Quality Management System Manual ISO 9001-15

Fowler's Sheet Metal, Inc.

4700 Georgia Avenue

West Palm Beach, FL 33405

Manual Content

SECTION 1
Introduction

1.1 Introduction

Fowler's Sheet Metal, Inc. (FSM) developed and implemented a Quality Management System to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of FSM meets the requirements of the international standard ISO 9001-15. This system addresses the production, installation, and servicing of the company's products to implement this quality management system, FSM has:

- Identified the processes required for the quality management system;
- Determined the sequence and interaction of these processes;
- Determined criteria and methods required to verify the effective operation and control of these processes
- Verified the availability of information necessary to support the operation and monitoring of these processes;
- Measured, monitored and analyzed these processes, and implemented action necessary to achieve planned results and continual improvement.

FSM has committed to control outsourced process to verify such processes are carried out based on the contractual requirements. The extent of control will be as follows:

- the potential impact of the externally provided processes, products and services on FSM's ability to consistently meet customer and applicable statutory and regulatory requirements;
- Degree to which the control of the process is shared
- Capability of achieving the control through paragraph 7.4 Communication of this Quality Manual

The manual is divided into twelve sections; the first ten sections correlate to the Quality Management System sections of ISO 9001-15. Sections eleven and twelve contain additional information. Each section begins with a policy statement expressing FSM's obligation to implement the basic requirements of the referenced Quality Management System section.

1.2 Objective of the Quality Manual

The Quality Manual specifies requirements for a quality management system (QMS) to be applied to FSM when an organization:

1. needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
2. Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
3. Intends to be certified per ISO 9001-15

All the requirements of the Quality Manual are intended to be applicable to FSM. This manual also provides the guideline to implement the process in systematic way and where necessary, the generation of procedures could be important as an explanatory statement for each unit of operation to run the process.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to verify compliance to the necessary requirements of the standard.\

1.3 Normative Reference

- American National Standard ANSI/ISO/ASQ Q9000-2015, Fundamental and Vocabulary.

1.4 Terms and Definitions

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

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

1.5 Vision Statement

FSM desires to be provider of precision fabricated metal services that surpasses the customers' expectations.

1.6 Mission Statement

Mission –

a) Commitment and desire to go above and beyond the customer's expectations
b) Embrace opportunities and overcome challenges
c) Work hard, get along with each other and be happy!

1.7 Quality System Documentation Distribution

The quality manual and all system documentation will be distributed and maintained electronically on the company server. All employees that may have an impact on quality have access to this information through the computer network. FSM does not utilize a paper copy distribution system. The Office Manager will maintain a paper copy of initial document releases and all subsequent revisions until such time the registration company approves electronic record files.

SECTION 2
Fowler's Sheet Metal, Inc. Profile

FSM developed and implemented a Quality Management System to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of FSM meets the requirements of the international standard ISO 9001 (2015). This system addresses the production, installation, and servicing of the company's products.

The manual is divided into ten sections that correlate to the Quality Management System sections of ISO 9001 - 2015. Each section begins with a policy statement expressing FSM's obligation to implement the basic requirements of the referenced Quality Management System section.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides references for all activities comprising the Quality Management System to verify compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained to verify customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

SECTION 3
Abbreviations & Anachronisms

Integrated Phased Processes (IPP)

(Product Life Cycle Phases like the following)

1. Planning
2. Product design and development
3. Process design and development
4. Product and process validation
5. Production

SECTION 4

Description of the Quality System

4. Organizational Context (business environment)

4.1 Understanding the context (business environment) of FSM

The management of FSM has determined external and internal concerns that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. **Procedure P-400 – Context (business environment) of the Organization**, Resolution of the concerns has been demonstrated using risk analysis methods and documentation. Realization of risk analysis will be performed per the guidance documented in section 6.1 Risk Management in the Quality Manual.
FSM monitors and reviews the risk analysis documents to verify prevention of negative impacts or risks to FSM's business and verify consequences of the concerns will not jeopardize the opportunities for FSM;

- Concerns can include positive and negative factors or conditions for consideration
- Understanding the external context (business environment) can be achieved by considering concerns arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
- Understanding the internal context (business environment) can be achieved by considering concerns related to values, culture, knowledge and performance of the organization.

Any changes in external and internal concerns that are relevant to the quality management system, will be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on FSM's ability to consistently provide products and / or services that meet customer and applicable statutory and regulatory requirements, the **top management** of FSM has determined:

1. the interested parties that are relevant to the quality management system implemented within FSM
2. the requirements of these interested parties that are relevant to the quality management system. These includes the fulfillment of requirement to meet the product specification and compliance with the applicable laws.

The organization will monitor and review information about the needs of interested parties and their relevant requirements.

4.3 Scope of Quality Management System

The **top management** of FSM has determined the limitations and applicability of the quality management system to establish its scope for certification. Consideration of the following points is important for FSM before determining the scope of certification

1. the external and internal concerns referred to in paragraph 4.1 Understanding the organization and its context (business environment) of the ISO 9001 standard
2. the requirements of relevant interested parties referred to in paragraph 4.2 Understanding the needs and expectations of interested parties of the ISO 9001 standard
3. the products and services of FSM.

FSM will apply all the requirements of ISO 9001 as applicable within the determined scope of quality management system.

By stating the above-mentioned scope, justification is also being provided to determine any requirement of the ISO 9001 Standard that FSM is not required to maintain.
FSM confirmed that the following elements are not applicable and do not affect the organization's ability or responsibility to verify the conformity of its products and services and the enhancement of customer satisfaction;

1. The design and development requirements do not apply to Fowler's Sheet Metal.
FSM does not engage in the design of product and does not have design change authority.

4.4 Quality Management System and its processes

The **top management** of FSM shall establish, implement, maintain and continually improve a quality management system, including the processes required and their interactions, in accordance with the requirements of ISO 9001- 2015.
FSM has determined the processes required for the quality management system and its application throughout the FSM as follows:

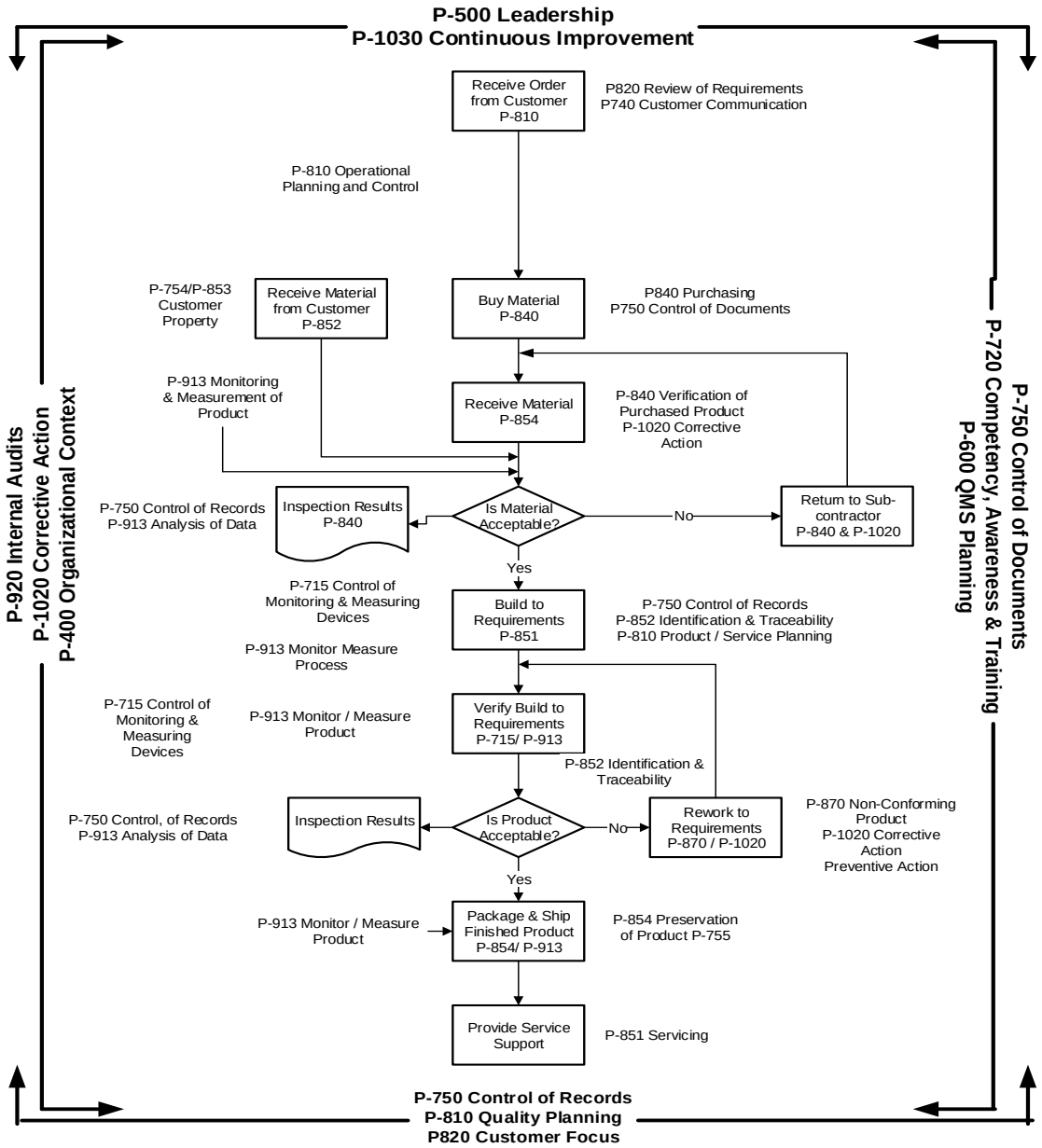
To design and implement the QMS FSM has:

- Determined the processes and necessary monitoring, including outsourced processes required for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods required to verify that the operation and control of the processes are effective, and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table F913-02A
- Verified the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyze these processes, and

- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

All above mentioned documented information will be maintained and controlled through **Documented Information Control Procedure P-750**

ISO QMS Process Flow Diagram



SECTION 5
Leadership and Commitment

Top management of FSM shall demonstrate leadership and commitment with respect to the quality management system through **Procedure P-500 Leadership and Commitment** and the following;

5.1 General responsibilities;

1. accepting accountability for the effectiveness of the quality management system
2. ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context (business environment) and strategic direction of the organization;
3. ensuring the integration of the quality management system requirements into the organization's business processes
4. promoting the use of the process approach and risk-based thinking;
5. ensuring that the resources required for the quality management system are available;
6. communicating the importance of effective quality management and of conforming to the quality management system requirements;
7. ensuring that the quality management system achieves its intended results;
8. engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
9. promoting improvement;
10. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
    - Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.2 Customer Focus

Top management of FSM has demonstrated leadership and commitment with respect to customer focus by:

- Ensuring customer requirements are determined, understood and consistently met Refer to paragraph 8.2. Requirement for products and services in the Quality Manual
- applicable statutory and regulatory requirements are determined, understood and consistently met Reference: Legal Register List and Evaluation
- mitigate the risks and opportunities that can affect conformity of products and services. Reference: Risk analysis documents
- ensuring the ability to enhance customer satisfaction is determined and addressed and maintained to focus on enhancing customer satisfaction. Reference: Paragraph 9.1.2 Customer satisfaction in the Quality Manual

5.2 Quality Policy

Top management of FSM established, implemented and maintained a quality policy that:

- is appropriate to the purpose and context (business environment) of the organization and supports its strategic direction
- provides a framework for setting quality objectives
- includes a commitment to satisfy applicable requirements, statutes and regulations
- includes a commitment to continual improvement of the quality management system.

This quality policy shall be:

- maintained as documented information; and controlled through Documented Information in the Quality Manual
- communicated, understood and applied within the organization
- available to relevant interested parties, as appropriate.

The Quality Policy stated in the Quality Policy Document P-520

5.3 Organizational Roles, Responsibility and Authorities

Top management of FSM verify that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. **Top management** of FSM assigns the responsibility and authority for executing the following tasks:

- **Responsibility**; ensuring that the quality management system conforms to the requirements of the ISO 9001 standard. Achieved through:

    1. Internal Audit (refer to paragraph 9.2 Internal Audit in the Quality Manual and
    2. Management review per paragraph 9.3 Management Review in the Quality Manual
       Awareness of every staff through paragraph 7.3 Awareness in the Quality Manual

- **Responsibility:** ensuring that the processes are delivering their intended outputs; Achieved through:

    1. Business Process Mapping,
    2. Paragraph 8.5.1 Production control in the Quality Manual

- **Responsibility**: Reporting on the performance of the quality management system.
  Achieved through: Key Process Indicators and Management review

- **Responsibility**: Reporting on opportunities for improvement (see 10.1), to **top management** of FSM achieved through: Quality Manual

    1. Paragraph 10.2 Nonconformity and corrective action, and
    2. Paragraph 10.3 Continual Improvement

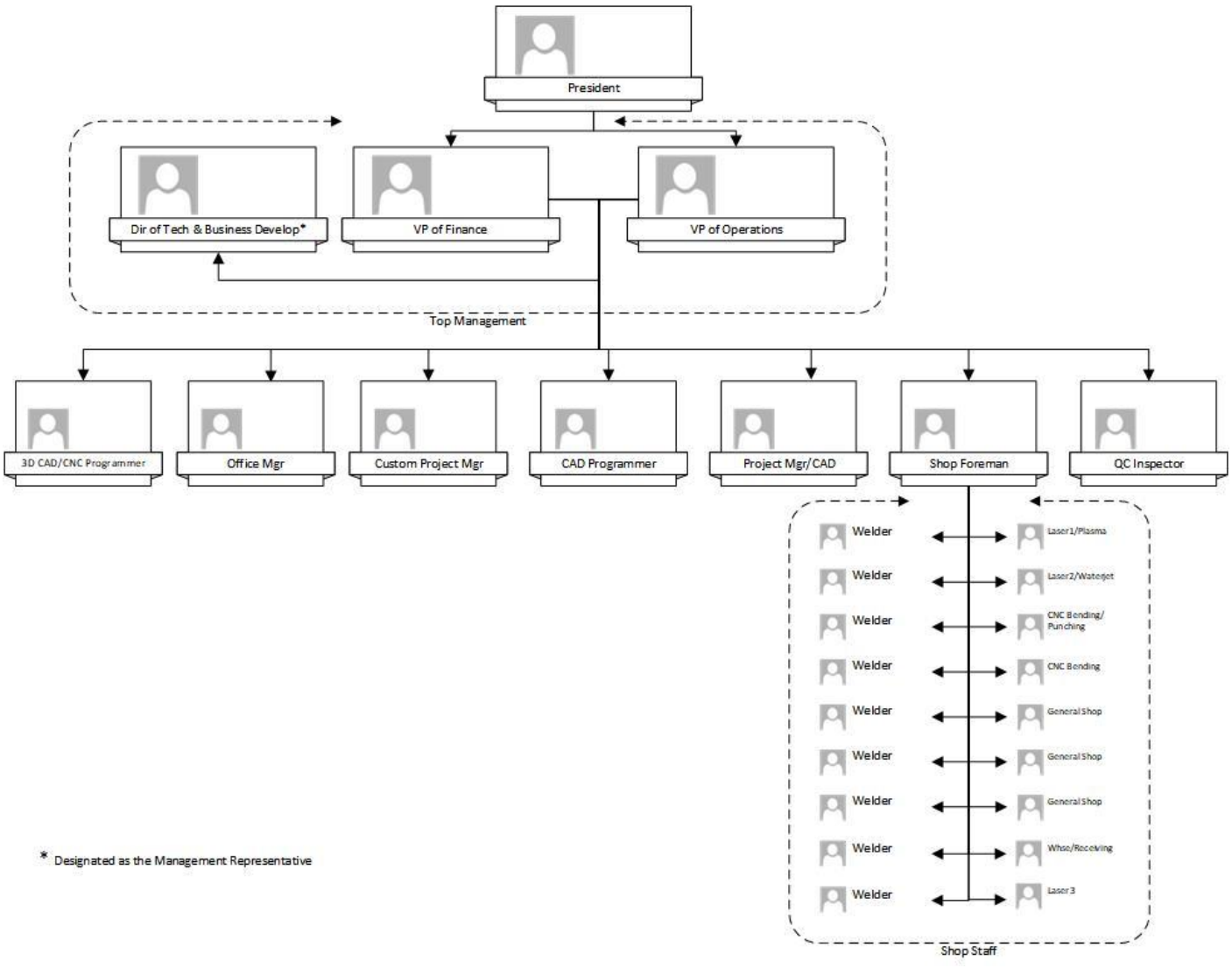
- **Responsibility:** ensuring the promotion of customer focus throughout FSM Achieved through: Quality Manual;

    1. Paragraph 5.1 General responsibilities;

2. Paragraph 7.3 Awareness

- **Responsibility**: ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented Achieved through: **P-750, Documented Information Control Procedure**

5.3 Company Organizational Chart



SECTION 6

Management of Risks and Quality Objectives

6.1 Risk Management

When planning for the QMS, FSM has considered the concerns addressed in paragraph 4.1 of the standard and the requirements addressed in paragraph 4.2 of the standard and utilizes **Procedure P-600, Planning for the Quality Management System.**

This activity correlates with the concerns described in paragraph 4.1 Understanding the context (business environment) of FSM where the internal and external concerns will be addressed.

Therefore, determination of the risks and opportunities is required to:

1. give assurance that the quality management system can achieve its intended result(s);
2. enhance desirable effects;
3. prevent, or reduce, undesired effects;
4. achieve improvement.

The planning of risk management has concentrated on the following areas of concern;

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its QMS (according to 4.4 of the standard), and
2) evaluate the effectiveness of the actions taken. (see paragraph 9.2.1 and 9.3.1 of the standard)

- Options to address risks can include avoiding risk, taking risk to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.
- Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

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

In the context (business environment) of FSM, risk management shall, concentrate on the following aspects:

1. Applicable legal compliance
2. Working environment (see 7.1.4 Environment for the operation of processes in the Quality Manual)

Reference: Risk Management analysis per specific process.

In conformance with paragraph 4.4, Quality Management System and defined processes in the Quality Manual, documented information regarding risk management will be established, implemented and maintained. The requirement of **P-750, Documented Information Control Procedure** is followed.

The effectiveness of actions taken to address risks and opportunities shall be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

6.2 Quality Objective

Statement of Quality Objectives is located in the Quality Objectives Document P-620

6.3 Planning of changes

When FSM determines the need for changes to the QMS, the changes must be carried out in a planned manner (according to paragraph 4.4.1 and 4.4.2 of the standard).

The company considers:

a) the purpose of the changes and their potential consequences; see paragraph 6.1 (Risk Management in the Quality Manual)
b) the integrity of the quality management system; (See 7.5 in the Quality Manual)
c) the availability of resources; (see paragraph 7.1.1 in the Quality Manual

Where the changes are applied, they shall be performed per the **Documented Information Control Procedure P-750**

SECTION 7
Support

7.1 Resource

7.1.1 General

FSM has determined and provided the resources required for the establishment, implementation, maintenance and to continually improve the QMS. Determination will include **Procedure P-710, Resource Management** as well as the following;

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

The adequacy of resources laid down in paragraphs 7.1.2 People, 7.1.3 Infrastructure, 7.1.4 Environment for the operation of processes, 7.1.5 Monitoring and measuring resources and 7.1.6 Organizational Knowledge shall be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

7.1.2 People

The organization determined and provided the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. Determination of qualified personnel will be addressed in paragraph 7.2 Competence in the Quality Manual

7.1.3 Infrastructure

FSM has determined, provided and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Determination of Infrastructure within FSM may include:

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

All necessary infrastructure will be appropriately maintained to facilitate positive outcome and to verify the adequacy of process control as it defined in paragraph 8.5.1 Production control in the Quality Manual. Reference **Procedure P-710, Resource Management**.

7.1.4 Environment for the operation of processes

FSM has determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services.

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

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

These above-mentioned factors may be associated with the elements defined in section 6.1 Risk Management.

The maintenance of environment is also important to verify the efficiency of process control as it defined in paragraph 8.5.1 Production control in the Quality Manual.

7.1.5 Measurement Traceability

FSM has determined and provided the resources required to verify valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. Therefore, FSM will verify that the resources provided: **Procedure P-715, Measurement Traceability**

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

Evidence of fitness for purpose of the monitoring and measurement resources will be retained as documented information and controlled according to the **Documented Information Control Procedure, P-750**

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 will be:

- 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 will be retained as documented information;
- identified to determine their status;
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Where the validity of previous measurement results may be adversely affected when measuring equipment is found to be unfit for its intended purpose, action must be taken in accordance with paragraph 8.7 Control of Nonconforming output in the Quality Manual.

7.1.6 Organizational Knowledge

FSM has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge has been maintained through documentation and will be made available to the extent necessary. When addressing changing needs and trends, the organization does consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

Organizational knowledge is mandatory to demonstrate conformity to positive outcomes of FSM scope of certification as addressed in section 4.3 in the Quality Manual.

Organizational knowledge gained by experience is used and shared to achieve the organization's objectives. Organizational knowledge also can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers). Management of organizational knowledge will be addressed in paragraph 7.2 Competence in the Quality Manual

7.2 Competence

7.2.1 Determination of competence

The organization shall, through the use of **Procedure P-720 Competence** and the following;

a) Determine personnel competency based upon review of respective Job Descriptions, applications or resumes. These documents detail the qualifications required / possessed for staff doing the work under their control that affects the performance and effectiveness of the quality management system.

b) The competency of personnel is mandated to verify the efficiency of process control as it is defined in paragraph 8.5.1 Production control in the Quality Manual

c) Consideration of competency may associate the subjects addressed in the Quality Manual through following paragraph;

a. Paragraph 5.3 Organizational Roles, Responsibility and Authorities
b. Paragraph 7.1.2 People
c. Paragraph 7.1.6 Organizational Knowledge
d. Paragraph 7.3 Awareness

d) Competency may be determined when an issue is raised from **P-870 Control of Non-Conformity Procedure**

7.2.2 Competency

a) Job Description of key functions will describe education, experience and related skills required.
b) Skill may be determined from the training attended by the staff to demonstrate appropriate expertise to provide effectiveness of QMS.
c) Where the training is applicable, evaluation of effectiveness to measure the positive impact after personnel attended the training.
d) Update documentation as necessary
e) Retain appropriate documented information and comply with **Documented Information Control Procedure – P-750**

7.3 Awareness

FSM has verified that persons doing work under the organization's control are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) the implications of not conforming with the quality management system requirements

Where necessary, training will be conducted and the process shall be performed per section 7.2 Competence in the Quality Manual.

7.4 Communication

FSM has determined the internal and external communications relevant to the quality management system through the information provided in **Procedure P-740, Communication**, including the following:

1. What will be communicated,
2. When communication is to take place,
3. Who will be communicated to,
4. How communication will be undertaken,
5. Who will carry out the communication

7.4.1 Importance of effective communication

It is imperative for FSM to consider internal and external communication input from interested parties to verify that messages and information from them will be managed in a professional, proper manner. Communication refers to all types of communications, both internal, and external to, the organization.

- The standard requires organizations to establish and maintain process for internal communications between the various levels and functions of the organization such as:

    1. Examples of internal communications include:
    2. Communicating environmental objectives and targets to employees.
    3. Raising awareness of environmental issues to employees.
    4. Communicating the environmental policy to employees.
    5. Advising of nonconformance to relevant departmental heads.
    6. Reporting incidents arising from abnormal or emergency operation to senior management.

- External communication requirements may include suppliers and sub contract services and may be comprised of the following example:

    1. Quality Policy,
    2. Contracts
    3. terms and conditions
    4. service level agreements
    5. order fulfilment
    6. performance reporting etc.

Maintenance of communication tools shall be performed per section 7.1.3 Infrastructure in the Quality Manual. Failed communication may cause the following situations to occur;

a) Complaint from customer or stakeholder
b) Output does not match the intended result(s) of the quality management system.
c) The process is not delivering its intended product or service results

Where appropriate, problem solving methods shall be performed per Control of Non-Conformity Procedure and Corrective Action Procedure P-1020

7.5 Documented Information

Top management of FSM will verify the quality management system includes:

7.5.1 Top Management of FSM will verify the quality management system includes:

a) documented information required by ISO 9001-15;
b) documented information determined by FSM as being necessary for the effectiveness of the quality management system.

Therefore, FSM has determined the necessary documented information to be applied within FSM as follows;

7.5.2 Creating and Updating

When creating, and updating documented information, FSM shall ensure appropriate:

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

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the 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 For the control of documented information, FSM shall address the following activities, as applicable:

a. distribution, access, retrieval, and use;
b. storage and preservation, including preservation of legibility;
c. control of changes (e.g., version control);
d. retention and disposition**;**
e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose. (ref. para. 5.6 of P-750)

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

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

When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage). (ref. para. 5.5.4 of P-750)

Documented information that provides evidence of product origin, conformity,

Control of documented information shall be performed per **Documented Information Control Procedure P-750**

SECTION 8
Operation

8.1 Operational Planning

FSM plans, implements and controls the processes, as defined in paragraph 4.4 Quality Management System and by the following table, that are required to meet the requirements for the provision and scope of which FSM is certified. **Procedure P-810, Operational Planning and Control and F-810-01 and F-810-02.**

a). determining the requirements for the products and services Realization: Refer to paragraph 8.2. Requirement for products and services in the Quality Manual

b). **establish criteria for**: 1. **the processes**; 2. **the acceptance of products** and services

c). **implementing control of the processes** in accordance with the criteria

1. Business Process Mapping to overview the process criteria,
2. Paragraph 8.4 Control of externally provided processes, products and services of Quality Manual for purchasing activities or if outsourced, process is applicable
3. Paragraph 8.5.1 Production control in the Quality Manual for operational control process,
4. Paragraph 8.6 Release of products and services in the Quality Manual for handing over process

d). **determining the resources required** to achieve conformity to the product and service requirements:

1. Paragraph 7.1 Resource in the Quality Manual
2. If outsourced processes or external provided process are applied, paragraph 8.4 Control of externally provided processes, products and services in the Quality Manual shall be referenced.

e). **determining and keeping 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. Realization: Control of documented information shall per paragraph 7.5 Documented Information

Control of documented information shall be per paragraph 7.5 Documented Information

All above mentioned activity will be maintained to verify;

1. The output of planning activities remain suitable for FSM's operations.

2. The planning activities are adequately controlled and consequences of unintended changes can be reviewed so that action can be taken to mitigate any adverse effects.

8.2. Requirement for products and services

See - Procedure P-820, Requirements for Products and Services

8.2.1 Customer communication

Communication with customers shall be performed per paragraph 7.4 Communication in the Quality Manual to verify the efficiency of the following process

a) providing information relating to products and services; during quoting / bidding process
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, which includes receiving complaints from customer. Solution shall be based on **Procedure P - 1020, Nonconformity and Corrective Action** in the Quality Manual System
d) handling or controlling customer property, if applicable. (Refer to paragraph 8.5.3 Property belonging to customers or external providers in the Quality Manual for details)
e) establishing specific requirements for resolving unforeseen event actions.

8.2.2 Determining the requirements related to products and services

When determining the requirements for the products and services to be offered to customers, the designated person will verify that:

a) the requirements for the products and services as defined in the Contract Document, include:
    1) any applicable statutory and regulatory requirements;
    2) those requirements considered necessary by the FSM;
b) the organization can meet the requirements for the products and services it offers as defined in the contract document.

8.2.3 Review of requirements related to products and services

FSM verifies that it can meet the requirements for products and services to be offered to customers. FSM conducts a review before committing to supply products and services to a customer, to include:

Review Requirements,

- **Requirements specified by the customer**, including the requirements for delivery and post-delivery activities; - Contract Review
- **Requirements not stated by the customer**, but necessary for the specified or intended use, when known; - Legal, regulatory, industry standards, organizational standards

- **Requirements specified by the organization**; Per paragraph 8. Operation in the Quality Manual
- **Statutory and regulatory requirements** applicable to the products and services; Source: Per contract document - Risk analysis
- **Contracts or order requirements** differing from those previously expressed. - Contract document review and resolve

The customer's requirements shall be confirmed by the authorized person before acceptance, when the customer does not provide a documented statement of their requirements.
Documented information, shall be controlled per paragraph **P-750 Documented Information** in the Quality Manual as applicable when:

a) based upon the results of the review;
b) based upon any new requirements for the products and services

8.2.4 Changes to requirements for products and services

The organization verifies 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 during to quote process or after order acceptance.

8.4 Control of externally provided processes, products and services

FSM verifies that externally provided processes, products and services more commonly known as the purchasing process **Procedure P-840, Control of Externally Provided Processes, Products and Services** conform to requirements as stated in the ISO 9001-2015 standard.

Note: Scope of activity of externally provided processes has been explained in Annex A.8 control of externally provided processes, products and services of the ISO 9001 standard.
Control of externally provided process include;

a) Determination of purchasing control including selection, evaluation, re-evaluation and monitoring of external provider (supplier)
b) Type and extent of control of purchasing process
c) Effective communication to external provider or supplier

Details of externally provided process control should refer to Purchasing Procedure. Result of performance of external provider shall be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

8.5 Production and service provision

8.5.1 Production control

FSM has implemented a production and service procedure **P-851 Production and Service Provision** which maintains controlled conditions through the various processes.

Controlled conditions of process control may be as follows:

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;

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.

8.5.2 Identification and traceability

FSM uses suitable means to identify outputs when it is necessary to verify the conformity of products and services. That is including the control of; the process as defined in **P-852, Identification and Traceability** and the following:

Product identification:

- Paperwork accompanies each lot of product through production. Travelers, Bill of Materials and Prints are included in the paperwork.
- Travelers identify the product and the lot number of the in-process items. Travelers are always kept with the lot of product, either by posting at the workstation doing work, or by being placed in the containers with product as it travels through production.

Identification of Measuring and Monitoring Status:

- Travelers identify the inspection and test required at each workstation. Operators initial the inspection and test point as the product passes inspection. All product that does not pass inspection is identified with a red hold tag and handled per the **Control of Nonconforming Product Procedure P-870.**

Traceability:

- The materials group, with input from appropriate departments, determines traceability requirements.
- Traceability requirements are documented in work instructions for the processes requiring it.
- Traceability is maintained by documentation of lot numbers of materials used, and operator initials on the traveler.

Identification and traceability is maintained by retaining the documented information according to **Documented Information Control Procedure P-750**

8.5.3 Property belonging to customers or external providers

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

FSM 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, the designated person shall report this to the customer or external provider and retain documented information on what has occurred.

Note: A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

FSM has preserves the conformity of product during internal processing, service provision, and delivery to the intended destination to the extent necessary to verify conformity to requirements. Reference procedure – **P-854 - Preservation**

- Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. Preservation also applies to the constituent parts of a product.

8.5.5 Post-delivery activities

The organization will meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization has considered:

- statutory and regulatory requirements;
- the potential undesired consequences associated with the products and services;
- the nature, use and intended lifetime of its products and services;
- customer requirements;
- customer feedback.

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

8.5.6 Control of changes

FSM reviews and controls changes for production or service provision, to the extent necessary to verify continuing conformity with requirements. The organization will retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review. When the changes are implemented, a documented change notice will be initiated.

8.6 Release of products and services

FSM shall implement planned arrangements, at appropriate stages, to verify 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 in accordance with paragraph 8.5.1 Production control in the Quality Manual.
Any product or service which does not meet with customer requirements must be resolved through paragraph **8.7 Control of Nonconforming product** in the Quality Manual
The release of products and services to the customer will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved, in writing, by a relevant authority as applicable, by the customer.
The organization will retain documented information on the release of products and services. The documented information shall include:

1. evidence of conformity with the acceptance criteria;
2. traceability to the person(s) authorizing the release.

8.7 Control of Nonconforming output

FSM verifies that outputs (product or services) that do not conform to requirements are identified and controlled per **P-870 Control of Nonconforming Procedure** to prevent their unintended use or delivery. FSM takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This action also applies to nonconforming products and services detected after delivery of products, during or after the provision of services. The ways of dealing with nonconforming outputs must be per one or more of the following measures:

a) correction; (rework / replace)
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession. Conformity to the requirements will be verified when nonconforming outputs are corrected.

The organization retains documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority determining the resolution of nonconformities shall be per **P-870 Control of Nonconforming Procedure.**

Information on nonconformities shall be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

SECTION 9
Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

FSM

1. Determines:

    a) what criteria is to be monitored and measured;
    b) the methods for monitoring, measurement, analysis and evaluation required to verify rational results;
    c) when the monitoring and measuring shall be performed;
    d) when the results from monitoring and measurement shall be analyzed and evaluated.

2. Evaluate the performance and the effectiveness of the quality management system.

3. Retain appropriate documented information as evidence of the results according to **P-750, Documented Information Control Procedure**

9.1.2 Customer satisfaction

FSM monitors customers' perceptions through the procedure **P-912 Customer Satisfaction** of the degree to which their needs and expectations have been fulfilled.

The organization determines the methods for obtaining, monitoring and reviewing this information. Method of evaluation should refer to paragraph 9.1.3 Analysis and evaluation in the Quality Manual Result of monitoring activity will be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

9.1.3 Analysis and evaluation

FSM analyzes and evaluates appropriate data through procedure **P-913 Analysis and Evaluation** and information arising from monitoring and measurement. The results of analysis shall be used in accordance with below table;
conformity of products and services; Key Process Indicators Monthly Quarterly

a) Customer Satisfaction evaluation annually
b) Performance and effectiveness of the quality management system

c) Effectiveness of quality management system planning - Internal Audit - minimum annually
d) The effectiveness of actions taken to address risks and opportunities;
    1. Internal Audit, and
    2. Paragraph 10.2 Nonconformity and corrective action

9.1.4 Root Cause Analysis (RCA)

It would be virtually impossible not to incorporate Root Cause Analysis as a part of the continuous improvement process, though not specifically required to meet the intent of the continuous improvement requirements of the current revision of the ISO 9001

RCA is an excellent method of determining the actual cause(s) of the problem as there may be several reasons for the abnormality to occur. Procedure **P-914 Root Cause Analysis** describes, in detail, the necessary steps to take to utilize RCA as a useful tool.

Management Review of analysis and evaluation is reviewed by **top management** of FSM as is required by paragraph 9.3 Management, the performance of external providers; Supplier evaluation annually and needs for improvements to the quality management system.

9.2 Internal Audit

FSM conducts internal audits (monthly, quarterly, semi-annually or annually) to provide information on whether the quality management system:

a) conforms to:
    1) the organization's own requirements for its quality management system;
    2) the requirements of ISO 9001;
b) is effectively implemented and maintained.

Execution of internal audit include;

c) planning, establishing, implementing and maintaining an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
d) defining the audit criteria and scope for each audit; (see individual process audit checklist)
e) select auditors and conducting audits, verifying objectivity and the impartiality of the audit process; verifying that the results of the audits are reported to relevant management;
f) take appropriate correction and corrective actions without undue delay
g) retain documented information as evidence of the implementation of the audit program and the audit results.

Internal audit activities shall be performed per **Internal Audit Procedure P-920**. Results of internal audit activity shall be reviewed by **top management** of FSM as is required by paragraph **9.3 Management Review** in the Quality Manual

9.3 Management Review

9.3.1 General

Top management of FSM reviews the organization's quality management system, at a minimum of once a year, to verify its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of FSM. The company may elect to review the management system on a more frequent basis than once per year, as business conditions dictate. These reviews will be documented per **P-930 Management Review.**

9.3.2 Management Review Inputs

The management of FSM review is planned and carried out taking into consideration:

a) the status of actions from previous management reviews;
b) changes in external and internal concerns 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;
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 reviews include decisions and actions related to:

a. opportunities for improvement;
b. any need for changes to the quality management system;
c. resource needs.

Documented information of Management Review outputs has been retained as an evidence of the results of management reviews.

SECTION 10

Improvement

10.1 General

FSM determines and selects opportunities for improvement and implements all actions necessary to meet customer requirements and enhance customer satisfaction. These opportunities shall include at a minimum, the following:

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

The input of information used for improvement activities shall be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review in the Quality Manual

10.2 Nonconformity and corrective action

When a nonconformity occurs, including any arising from external complaints, designated personnel shall respond accordingly per procedure **P-1020 Nonconformity and Corrective Action (CIAP):**

a) react to the nonconformity and, as applicable:
    1) act to control and correct nonconformities
    2) mitigate 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; (RCA)
    3) determining if similar nonconformities exist, or could potentially occur within the organization
c) implement any actions required to mitigate the situation;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, as required;
f) make changes to the quality management system, as required.

Corrective actions must be appropriate to the effects of the nonconformities encountered. The company shall retain documented information as evidence of:

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

Details of measures for acting on nonconformity shall be performed per **P-1020, Corrective Action Procedure** Information on nonconformities and corrective action shall be reviewed by **top management** of FSM as is required by paragraph 9.3 Management Review of the Quality Manual.

10.3 Continual Improvement

The organization of FSM will continually improve the suitability, adequacy and effectiveness of the quality management system per procedure **P-1030 Continuous Improvement**. The consideration given to be taken regarding continuous improvement will be based on following inputs.

a) Results of analysis and evaluation as defined in paragraph 9.1.3 Analysis and evaluation in the Quality Manual, and

b) The outputs from management review as defined in paragraph 9.3.3 Management Review Outputs based on inputs from the above mentioned, **top management** of FSM has determined if there are needs or opportunities that shall be addressed as part of continual improvement.

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

The ideas of opportunity for improvement shall be reviewed by **top management** of FSM as required by paragraph 9.3 Management Review in the Quality Manual

Section 11

Business Management Principals

1. Focus on customers and interested parties

To enhance corporate performance and achieve sustained success, organizations must focus on both their customers and their interested parties. Organizations can establish this focus by trying to understand the current and future requirements and expectations of both their customers and their interested parties and by constantly trying to meet these requirements and exceed these expectations.

2. Provide leadership for your organization

To enhance corporate performance and achieve sustained success, organizations must verify that suitable leadership is provided at all levels. Suitable leadership is provided whenever leaders at all levels establish a unity of purpose and whenever they create an environment that encourages people to pursue a common direction and achieve a common set of objectives. By establishing a common purpose, leaders can verify that all strategies, policies, processes, and resources are aligned and being used to pursue a common direction and to achieve a common set of objectives.

3. Engage and involve your people

To enhance corporate performance and achieve sustained success, organizations must be able to create and deliver value. To do so they must have people who are competent, they must enhance their knowledge and skills, and they must manage them effectively by empowering them, by encouraging their involvement and engagement at all levels, and by recognizing their achievements.

4. Use a process approach

To enhance corporate performance and achieve sustained success, organizations must use a process approach to manage their activities. The process approach is a management strategy. When managers use this approach, it means that they manage and control their processes, the interactions between these processes, and the inputs and outputs that tie these processes together. It also means that they manage these interactions as a system. When this approach is applied to quality management, it means that they manage their processes and their process interactions as a coherent quality management system.

5. Encourage improvement

To enhance corporate performance and achieve sustained success, organizations must encourage and support improvement. If they wish to maintain current levels of performance, if they wish to respond to changing conditions, and if they wish to identify, create, and exploit new opportunities, organizations must establish and sustain an ongoing focus on improvement.

6. Use evidence to make decisions

To enhance corporate performance and achieve sustained success, organizations must establish an evidence-based decision making process. Decision making is evidence-based whenever multiple types of input are gathered from multiple sources, whenever facts are identified, whenever data is analyzed objectively, whenever cause and effect relationships are examined, whenever potential unintended consequences are considered, and whenever all of this is used to make corporate decisions.

7. Manage your corporate relationships

To enhance corporate performance and achieve sustained success, organizations must manage their relationship with suppliers, partners, and other interested parties. Relationships must be carefully managed because suppliers, partners, and other interested parties can influence corporate performance and undermine corporate success.

Section 12

Quality Terms & Definitions

Audit - An audit is a systematic evidence gathering process. Audits must be independent and evidence must be evaluated objectively to determine how well audit criteria are being met. There are three types of audits: First-party, second-party, and third-party. First-party audits are internal audits while second and third party audits are external audits.

Organizations use first party audits to audit themselves. First party audits are used to provide input for management review and for other internal purposes. They're also used to declare that an organization meets specified requirements (this is called a self-declaration).

Second party audits are external audits. They're usually done by customers or by others on their behalf. However, they can also be done by regulators or any other external party that has an interest. In an organization. Third party audits are external audits as well. However, they're performed by independent organizations such as registrars (certification bodies) or regulators.

ISO also distinguishes between combined audits and joint audits. When two or more management systems of different disciplines are audited together at the same time, it's called a combined audit; and when two or more auditing organizations cooperate to audit a single auditee organization it's called a joint audit.

Audit criteria - Audit criteria are used as a reference point and include policies, requirements, and other forms of documented information. They are compared against audit evidence to determine how well they are being met. Audit evidence is used to determine how well policies are being implemented and how well requirements are being followed.

Audit evidence - Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria include policies, requirements, and other documented information.

Audit findings - Audit findings result from a process that evaluates audit evidence and compares it against audit criteria. Audit findings can show that audit criteria are being met (conformity) or that they are not being met (nonconformity). They can also identify best practices or improvement opportunities.

Audit program - An audit program refers to a set of one or more audits that are planned and carried out within a specific time frame and are intended to achieve a specific audit purpose.

Characteristic - A characteristic is a distinctive feature or property of something. Characteristics can be inherent or assigned and can be qualitative or quantitative. An inherent characteristic exists in something or is a permanent feature of something while an assigned characteristic is a feature that is attributed or attached to something.

Competence - Competence means being able to apply knowledge and skill to achieve intended results. Being competent means having the knowledge and skill that you need and knowing how to apply it. Being competent means that you're qualified to do the job.

Complaint - In the context (business environment) of ISO 9001, a complaint refers to an expression of dissatisfaction with a product or service and is filed by a customer and received by an organization. Whenever a customer lodges a complaint, a response is either explicitly or implicitly required.

Concession - A concession is a special approval that is granted to release a nonconforming product or service for use or delivery. Concessions are usually restricted to a specific use and limited by time and quantity and tend to specify that nonconforming characteristics may not violate specified limits.

Conformity - Conformity is the "fulfillment of a requirement". To conform means to meet or comply with requirements and a requirement is a need, expectation, or obligation. There are many types of requirements including customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

Context (business environment) of the organization - An organization's context (business environment) is its context (business environment). It includes all the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.

An organization's external context (business environment) includes all the needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment. An organization's internal context (business environment) includes its values, culture, knowledge, and performance.

ISO 9001 2015 expects you to consider your organization's internal and external context (business environment) when you define the scope of its QMS and when you plan its design and development.

Continual improvement - Continual improvement is a set of recurring activities that are carried out to enhance performance. Continual improvements can be achieved by carrying out audits, self-assessments, and management reviews. Continual improvements can also be realized by collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions.

Contract - A contract is a binding agreement between multiple parties.

Correction - A correction is any action that is taken to eliminate a nonconformity. However, corrections do not address root causes. When applied to products, corrections can include reworking products, reprocessing them, regrading them, assigning them to a different use, or simply destroying them.

Corrective action - Corrective actions are steps that are taken to eliminate the causes of existing nonconformities to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations don't happen again.

Customer - A customer is anyone who receives products or services (outputs) from a supplier. Customers can be either people or organizations and can be either external or internal to the supplier organization. Examples of customers include clients, consumers, users, guests, patients, purchasers, and beneficiaries.

Customer satisfaction - Customer satisfaction is a perception. It's also a question of degree. It can vary from high satisfaction to low satisfaction. If customers believe that you've met their requirements, they experience high satisfaction. If they believe that you've not met their requirements, they experience low satisfaction.

Since satisfaction is a perception, customers may not be satisfied even though you've met all contractual requirements. Just because you haven't received any complaints doesn't mean that customers are satisfied.

There are many ways to monitor and measure customer satisfaction. You can use customer satisfaction and opinion surveys; you can collect product quality data (post-delivery), track warranty claims, examine dealer reports, study customer compliments and criticisms, and analyze lost business opportunities.

Data - The term data is defined as any facts about an occurrence or object.

Defect - A defect is a type of nonconformity. It occurs when a product or service fails to meet specified or intended use requirements.

Determination - To determine means to find or to identify the value of a characteristic.

Documented information - The term documented information refers to information that must be controlled and maintained and its supporting medium. Documented information can be in any format and on any medium and can come from any source.

Documented information includes information about the management system and related processes. It also includes all the information that organizations need to operate and all the information that they use to document the results that they achieve (aka records).

Effectiveness - Effectiveness refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are carried out and planned results are effective if these results are achieved.

Feedback - The term feedback is used to refer to a comment or an opinion expressed about a product or service or an interest expressed in a product or a service. It may also be used to refer to the customer complaints-handling process itself.

Function - A function is a role that is performed by an individual within an organization.

Improvement - Improvement is a set of activities that organizations carry out to enhance performance (get better results). Improvement can be achieved by means of a single activity or by means of a recurring set of activities.

Information - Information is "meaningful data." While it's not entirely clear what the word "meaningful" is supposed to mean in this context (business environment), dictionaries tend to say that something is meaningful if it is significant, relevant, material, valid, or important.

Information system - In the context (business environment) of this ISO 9001 standard, an information system is a network of communication channels used within an organization.

Infrastructure - The term infrastructure refers to the entire system of facilities, equipment, and support services that organizations need to function. Per ISO 9001, section 7.1.3, the Term infrastructure can include buildings, equipment, utilities, and technologies (both hardware and software).

Innovation - Innovation is a process that results in a new or substantially changed object. An object is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, machines, tools, technologies, techniques, and resources.

Interested party - An interested party is anyone who can affect, be affected by, or believe that they are affected by a decision or activity. An interested party is a person, group, or organization that has an interest or a stake in a decision or activity.

Involvement - Involvement occurs when people share objectives and are actively engaged in and contribute to their achievement.

Knowledge - Knowledge is a collection of information and a justified belief that this information is true with a high level of certainty.

Management - The term management refers to all the activities that are used to coordinate, direct, and control organizations. These activities include developing policies, setting objectives, and establishing processes to achieve these objectives. In this context (business environment), the term management does not refer to people. It refers to what managers do.

Management system - A management system is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are required to verify that policies are followed and objectives are achieved. These elements include structures, programs, procedures, practices, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

There are many types of management systems. Some of these include quality management systems, environmental management systems, financial management systems, information security management systems, business continuity management systems, emergency management systems, disaster management systems, food safety management systems, risk management systems, and occupational health and safety management systems.

The scope or focus of a management system could be restricted to a specific function or section of an organization or it could include the entire organization. It could even include a function that cuts across several organizations.

Measurement - Measurement is a process that is used to determine a value. In most cases this value will be a quantity.

Measuring equipment - Measuring equipment includes all the things required to carry out a measurement process. Accordingly, measuring equipment includes instruments and apparatuses as well as all the associated software, standards, and reference materials.

Monitoring - To monitor means to determine the status of an activity, process, or system at different stages or at different times. To determine status, you need to supervise and to continually check and critically observe the activity, process, or system that is being monitored.

Nonconformity - Nonconformity is a nonfulfillment or failure to meet a requirement. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization or interested parties.

Object - An object is any entity that is either conceivable or perceivable. Objects can be real or imaginary and could be material or immaterial. Examples include products, services, systems, organizations, people, practices, procedures, processes, plans, ideas, documents, records, methods, tools, machines, technologies, techniques, and resources.

Objective - An objective is a result you intend to achieve. Objectives can be strategic, tactical, or operational and can apply to an organization or to a system, process, project, product, or service. Objectives may also be referred to as targets, aims, goals, or intended outcomes.

Quality objectives are generally based on or derived from an organization's quality policy and must be consistent with it.

Objective audit evidence - Objective audit evidence is information that is verifiable and generally consists of records and other statements of fact that are relevant to the audit criteria being used.

Objective evidence - Objective evidence is data that shows or proves that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or using other suitable methods.

Organization - An organization can be a single person or a group that achieves its objectives by using its own functions, responsibilities, authorities, and relationships. It can be a company, corporation, enterprise, firm, partnership, charity, association, or institution and can be either incorporated or unincorporated and be either privately or publicly owned. It can also be an operating unit that is part of a larger entity.

Output - An output is the result of a process. Outputs can be either tangible or intangible. The output from one process is often the input for another process.

ISO 9001 lists four generic output categories: services, software, hardware, and processed materials. Outputs often combine several of these categories. For example, an automobile (an output) combines hardware (e.g. tires), software (e.g. engine control algorithms), and processed materials (e.g. lubricants).

Outsource - When an organization arranges with an outside organization to perform part of a function or process, it is referred to as outsourcing. To outsource means to ask an external organization to perform part of a function or process normally done in-house. While an outsourced organization is beyond the scope of your QMS, the outsourced process or function itself falls within your scope.

Performance - Per ISO, the term performance refers to a measurable result. It refers to the measurable results that activities, processes, products, services, systems and organizations can achieve.

Whenever they perform well it means that acceptable results are being achieved and whenever they perform poorly, unacceptable results are achieved.

Performance indicator - A performance indicator (metric) is a characteristic that is used to measure customer satisfaction and how well outputs are realized.

Policy - A policy is a general commitment, direction, or intention and is formally stated by **top management**. A quality policy statement should express **top management**'s commitment to the implementation and improvement of its quality management system and should allow managers to set quality objectives.

Process - A process is a set of activities that are interrelated or that interact with one another. Processes use resources to transform inputs into outputs. Processes are interconnected because the output from one process often becomes the input for another process.

While processes usually transform inputs into outputs, this is not always the case. Sometimes inputs become outputs without transformation.

Organizational processes should be planned and carried out under controlled conditions. An effective process is one that realizes planned activities and achieves planned results.

Process approach - The process approach is a management strategy. When managers use a process approach, it means that they manage and control the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.

Process-based quality management system - A process-based quality management system uses a process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.

Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated process-based QMS.

Product - A product is a tangible or intangible output that is the result of a process that does not include activities that are performed at the interface between the supplier (provider) and the customer.

Products can be tangible or intangible. Per a note to this definition, there are three generic product categories: hardware, processed materials, and software. Many products combine several of these categories. For example, an automobile (a product) combines hardware (e.g. tires), software (e.g. engine control algorithms), and processed materials (e.g. lubricants).

Provider - A provider is a person or an organization that supplies or provides products or services. Providers can be either internal or external to the organization. Internal providers supply products or services to people within their own organization while external providers supply products or services to other organizations.

Quality - The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements. An object is any entity that is either conceivable or perceivable and an inherent characteristic is a feature that exists in an object. The quality of an object can be determined by comparing a set of inherent characteristics against a set of requirements. If those characteristics meet all requirements, high or excellent quality is achieved but if those characteristics do not meet all requirements, a low or poor level of quality is achieved. The quality of an object depends on a set of characteristics and a set of requirements and how well the former complies with the latter.

Quality management - Quality management includes all the activities that organizations use to direct, control, and coordinate quality. These activities include formulating a quality policy and setting quality objectives. They also include quality planning, quality control, quality assurance, and quality improvement.

Quality management system - A quality management system (QMS) is a set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are required to verify that policies are followed and objectives are achieved. These elements include structures, programs, practices, procedures, plans, rules, roles, responsibilities, relationships, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources.

Quality objective - A quality objective is a quality result that you intend to achieve. Quality objectives are based on or derived from an organization's quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions.

The adjective quality applies to objects and refers to the degree to which a set of inherent characteristics fulfills a set of requirements; and an object is any entity that is either conceivable or perceivable. Therefore, a quality objective can be set for any kind of object.

Quality policy - A quality policy should express **top management**'s commitment to the quality management system (QMS) and should allow managers to set quality objectives. It should be based on ISO's quality management principles and should be compatible with your organization's other policies and be consistent with its vision and mission.

ISO's quality management principles ask you to focus on customers and interested parties, to provide leadership, to engage and involve people, to use a process approach, to encourage improvement, to use evidence to make decisions, and to manage corporate relationships.

Regulatory requirement - A regulatory requirement is an obligation that is specified by an authority which gets its mandate from a legislative body.

Release - To release means to grant permission to proceed to the next stage of a process. The term release is also used to refer to a version of software or documented information.

Requirement - A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. A specified requirement is one that has been stated (in a document for example), whereas an implied requirement is a need, expectation, or obligation that is common practice or customary.

There are many types of requirements. Some of these include customer requirements, quality requirements, quality management requirements, management requirements, product requirements, service requirements, contractual requirements, statutory requirements, and regulatory requirements.

Review - A review is an activity. Its purpose is to figure out how well the thing being reviewed can achieve established objectives. Reviews ask the following question: is the subject (or object) of the review a suitable, adequate, effective, and efficient way of achieving established objectives.

There are many kinds of reviews. Some of these include management reviews, design and development reviews, customer requirement reviews, nonconformity reviews, and peer reviews.

Per ISO 9000, is the “effect of uncertainty on an expected result” and an effect is a positive or negative deviation from what is expected. The following two paragraphs will explain what this means.

> This definition recognizes that all of us operate in an uncertain world. Whenever we try to achieve something, there’s always the chance that things will not go per plan. Sometimes we get positive results and sometimes we get negative results and occasionally we get both. Because of this, we need to reduce uncertainty as much as possible.
>
> Uncertainty (or lack of certainty) is a state or condition that involves a deficiency of information and leads to inadequate or incomplete knowledge or understanding. In the context (business environment) of management, uncertainty exists whenever the knowledge or understanding of an event, consequence, or likelihood is inadequate or incomplete.

While this definition argues that can be positive as well as negative, a note acknowledges that "the term is sometimes used when there is only the possibility of negative consequences".

Risk-based thinking - Risk-based thinking refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives. Risk-based thinking replaces what the old standard used to call preventive action.

While risk-based thinking is now an essential part of the new standard, it does not actually expect you to implement a formal risk management process nor does it expect you to document your organization’s risk-based approach.

Root Cause Analysis – A method of problem solving used for identifying the true causes of errors or problems. An element is considered a root cause if removal from the problem prevents the final undesirable event from recurring.

Service - A service is an intangible output and is the result of a process that includes at least one activity that is carried out at the interface between the supplier (provider) and the customer.

Service provision can take many forms. Service can be provided to support an organization’s own products (e.g. warranty service or the serving of meals). Conversely, it can be provided for a product supplied by a customer (e.g. a repair service or a delivery service). It can also involve the provision of an intangible thing to a customer (e.g. entertainment, ambience, transportation, or advice).

Statutory requirement - A statutory requirement is defined by a legislative body and is obligatory.

Strategy - A strategy is a plan for achieving an objective.

Supplier - A supplier is a person or an organization that provides products or services. Suppliers can be either internal or external to an organization. Internal suppliers provide products or services to people within their own organization while external suppliers provide products or services to other organizations.

Examples of suppliers include organizations and people who produce, distribute, or market products, provide services, or publish information. While ISO still includes a definition for this term, the new ISO 9001 2015 standard no longer actually uses it. It prefers, instead, to use the term external provider.

System - A system is defined as a set of interrelated or interacting elements. A management system is one type of system. It is a set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are required to verify that policies are followed and objectives are achieved.

Top management - The term **top management** normally refers to the people at the top of an organization. It refers to the people who provide resources and delegate authority and who coordinate, direct, and control organizations.

However, if the scope of a management system covers only part of an organization, then the term **top management** refers, instead, to the people who direct and control that part of the organization

Traceability - Traceability is the ability to identify and trace the history, distribution, location, and application of products, parts, materials, and services. A traceability system records and follows the trail as products, parts, materials, and services come from suppliers and are processed and ultimately distributed as final products and services.

Validation - Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is established. Validation can be carried out under realistic use conditions or within a simulated use environment.

There are several ways to confirm that the requirements which define an intended use or application have been met. For example, you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them.

Verification - Verification is a process. It uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a verified status is achieved.

There are many ways to verify that requirements have been met. For example: you could inspect something, you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them.