

4. Context of the Organization

4. 1 Understanding the Organization and its Context

The organization shall determine external and internal issues that

1. Are relevant to its purpose
2. That affect its ability to achieve the intended outcome(s) of its QMS

4. 2 Understanding the Needs and Expectations of Interested Parties

Interested Parties

1. Direct customers, end users
2. Suppliers, Distributors, Retailers, Partners, Competitors
3. Shareholders
4. Employees and Labour Unions
5. Society, including regulators

4. 3 Determining the Scope of the QMS

When an organization chooses to outsource process that affects product conformity to requirements, these processes shall be included within the scope of the QMS.

The scope and exclusions shall be:

1. Available as documented information
2. Shall be made available to interested parties on request

4. 4 Quality Management System

The organization shall establish, implement, maintain and continually improve a QMS, including the processes needed and their interactions

In accordance with the requirements of this International Standards

- Input > Process > Output
- Sequence and Interaction
- Risks to Quality Performance if
 - Unintended outputs are produced
 - Process Interaction is ineffective
- Criteria, methods and measurements
- Availability of resources
- Responsibilities and authorities
- Monitoring, analysis and review
- Actions to achieve planned results and continual improvement of these processes
- Delivery of intended outcomes

5. Leadership

5.1 Leadership and Commitment

Top Management shall demonstrate leadership and commitment with respect to the QMS

1. Policies and Objectives are:
 - Established for the QMS
 - Compatible with the strategic direction of the organization based on 7 QMPs
2. Integration of the QMS Requirements into the organization's business processes

Top Management shall demonstrate leadership and commitment with respect to the QMS

3. Availability of resources
4. Communicating the importance of:
 - Effective QMS
 - Conformance to the QMS requirements
 - Statutory and Regulatory Requirements
5. Ensuring that the QMS and its processes achieve its intended outcome(s)

Top Management shall demonstrate leadership and commitment with respect to the QMS

6. Risks – identified, assessed and managed
7. Involving, directing and supporting persons to contribute to the effectiveness of the QMS
8. Customer requirements – determined and met
9. Promoting continual improvement
10. Supporting other relevant management roles
11. Quality Policy – understood and followed

5.2 Quality Policy

We, at F2 Logistics Philippines Inc., are committed to be a partner of choice by providing customized supply chain solutions to our customers.

We will maintain good relationships with our customers by:

1. Giving the highest quality service that is measured through performance standards
2. Complying to customer, statutory and regulatory requirements, and
3. Constantly improving our quality management system that will enable to company to exceed customer expectations

5.3 Organizational Roles, Responsibilities and Authorities

Top Management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization

- ✓ Organizational Charts
- ✓ Job Descriptions
- ✓ Policies and Procedures

6. Planning

6.1 Actions to Address Risks and Opportunities

When planning for the QMS, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2, and determine the risks and opportunities related to product conformity and customer satisfaction that needed to be addressed to:

- ✓ Assure the QMS can achieve its intended outcome(s)
- ✓ Prevent, or reduce undesired effects
- ✓ Achieve continual improvement

The organization shall plan actions to address these risks and opportunities and how to:

- ✓ Integrate and implement the actions into its QMS processes (see 4.4)
- ✓ Evaluate the effectiveness of these actions

The organization shall ensure that the need to consistently provide products that meets customer requirements and enhance customer satisfaction is a deciding factor when determining actions to address risks. E.g. when choosing between options such as risk avoidance, risk mitigation or risk acceptance

6.2 Quality Objectives and Planning to Achieve Them

The organization shall establish quality objectives at relevant functions and levels and in accordance with its overall business objectives and product conformity and customer satisfaction

The quality objectives shall:

- ✓ be consistent with the quality policy
- ✓ be measurable
- ✓ take into account the applicable requirements
- ✓ be monitored
- ✓ be communicated
- ✓ be updated

Quality objectives that impact on product conformity or customer satisfaction shall be implemented in a timely and effective manner

The organization shall retain documented information on the quality objectives.

When planning how to achieve its quality objectives, the organization shall determine

- ✓ What will be done
- ✓ What resources will be required (7.1)
- ✓ Who will be responsible
- ✓ When will it be completed
- ✓ How the results will be evaluated

The organization shall undertake change in a planned and systematic manner, reviewing the potential consequences of changes and taking action as necessary, to ensure the integrity of the QMS is maintained.

The organization shall ensure that changes to product, infrastructure, QMS processes, documented information or other changes arising from considerations as part of management review are assessed for suitability and approved prior to implementation.

6.3 Planning and Control of Changes

The assessment shall include

- ✓ Identification of risks and risk control measures associated with the change
- ✓ Consequences for resource needs
- ✓ Any necessary verification or validation, and
- ✓ Confirmation that the desired effect has been achieved without adverse effects to product conformity

Personnel authorized to approve changes shall be identified.

Documented information describing the results of the review of changes and any necessary actions shall be maintained (7.5)

7. Support

7.1 Resources

7.1.1 General

In determining the resource requirements, the organization shall consider

- ✓ Current in-house capabilities and limitations
- ✓ Which process or product needs can be supported with existing resource
- ✓ Which process or product needs require additional or changed resource that is to be deployed under the organization's own direct control
- ✓ Which process or product needs are to be satisfied by outsourcing to an external party

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Any new or additional resource to be deployed shall be subject to change management in accordance to Clause 6.3

The organization shall establish, implement and maintain the controls needed temporarily or permanently to utilize external parties.

Outsourced process

- Is a process that the organization needs for its QMS and which the organization chooses to have performed by an external party

7.1.2 Infrastructure and Work Environment

The organization shall determine and provide the infrastructure and work environment needed to achieve conformity to product requirements

Infrastructure includes:

- ✓ Buildings
- ✓ Workspace and associated utilities
- ✓ Process Equipment (hardware and software)
- ✓ Supporting services (such as transport, communication or information systems)

Work Environment – relates to those conditions under which work is performed including:

- ✓ Physical, Environmental
- ✓ Other factors such as – noise, temperature, humidity, lighting or weather

Work environment includes remote locations

Similar controls need to be considered for outsourcing

7.1.3 Monitoring and Measuring Instruments

The organization shall ensure the availability of the monitoring and measuring instruments needed to verify conformity to product requirements and shall ensure that it is controlled and maintained fit for purpose

- ✓ Calibration (with records and status)
- ✓ Safeguard from adjustments
- ✓ Protection from damage and deterioration during handling, maintenance and storage

7.1.4 Knowledge Requirements

The organization shall determine, provide, and maintain the knowledge resources needed to:

- Consistently provide product that meets customer needs and expectations
- Enhance customer satisfaction

7.1.4 Knowledge Requirements

This shall include

1. Consideration of the knowledge resources to respond to changing business
2. Changing business environments
3. Changing customer and interested party needs and expectations
4. Innovation and Improvement Initiatives

7.2 Competence

The organization shall

1. Determine the competence requirements
2. Ensure that the persons doing work are competent on the basis of education, training or experience
3. If with gaps, take actions to acquire the necessary competence and evaluate the actions taken
4. Retain documented information as evidence of competence

7.3 Awareness

Persons doing work under the organization's control shall be aware of

1. The Quality Policy
2. Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance
3. The implications of not conforming with the QMS requirements

7.4 Communication

The organization shall determine the need for internal and external communications relevant to the QMS including:

1. On what it will communicate
2. When to communicate
3. With whom to communicate

7.5 Documented Information

7.5.1 General

The organization's QMS shall include:

1. Documented information required by ISO 9001
2. Documented information determined by the organization as being necessary for the effectiveness of the QMS
3. A description of the interaction between the processes of the QMS

7.5.2 Creating and Updating

When creating and updating documented information, the organization shall ensure appropriate

1. Identification and description (e.g Title, Date, Author or Reference Number)
2. Format and media
3. Review and approval for suitability and adequacy

7.5.3 Control of Documented Information

Documented information required by the QMS and by ISO 9001 shall be controlled to ensure

1. It is available and suitable for use, where and when it is needed
2. It is adequately protected (from loss of confidentiality, improper use, or loss of integrity)

For the control of documented information, the organization shall address the following activities as applicable:

- ✓ Distribution, access, retrieval and use
- ✓ Storage and preservation, including preservation of legibility
- ✓ Control of changes (version control)
- ✓ Retention and Disposition

Documented information of external origin (Externally-Generated Documents)

Requirements:

Identified

Controlled

Documented Information

Previously known as "documents and records"

"Documents" need to be "maintained as documented information"

"Records" need to be "retained as documented information"

8. Operations

8.1 Operational Planning and Control

Quality Planning

- Criteria for the processes
- Control methodologies
- Documented information
- Control for outsourced processes

Change Management

- Planned changes – Control
- Unintended changes – Review the consequences, do contingent actions

8.2.1 Determination of Requirements Related to the product

- a) Requirements specified by the customer including the requirements for delivery and post-delivery activities
- b) Requirements not stated by the customer but necessary for specified or intended use where known
- c) Statutory and regulatory requirements related to the product, including risks and risk controls
- d) Requirements that are related to the product arising from other relevant interested parties
- e) Any additional requirements determined by the organization

8.2.2 Review of Requirements Related to the product

- Shall happen prior commitment
- Product requirements are defined
- Contract or order requirements differing from those previously ordered are solved
- The organization has the ability to meet the defined requirements

If there is no documented requirement, the “requirement” shall be confirmed by the organization before acceptance

If the requirements has changed, the organization shall ensure that the relevant documented information is

1. Amended and
2. The relevant personnel are made aware of the changed requirements

8.2.3 Customer Communication

Determine effective arrangements for communicating with customers in relation to

- a) product information
- b) inquiries, contracts or order handling, including amendments
- c) customer feedback including customer complaints
- d) expectations for handling customer property* and
- e) emergency and contingency needs

*Customer property can include intellectual property and personal or confidential data

8.3 Operational Preparedness

In preparing for implementation, the organization shall determine the following as appropriate

- a) Quality objectives and requirements for the product
- b) Risk identification, evaluation and control actions necessary on an ongoing basis
- c) The need to establish processes and documented information
- d) The resources required arising from the requirements for the product
- e) The criteria for product acceptance
- f) Required verification, validation, monitoring, inspection and test activities specific to the product
- g) Documented information to be retained to evidence that the processes and resulting product meet requirements; and
- h) Contingency Plans as applicable

8.4 Control of External Processes or Product

Extent of control shall be dependent upon:

- a) The risks identified
- b) The potential impact of the provided processes or product on implementation activities or the organization's capability to provide product that conforms to requirements
- c) The degree to which the control for the externally provided process is shared between the parties involved
- d) The capability of achieving the necessary control through other means

The organization shall establish the criteria for external parties':

- 1. Selection
- 2. Evaluation
- 3. Re-evaluation

Based on:

- 1. Risks and risk controls
- 2. Ability to provide products/services

*Property belonging to external parties can include intellectual property and personal or confidential data

Documented information describing the results of evaluations and any necessary actions arising from the evaluation shall be maintained

- 1. Requirements for product, processes or equipment
- 2. Requirements for competence or qualification of personnel including necessary qualification
- 3. QMS requirements
- 4. Requirements for handling supplier's property provided to the organization
- 5. Any activities that the organization intends to perform at the external party'

*External Party's property can include intellectual property and personal or confidential data

8.5.1 Define - Requirements, risks, previous designs and learnings

8.5.2 Analyze - Process, responsibilities and authorities, resources and the review, verification and validation per stage

8.5.3 Implement - Output shall be suitable for verification vs. Input, approved prior release

8.5.4 Verify and validate - According to planned arrangements. Documentation shall be maintained

8.5.5 Transfer to Operations - Ensure suitability for Operations prior final approval

8.5.6 Execution / Implementation

8.6.1 Control of Production and Service Provision

The organization shall plan and implement production and service provision under controlled conditions. Controlled conditions shall include

- a) The availability of information that describes the characteristics of the product
- b) The availability of work instructions, as necessary
- c) The use of suitable equipment
- d) The availability and use of monitoring and measuring equipment
- e) The implementation of monitoring and measurement,
- f) The requirements for competence of personnel or their qualification
- g) The implementation of product release, delivery and post-delivery activities
- h) The implementation of risk controls

8.6.2 Validation of Processes for Production and Service Provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

- Validation shall demonstrate the ability of these processes to achieve planned results.
- The organization shall establish arrangements for these processes including, as applicable
 - a) defined criteria for review and approval of the processes
 - b) approval of equipment and qualification of personnel,
 - c) use of specific methods and procedures,

8.6.3 Identification and Traceability

Where appropriate, the organization shall identify the product by suitable means throughout implementation.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout implementation

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain documented information

8.6.4 Monitoring and Measurement of Product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the implementation. Evidence of conformity with the acceptance criteria shall be maintained.

8.6.5 Control of Nonconforming Product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented information shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

8.6.6 Property belonging to external Parties

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4). NOTE Customer property can include intellectual property and personal data.

8.6.7 Preservation of Product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include:

1. Identification
2. Handling
3. Packaging
4. Storage and protection

Preservation shall also apply to the constituent parts of the product

8.6.8 Post Delivery Activities

The organization shall establish and implement processes to conduct necessary post-delivery activities associated with the nature and intended lifetime of the product.

The extent of post-delivery activities that are required shall be established on the basis of

1. Risks associated with the product
2. Customer feedback
3. Statutory and regulatory requirements

And shall include necessary actions when nonconforming product is detected after delivery after delivery or use has started

Examples - Post Delivery Activities

1. Actions under warranty provisions
2. Contractual obligations such as maintenance services
3. Supplementary services such as recycling or final disposal

8.7 Control of Nonconforming Outputs

8.7.1

The organization shall ensure that outputs do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The 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.

The organization shall deal with nonconforming outputs in one or more of the following ways:

- a. correction;
- b. segregation, containment, return or suspension of provision of products and services;
- c. informing the customer;
- d. obtaining authorization for acceptance under concession.

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

8.7.2

The organization shall retain documented information that:

- a. describes the nonconformity
- b. describes the action 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

The organization shall determine what needs to be monitored and measured.

This shall include but not limited to:

- a) Conformity to product requirements
- b) Conformity of the QMS
- c) Effectiveness of the QMS and its processes
- d) Achievement of quality objectives
- e) Customer feedback / satisfaction

The organization shall consider the type and extent of monitoring and/or measurement in relation to risk encountered and on the effectiveness of the QMS

9.1.2 Customer Satisfaction

The organization shall monitor customer feedback to determine customer perceptions of the degree to which their requirements have been fulfilled.

The results of this monitoring shall include information related to:

- 1. The organization's needs and expectations
- 2. The customer's views and perceptions of the organization, its processes and its products

The methods for obtaining and using this information shall be determined

9.1.3 Analysis of Data

The organization shall analyse appropriate data from monitoring, measurement and other relevant sources of information to:

- 1. Demonstrate the suitability and effectiveness of the QMS
- 2. Evaluate where continual improvement of the effectiveness of the QMS can be made

The results of analysis and evaluation shall be used to prepare an input to the management review

9.2 Internal Audit

The organization shall conduct internal audits at planned intervals to provide information on whether the QMS system:

- a) Conforms to the organization's own requirements for its QMS and the requirements of ISO 9001
- b) Is effectively implemented and maintained

9.2 Internal Audit

The organization shall:

- a) Plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting. The audit programme(s) shall take into considerations, the processes concerned, the related QMS risks / opportunities, QMS Objectives, and the results of previous audits;
- b) Define the audit criteria and scope for each audit;
- c) Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) Ensure that the results of the audits are reported to relevant management;
- e) Take necessary correction and corrective actions without undue delay;
- f) Retain documented information as evidence of the implementation of the audit programme and the audit results.

9.3 Management Review

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness.

The management review shall include consideration of:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the QMS including any determined risks and opportunities

The management review shall include consideration of:

- c) information on the quality performance, including trends and indicators for:
 - 1) Nonconformities and corrective actions;
 - 2) Monitoring and measurement results;
 - 3) Audit results;
 - 4) Customer feedback
 - 5) Process performance and product conformity
 - 6) Opportunities for continual improvement
 - 7) Indicators of QMS Performance

The outputs of the management review shall include

1. Decisions related to continual improvement opportunities and
2. Improvement of product related to customer requirements, resource needs and
3. Any need for changes to the QMS including quality policy and quality objectives

The organization shall retain documented information as evidence of the results of management reviews.

10. Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction.

This shall include, as appropriate:

- a) improving processes to prevent nonconformities;
- b) improving products and services to meet known and predicted requirements;
- c) improving quality management system results.

NOTE Improvement can be effected reactively (e.g. corrective action), incrementally (e.g. continual improvement), by step change (e.g. breakthrough), creatively (e.g. innovation) or by re-organization (e.g. Transformation).

10.2 Nonconformity and Corrective Action

When a nonconformity occurs, including those arising from complaints, the organization shall:

a) react to the nonconformity, and as applicable:

- take action to control and correct it;
- deal with the consequences;

When a nonconformity occurs, including those arising from complaints, the organization shall:

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:

- reviewing the nonconformity;
- determining the causes of the nonconformity;
- determining if similar nonconformities exist, or could potentially occur;
- implement any action needed;
- review the effectiveness of any corrective action taken;
- make changes to the quality management system, if necessary.