements

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 Related to Products and Services

During the intake of new business Swiss-Tech captures:

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 specified or intended use, where known

c) statutory and regulatory requirements related to products and services offered.

d) any additional requirements determined by Swiss-Tech.

These activities are defined in greater detail in the procedures SOP-SALES-002 (Quotes) & SOP-SALES-003 (Receiving and Processing Customer Orders).

8.2.3 Review of Requirements Related to Products and Services

Once requirements are captured, Swiss-Tech reviews the requirements prior to its commitment to supply the product. This review ensures that Swiss-Tech has the capability and capacity to:

a) meet all requirements specified by the customer, including requirements for delivery and post-delivery activities.

b) meet any requirements not stated by the customer, but which Swiss-Tech knows as being necessary.

c) meet all requirements determined necessary by Swiss-Tech itself.

d) meet all related statutory and regulatory requirements.

e) meet any contract or order requirements differing from those previously expressed (i.e., from a previous Swiss-Tech quote).

These activities are defined in greater detail in the procedures SOP-ENG-006 (New Product Introduction) & SOP-SALES-003 (Receiving and Processing Customer Orders).

8.2.4 Changes to Requirements for Products and Services

Swiss-Tech updates all relevant requirements and documents when the requirements are changed and ensures that all appropriate staff are notified; see the documented procedure SOP-ENG-005 (Job Change Request.

8.4 Control of Externally Provided Processes, Products and Services

Swiss-Tech ensures that purchased products and services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased products or services are dependent on the effect on subsequent product realization or the final product.

Swiss-Tech evaluates and selects suppliers based on their ability to supply products and services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not provide conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in the documents SOP-OPS-001 (Control of Purchasing), SOP-OPS-11 (Supplier Selection/Evaluation), and SOP-OPS-012 (Receiving Inspection).

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

To control its provision of products, Swiss-Tech considers, as applicable, the following:

a) the availability of documents or records that define the characteristics of the product, as well as the results to be achieved.

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

c) the implementation of monitoring and measurement activities

d) the use of suitable infrastructure and environment

e) the appointment of competent persons, including any required qualifications

f) the validation and revalidation of special processes if applicable (see below)

g) the implementation of actions to prevent human error.

h) the implementation of release, delivery, and post-delivery activities.

Swiss-Tech outsources some “special processes” where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to outside suppliers and controlled per SOP-OPS-001 (Control of Purchasing).

Swiss-Tech utilizes some “special processes” where the result of the process cannot be verified by subsequent monitoring or measurement. The special processes in use and the methods of validation of

each are defined in the document SOP-QA-013 (Process Validation).

8.5.2 Identification and Traceability

Swiss-Tech identifies products by suitable means throughout product realization. Such identification includes the status of the product with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all products shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, Swiss-Tech controls and records the unique identification of the products.

The documented procedures SOP-OPS-007 (Product ID & Traceability) & SOP-OPS-004(Material ID and Traceability) define these methods in detail.

8.5.3 Property Belonging to Customers or External Providers

Swiss-Tech exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected, and safeguarded. If any such property is lost, damaged, or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage, or inappropriate use.

This activity is defined in greater detail in the documents SOP-ENG-004 (Customer Drawings & Specs) SOP-OPS-010 (Customer Supplied Material).

8.5.4 Preservation

Swiss-Tech preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

The documented procedure SOP-OPS-009 Handling, Storage, Packaging, Preservation and Shipping defines the methods for preservation of product.

8.5.5 Post-Delivery Activities

Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, Swiss-Tech considers:

a) statutory and regulatory requirements

b) the potential undesired consequences associated with its products.

c) the nature, use and intended lifetime of its products.

d) customer requirements

e) customer feedback.

As applicable, Swiss-Tech conducts the following activities which are considered "post-delivery activities":

- **Complaint handling,**

Complaint handling at Swiss-Tech maintains documented procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures include at a minimum requirements and responsibilities for:

a) Receiving and Recording Information
b) Evaluating information to determine if the feedback constitutes a complaint.
c) Investigating complaints
d) Determining the need to report the information to the appropriate regulatory authorities.
e) Handling of complaint-related product
f) Determining the need to initiate corrections or corrective actions

If any complaint is not investigated, justification shall be documented.

- **Actions in response to nonconforming product detected after delivery.**

Actions in response to is maintained in documented procedure for the notification of Customer and Regulatory Agencies. Records of the documented communication are maintained.

These activities are defined in greater detail int procedure SOP-SALES-001 (Customer Satisfaction) and SOP-QA-019 (Control of Nonconformances)

8.5.6 Control of Changes

Swiss-Tech reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in the document SOP-ENG-005 (Job Change Request).

Documents are changed in accordance with procedure SOP-ENG-005 (Job Change Request).

8.6 Release of Products and Services

Acceptance criteria for products are defined in appropriate subordinate documentation. Reviews, inspections, and tests are conducted at appropriate stages to verify that the requirements have been met. This is done before products are released or delivered.

Each process utilizes different methods for measuring and releasing products. These methods are defined in procedures SOP-QA-008 (In process Inspection) & SOP-QA 004 (Final Inspection).

8.7 Control of Nonconforming Outputs

Swiss-Tech ensures that products that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The controls for such nonconformances are defined in SOP-QA-11 (Nonconforming Material).

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Swiss-Tech has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality System Manual and subordinate documentation.

Monitoring and measurement of the processes, as defined in 4.4 above, ensure that the performance and effectiveness of the quality management system itself are evaluated.

9.1.2 Customer Satisfaction

As one of the measurements of the performance of the management system, Swiss-Tech monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns.
- Customer corrective action requests
- changing volume of orders for product
- trends in on-time delivery
- obtain customer scorecards from certain customers.
- tracking new customer part numbers by key growth accounts

The corrective and preventive action system shall be used to 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

Swiss-Tech analyzes and evaluates the data and information arising from monitoring and measurement to evaluate:

a) conformity of products
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.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

9.2 Internal Audit

Swiss-Tech conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of the following standards [ISO 9001, ISO 13485, AS9100] and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in the document SOP-QA-009 (Internal Audits).

9.3 Management Review

9.3.1 General

Management reviews the management system, at planned intervals (April and October), to ensure its continuing suitability, adequacy, and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the Quality Policy and quality objectives.

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, corrective actions, preventive actions and complaints
5. monitoring and measurement results/processes
6. audit results
7. the performance of external providers
8. on-time delivery performance
9. the adequacy of resources
10. the effectiveness of actions taken to address risks and opportunities
11. opportunities for improvement.
12. reporting to regulatory authorities.
13. monitoring and measurement of processes
14. applicable new or revised regulatory requirements

9.3.3 Management Review Outputs

The output from management review shall be recorded and include the input reviewed and any decisions and actions. The outputs of the management review shall include decisions and actions related to:

a. opportunities for improvement in regard to the suitability, adequacy, and effectiveness of the quality management system and its processes.
b. any need for changes to the quality management system
c. resource needs
d. risks identified.
e. improvement of product related to customer requirements.
f. changes needed to respond to applicable new or revised regulatory requirements.

Records from management reviews are maintained.

10.0 Improvement

10.1 General

The organization 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

10.2 Nonconformity and Corrective Action

Swiss-Tech takes corrective action to eliminate the cause of nonconformity to prevent recurrence. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities to prevent their occurrence.

These activities are done using the formal Corrective Action system and are defined in the procedure SOP-QA-005 (Corrective Action).

10.3 Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, Swiss-Tech works to continually improve the suitability, adequacy, and effectiveness of the quality management system. This includes seeking opportunities for improvement.

The need for preventive action is defined in the procedure SOP-QA-012 (Preventive Action).

Appendix A: Overall Process Sequence & Interaction