AS9100:2016 Quality Manual

Table of Contents

1. Revision History

Revision	Date	Description	Approved By
A	07/17/2020	Initial Release for AS9100:2016	Craig Cougle

2. Introduction

Our organization has developed a Quality Management System to better satisfy the needs of its customers and to continually improve the overall management of the company.

The purpose of this manual is to document LAI International Inc.'s Quality Management System, define the Quality Policy and Objectives, instruct and guide employees, and define the controls implemented to assure product quality and customer satisfaction.

The quality system conforms to the requirements of the International Standard AS9100:2016. It describes the major processes associated with our business as identified in Appendix E [Process Flow Map].

This Flow Map also shows the interaction of these processes, identifies procedures along with Appendix G [QMS Structure] that detail how activities are performed, and identifies measuring methods for all processes so management can assure the system is functioning as intended. Appendix E [Process Flow Map] also identifies both the Core Processes and Support Processes our organization has determined to be necessary for the successful implementation and sustainment of our QMS.
Core Processes are those that directly impact the operational functions that drive the organizations product or service outputs.
Support Process are those that provide support for the effective operation of one or more Core Process and are typically evaluated in conjunction with each Core Process, as applicable.

3. Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO9000:2015.

4. Context of the organization

4.1. Understanding the organization and its context

Our organization determines external and internal issues that are relevant to our purpose and our strategic direction and that affect our ability to achieve the intended result of our quality management system.

Our organization monitors and reviews information about these external and internal issues as described in SOP-07 [Management Review].

4.2. Understanding the needs and expectations of interested parties

Due to their effect or potential effect on our organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, our organization sets forth Appendix F [Interested Parties] which defines:

a) the interested parties who are relevant to our quality management system;

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

Our organization monitors and reviews information about these interested parties and their relevant requirements as described in Appendix F [Interested Parties].

4.3. Determining the scope of the quality management system

Our organization defines the boundaries and applicability as well as the scope of our quality management system as set forth in the table below:

Facility	Scope of Work	Elements that are Applicable
LAI International, Inc. 1110 Business Parkway South, Westminster, MD, 21157	Provider of Conventional Machining, Laser, and Water-Jet Material Processing	All elements are applicable except section 8.3.

When determining this scope, our organization considers:

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 our organization.

Our organization applies all the requirements of the AS9100:2016 International Standard if they are applicable within the determined scope of our quality management system.

Justification for Elements that are Not Applicable:

Our organization does not perform any product design activity (8.3) as we provide goods or services based on customer requirements only.

The scope of our organization's quality management system (as stated above) shall be available and be maintained. It states the types of products and a service covered and provides justification for any requirement of this International Standard that our organization determines is not applicable to the scope of our quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect our organization'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

4.4.1. Quality Management System

Our organization has established, implemented, maintains and continually improves our quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

Our organization's quality management system also addresses customer and applicable statutory and regulatory quality management system requirements.

Our organization has determined the processes needed for our quality management system and their application throughout our organization, and:

a) defines the inputs required and the outputs expected from these processes in Appendix E [Process Flow Map];

b) defines the sequence and interaction of these processes in Appendix E [Process Flow Map];

c) defines and applies the criteria and methods needed to ensure the effective operation and control of these processes as described in Appendix E [Process Flow Map] and in specific procedures related to each Core Process;

d) defines the resources needed for these processes as described in Appendix E [Process Flow Map] and in specific procedures related to each Core Process and ensures their availability;

e) assigns the responsibilities and authorities for these processes in Appendix E [Process Flow Map] and in specific procedures related to each Core Process;

f) addresses risks and opportunities as defined in SOP-06 [Risk Management];

g) evaluates these processes as described in SOP-03 [Internal Audit] and implements any changes needed to ensure that these processes achieve their intended results as described in SOP-05 [Corrective Action];

h) improves the processes and the quality management system.

4.4.2. Documented Information

To the extent necessary, our organization:

a) maintains documented information to support the operation of its processes as described in SOP-01 [Document Control];

b) retains documented information to have confidence that the processes are being carried out as planned as described in SOP-02 [Record Control].
Our organization has established and maintains documented information that includes:

- a general description of relevant interested parties in Appendix F [Interested Parties]
- the scope of the quality management system, including boundaries and applicability in QM-1 [Quality Manual] Section 4.3
- a description of the processes needed for the quality management system and their application throughout the organization in Appendix E [Process Flow Map]
- the sequence and interaction of these processes in Appendix E [Process Flow Map]
- assignment of the responsibilities and authorities for these processes in Appendix E [Process Flow Map] and related Procedures

5. Leadership

5.1. Leadership and commitment

5.1.1. General

Top management shall demonstrate leadership and commitment with respect to our quality management system by:

a) taking accountability for the effectiveness of the quality management system through engagement in the Management Review process as outlined in SOP-07 [Management Review];

b) ensuring that Appendix A [Quality Policy] and Appendix B [Quality Objectives] are established for our quality management system and are compatible with the context and strategic direction of our organization;

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

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

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

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

i) promoting improvement;

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

5.1.2. Customer focus

Top management 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 as described in SOP-10 [Contract Review];

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed as described in SOP-06 [Risk Management];

c) the focus on enhancing customer satisfaction is maintained.

d) product and service conformity and on-time delivery performance are measured as described in Appendix B [Quality Objectives] 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 has established, implemented and maintains Appendix A [Quality Policy] that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for establishing Appendix B [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

Appendix A [Quality Policy] shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.3. Organizational roles, responsibilities and authorities

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

Through the use of Appendix C [Organization Chart] and Appendix D [Roles & Responsibilities], top management assigns the responsibility and authority for:

a) ensuring that our quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of our quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of our quality management system is maintained when changes to the quality management system are planned and implemented.

Top management has appointed a specific member of the organization's management in Appendix C [Organization Chart], identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.

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

6. Planning

6.1. Actions to address risks and opportunities

6.1.1. Consideration and Determination of Risk

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

a) give assurance that our quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

The result of the consideration and determination of these risks and opportunities is the Quality Management System itself. Procedures are put into place for controlling specific activities or processes. Our organization creates SOPs (i.e. Document Control, Internal Audit, Corrective Action, etc.) that we deem to be necessary to mitigate risk or capitalize on opportunities, and to ensure effective planning, operation, and control of our processes.

6.1.2. Risk Planning

As stated above, our organization sets forth procedures and instructions in our Quality Management System in order to 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

6.2. Quality Objectives and planning to achieve them

6.2.1. Establishing Quality Objectives

Our organization has established Appendix B [Quality Objectives] to describe measurements for relevant functions, levels and processes needed for our quality management system.

The Quality Objectives shall:

a) be consistent with Appendix A [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.

Our organization maintains Appendix B [Quality Objectives] as documented information.

6.2.2. Planning Quality Objectives

When planning how to achieve our Quality Objectives, our organization determines:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3. Planning of changes

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

Our organization considers:

a) the purpose of the changes and their potential consequences;

b) the integrity of our quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7. Support

7.1. Resources

7.1.1. General

Our organization determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of our quality management system.

Our organization considers:

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

b) what needs to be obtained from external providers.

7.1.2. People

Our organization determines and provides the persons necessary for the effective implementation of our quality management system and for the operation and control of our processes.

7.1.3. Infrastructure

Our organization determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4. Environment for the operation of processes

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

7.1.5. Monitoring and measuring resources

7.1.5.1. General

As described in SOP-09 [Calibration], our organization determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Our organization ensures 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.

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

7.1.5.2. Measurement Traceability

When measurement traceability is a requirement, or is considered by the organization 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.

Our organization has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification as described in SOP-09 [Calibration].

Our organization maintains a register of the monitoring and measuring equipment as described in SOP-09 [Calibration]. The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions as described in SOP-09 [Calibration].

Our organization determines 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

Our organization determines 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, our organization considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2. Competence

As described in SOP-08 [Training], our organization:

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

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

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

d) retains appropriate documented information as evidence of competence.

7.3. Awareness

Our organization ensures that persons doing work under our organization's control are aware of:

a) Appendix A [Quality Policy];

b) relevant measurements established in Appendix B [Quality Objectives];

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

d) the implications of not conforming with our 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

Our organization determines the internal and external communications relevant to our quality management system, including:

a) on what we will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

Our organization communicates through periodic internal and external correspondence as and when applicable, at the discretion of upper management.(sales meetings, customer discussions, shop floor walks, staff meetings, management reviews, etc.).

7.5. Documented Information

7.5.1. General

Our organization's quality management system includes:

a) documented information required by this International Standard;

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

7.5.2. Creating and updating

As described in SOP-01 [Document Control], when creating and updating documented information, our organization ensures appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3. Control of documented information

7.5.3.1. Protection and Availability

As described in SOP-01 [Document Control], documented information required by our quality management system and by this International Standard 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. Distribution

As described in SOP-01 [Document Control] and SOP-02 [Record Control], for the control of documented information, our organization addresses the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

e) prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled as described in SOP-01 [Document Control] .

Documented information retained as evidence of conformity shall be protected from unintended alterations as described in SOP-02 [Record Control].

When documented information is managed electronically, data protection processes shall be defined as described in SOP-02 [Record Control].

8. Operation

8.1. Operational planning and control

As described in SOP-12 [Production & Inspection], our organization plans, implements and controls 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;

b) establishing criteria for:
1) the processes;

2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

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) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

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

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

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

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

As appropriate to our organization, customer requirements, and products and services, our organization plans and manages product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints as described in SOP-12 [Production & Inspection].

The output of this planning shall be suitable for our organization's operations.

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

Our organization ensures that outsourced processes are controlled (see 8.4) as described in SOP-11[Purchasing & Receiving].

Our organization has established, implemented, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements as described in SOP-11[Purchasing & Receiving]. The process ensures that work transfer impacts and risks are managed.

8.1.1. Operational Risk Management

Our organization planned, implemented, and controls a process for managing operational risks to the achievement of applicable requirements as described in SOP-06 [Risk Management], which includes as appropriate to our organization and the products and services:

a) assignment of responsibilities for operational risk management;

b) definition of risk assessment criteria;

c) identification, assessment, and communication of risks throughout operations;

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

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

8.1.2. Configuration Management

Our organization planned, implemented, and controls 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 as described in SOP-12 [Production & Inspection].

This process:

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

b) ensures that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3. Product Safety

Our organization planned, implemented, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to our organization and the product through the use of specific instructions only where applicable. Product Preservation is addressed in section 8.5.4.

8.1.4. Prevention of Counterfeit Parts

Our organization planned, implemented, and controls processes, appropriate to our organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

8.2. Requirements for products and services

8.2.1. Customer communication

As governed by SOP-10 [Contract Review], 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

As described in SOP-10 [Contract Review], when determining the requirements for the products and services to be offered to customers, our organization ensures that:

a) the requirements for the products and services are defined, including:
1) any applicable statutory and regulatory requirements;

2) those considered necessary by the organization;

b) the organization can meet the claims for the products and services it offers

c) special requirements of the products and services are determined;

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

8.2.3. Review of the requirements for products and services

8.2.3.1. Organizational Ability

As described in SOP-10 [Contract Review], our organization ensures that it has the ability to meet the requirements for products and services to be offered to customers. Our organization conducts 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 the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

Our organization ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by our organization before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2. Retention of Documentation

As described in SOP-02 [Record Control] our organization retains documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4. Changes to requirements for products and services

As described in SOP-10 [Contract Review] our organization ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3. Design and development of products and services

Our organization does not design any product, and therefore Section 8.3 is not applicable.

8.4. Control of externally provided processes, products and services

8.4.1. General

As described in SOP-11[Purchasing & Receiving], our organization ensures that externally provided processes, products and services conform to requirements.

Our organization is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

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

Our organization identifies and manages the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers as described in SOP-11[Purchasing & Receiving].

Our organization requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met as described in SOP-11[Purchasing & Receiving].

Our organization determines the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into our organization's own products and services;

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

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

As described in SOP-11[Purchasing & Receiving], our organization determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Our organization retains documented information of these activities and any necessary actions arising from the evaluations as defined in SOP-02 [Record Control].

8.4.1.1. As described in SOP-11[Purchasing & Receiving] our organization:

a) defines 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) maintains 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 reviews external provider performance including process, product and service conformity, and on-time delivery performance as described in SOP-07 [Management Review] and Appendix B [Quality Objectives];

d) defines the necessary actions to take when dealing with external providers that do not meet requirements;

e) defines the requirements for controlling documented information created by and/or retained by external providers.

8.4.2. Type and extent of control

As described in SOP-11[Purchasing & Receiving], our organization ensures that externally provided processes, products and services do not adversely affect our organization's ability to consistently deliver conforming products and services to its customers.

Our organization 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;

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

8.4.3. Information for external providers

As described in SOP-11[Purchasing & Receiving], our organization ensures the adequacy of requirements prior to their communication to the external provider.

Our organization communicates to external providers its requirements for:

a) the processes, products and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);

b) the approval of:
1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with our organization;

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

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

g) design and development control;

h) special requirements, critical items, or key characteristics;

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

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

k) 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);

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

- flow down to external providers applicable requirements including customer requirements;

- provide test specimens for design approval, inspection/verification, investigation, or auditing;

- retain documented information, including retention periods and disposition requirements;

l) 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;

m) 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

8.5.1. Control of production and service provision

As described in SOP-12 [Production & Inspection], our organization implements 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;

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 (i.e., matching the sampling plan to the criticality of the product and to the process capability).

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

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

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

i) the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

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

k) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

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

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

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

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

p) the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);

q) the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

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 are validated prior to final release for production and are maintained.

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

8.5.1.2. Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, our organization has established arrangements for these processes including, as applicable:

a) definition of criteria for the review and approval of the processes;

b) determination of conditions to maintain the approval;

c) approval of facilities and equipment;

d) qualification of persons;

e) use of specific methods and procedures for implementation and monitoring the processes;

f) requirements for documented information to be retained.

8.5.1.3. Production Process Verification

Our organization has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.

As described in SOP-12 [Production & Inspection] our organization uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

Our organization retains documented information on the results of production process verification as described in SOP-02 [Record Control].

8.5.2. Identification and traceability

As described in SOP-12 [Production & Inspection], our organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Our organization maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

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

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), our organization establishes controls for the media.

Our organization controls the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability as described in SOP-02 [Record Control].

8.5.3. Property belonging to customers or external providers

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

The organization identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, our organization shall report this to the customer or external provider and retain documented information on what has occurred as described in SOP-02 [Record Control].

8.5.4. Preservation

Our organization preserves 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.

When our organization identifies the need for preservation methods outside of standard practices or those required by section 8.1.3, instructions to achieve those requirements will be included in the planning where applicable.

8.5.5. Post-delivery activities

Our 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, our organization considers:

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) 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);

i) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

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

8.5.6. Control of changes

As described in SOP-12 [Production & Inspection], our organization reviews 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.

Our organization retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review as described in SOP-02 [Record Control].

8.6. Release of products and services

As described in SOP-12 [Production & Inspection], our organization implements 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.

Our organization retains 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.

When required to demonstrate product qualification, our organization ensures that retained documented information provides evidence that the products and services meet the defined requirements as described in SOP-02 [Record Control].

Our organization ensures that all documented information required to accompany the products and services are present at delivery.

8.7. Control of nonconforming outputs

8.7.1. Unintended use

As described in SOP-04 [Control of Nonconforming Product], our organization ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Our organization 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.

Our organization's nonconformity control process is maintained as documented information in SOP-04 [Control of Nonconforming Product] 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.

Our organization deals with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession a relevant authority and, when applicable, by the customer.

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

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

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

Product dispositioned for scrap 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. Retention of Documentation

As described by SOP-02 [Record Control], our organization retains documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity.

9. Performance evaluation

9.1. Monitoring, measurement, analysis and evaluation

9.1.1. General

As described in Appendix B [Quality Objectives], our organization determines:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analyzed and evaluated.

Our organization shall evaluate the performance and the effectiveness of the quality management system as described in SOP-07 [Management Review].

Our organization retains appropriate documented information as evidence of the results as described in SOP-02 [Record Control].

9.1.2. Customer satisfaction

Our organization monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Our organization determines the methods for obtaining, monitoring and reviewing this information as described in Appendix B [Quality Objectives].

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. Our organization develops and implements 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

As described in SOP-07 [Management Review], our organization analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

9.2. Internal Audit

9.2.1. Conduct of Internal Audits

As described in SOP-03 [Internal Audit], our organization conducts internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:
    1) our organization's own requirements for its quality management system;

    2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2. Audit Program

As described in SOP-03 [Internal Audit], our organization:

a) plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) defines the audit criteria and scope for each audit;

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

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

e) takes appropriate correction and corrective actions without undue delay;

f) retains documented information as evidence of the implementation of the audit program and the audit results as described in SOP-02 [Record Control].

9.3. Management review

9.3.1. General

Top management shall review our organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization as described in SOP-07 [Management Review].

9.3.2. Management review inputs

As described in SOP-07 [Management Review], 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.

Our organization retains documented information as evidence of the results of management reviews as described in SOP-02 [Record Control].

10. Improvement

10.1. General

Our organization determines and selects opportunities for improvement and implements any necessary actions needed 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

10.2.1. Control and Correction

As described in SOP-05 [Corrective Action], when nonconformity occurs, including those arising from complaints, our organization 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;

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.

Our organization maintains documented information that defines the nonconformity and corrective action management processes in SOP-04 [Control of Nonconforming Product] and SOP-05 [Corrective Action].

10.2.2. Retention of Documentation

As described in SOP-02 [Record Control], our organization 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

Our organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

Our organization considers the results of analysis and evaluation and the outputs from management review, in order to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Our organization monitors the implementation of improvement activities and evaluates the effectiveness of the results as described in SOP-07 [Management Review].