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Back to **QMS Structure**

QUALITY MANAGEMENT SYSTEM

YEAR 2015

[You can add an abstract or other key statement here. An abstract is typically a short summary of the document content.]

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Quality Manual

SECTION1: INTRODUCTION

1.1 About the Company

Full Name Company Sdn. Bhd. or to be known as **Short Name** adopts the ISO 9001:2015 Quality Management System. Requirement as the principle for developing this Quality Management System (QMS). The extent of this QMS established is based on the nature of our organization, complexity and interaction of the processes and competency of our personnel. The Top Management of **Short Name** shall demonstrate its full commitment in establishing, documenting, implementing, maintaining and continual improvement of this QMS in accordance with the ISO 9001:2015 requirements.

To implement this quality management system, **Short Name** has :-

1. Identified the processes needed for the quality management system;
2. Determined the sequence and interaction of these processes;
3. Determined criteria and methods required to ensure the effective operation and control of these processes;
4. Ensured the availability of information necessary to support the operation and monitoring of these processes;
5. Measured, monitored and analyzed these processes, and implemented action necessary to achieve planned results and continual improvement.

MISB shall be committed to control outsourced process to ensure such processes are carried out based on the contractual requirements. The extent of control shall be as followed:

1. Potential impact that the product is provided
2. Degree to which the control of the process is shared
3. Capability of achieving the control through clause 7.4 Communication.

1.2 Objective of this Quality Manual

This Quality Manual specifies requirements for a quality management system (QMS) to be applied to **Full Name Company Sdn. Bhd.** when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) 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.
c) to be certified according to ISO 9001

All the requirements of this Quality Manual are intended to be applicable to **Short Name**.

This manual is 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.

If procedure is required to be outlined, it should be addressed in this manual remarked as reference.

NOTE 1 In this Quality Manual, the terms "product" or "service" only apply to products and services offered to customer as addressed in section 4.3 of the ISO9001 Standard.

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

SECTION 2. COMPANY PROFILE

A brief statement about organization and its activities

SECTION 3: ABBREVIATION

SECTION 4: DESCRIPTION OF QUALITY MANUAL

Full Name Company Sdn. Bhd

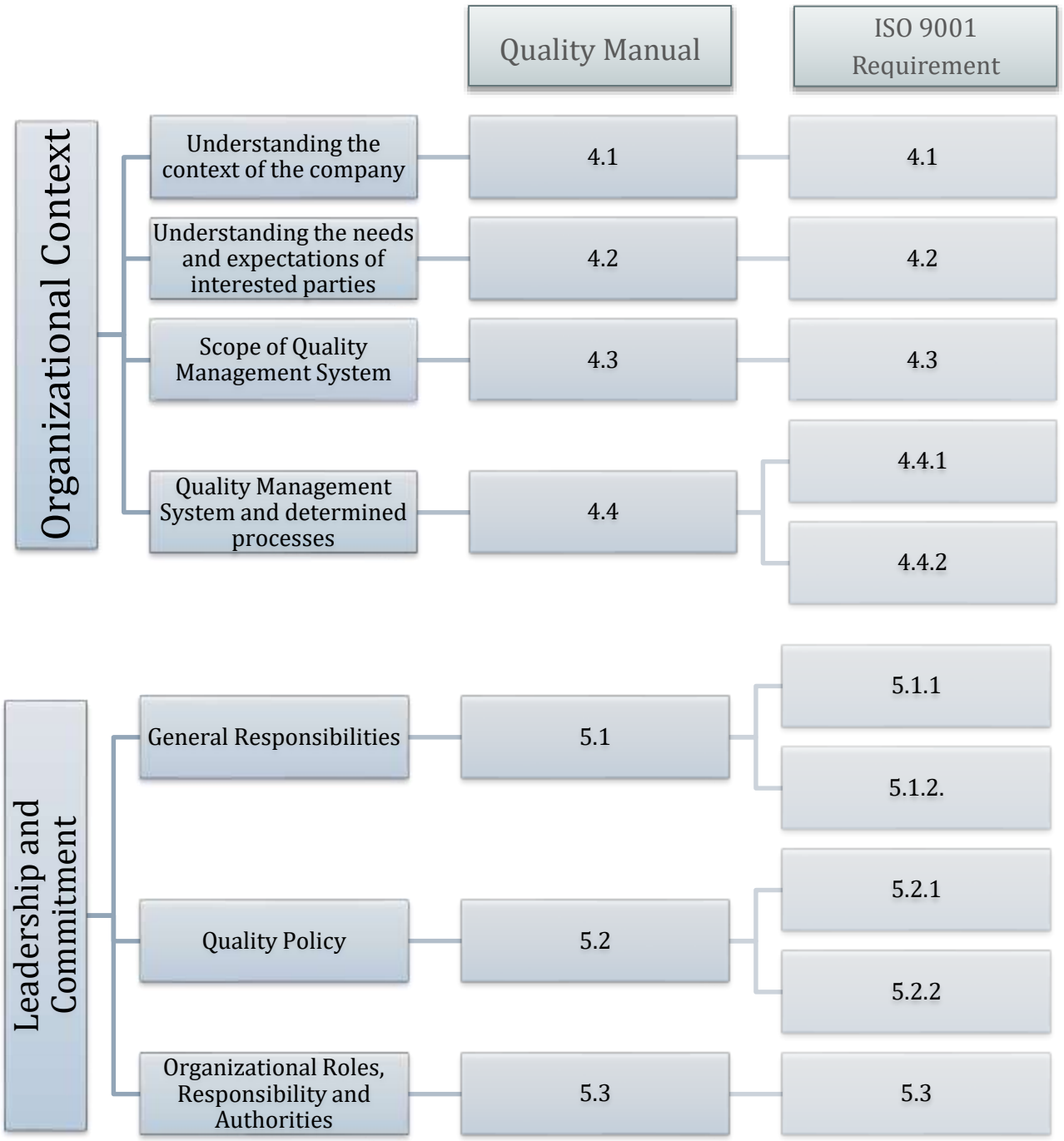
DOCUMENT REF. NO.: QM-0

REVISION HISTORY

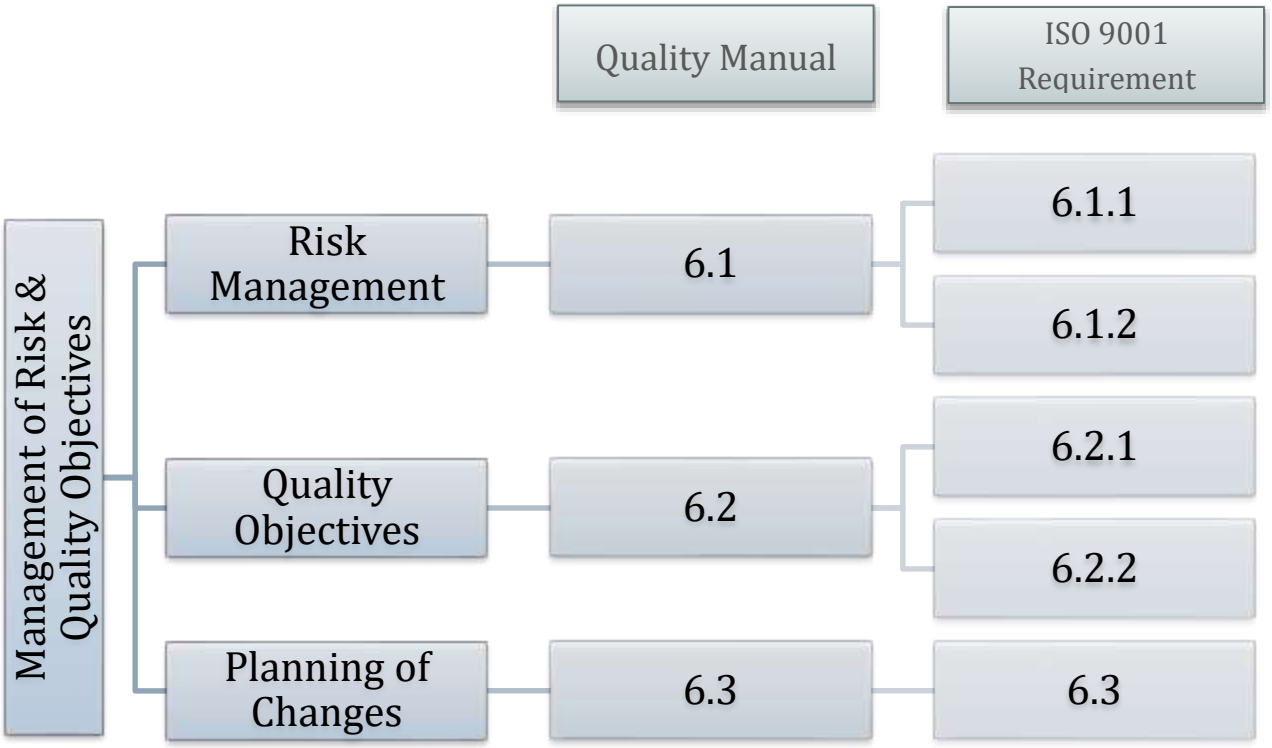
NO. PINDAAN	TARIKH	KETERANGAN PINDAAN	PEGAWAI
0	13-Sep-15	Versi awalan dilancarkan	

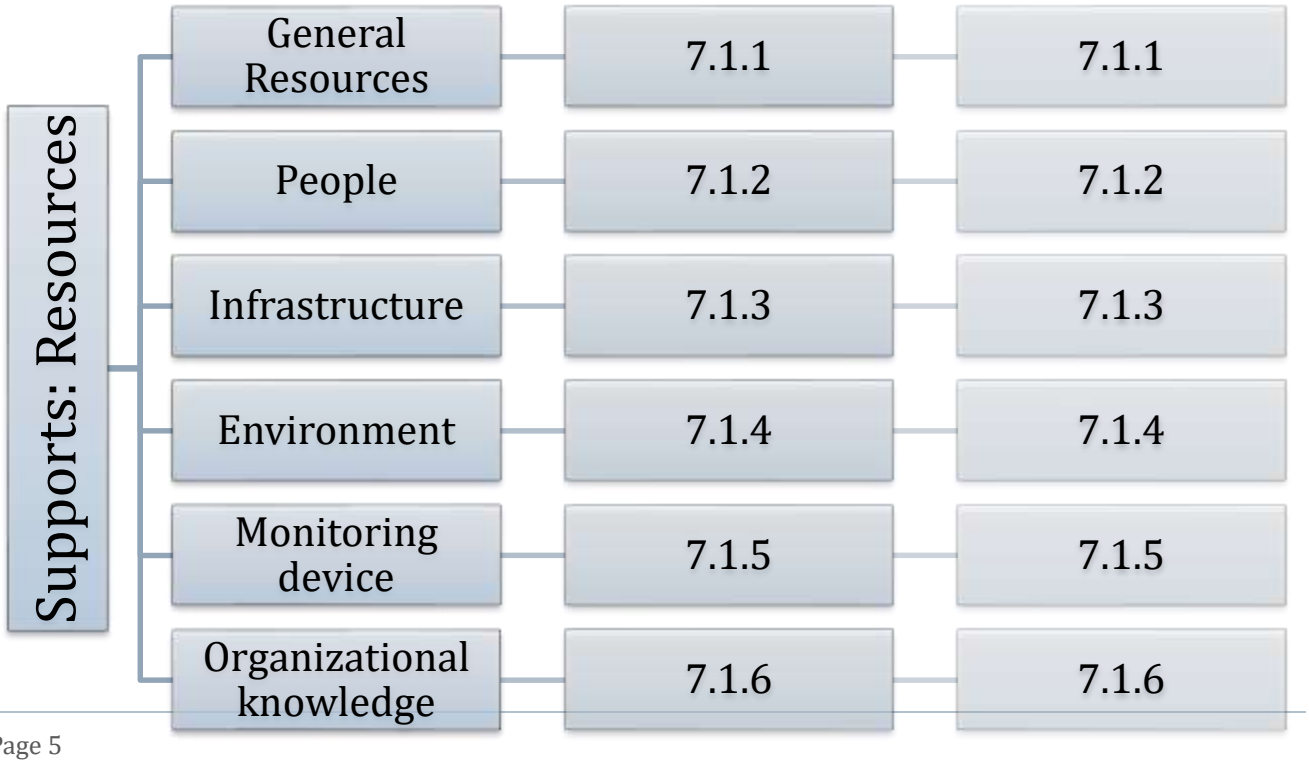
QMS DOCUMENT STRUCTURE

Organizational Context

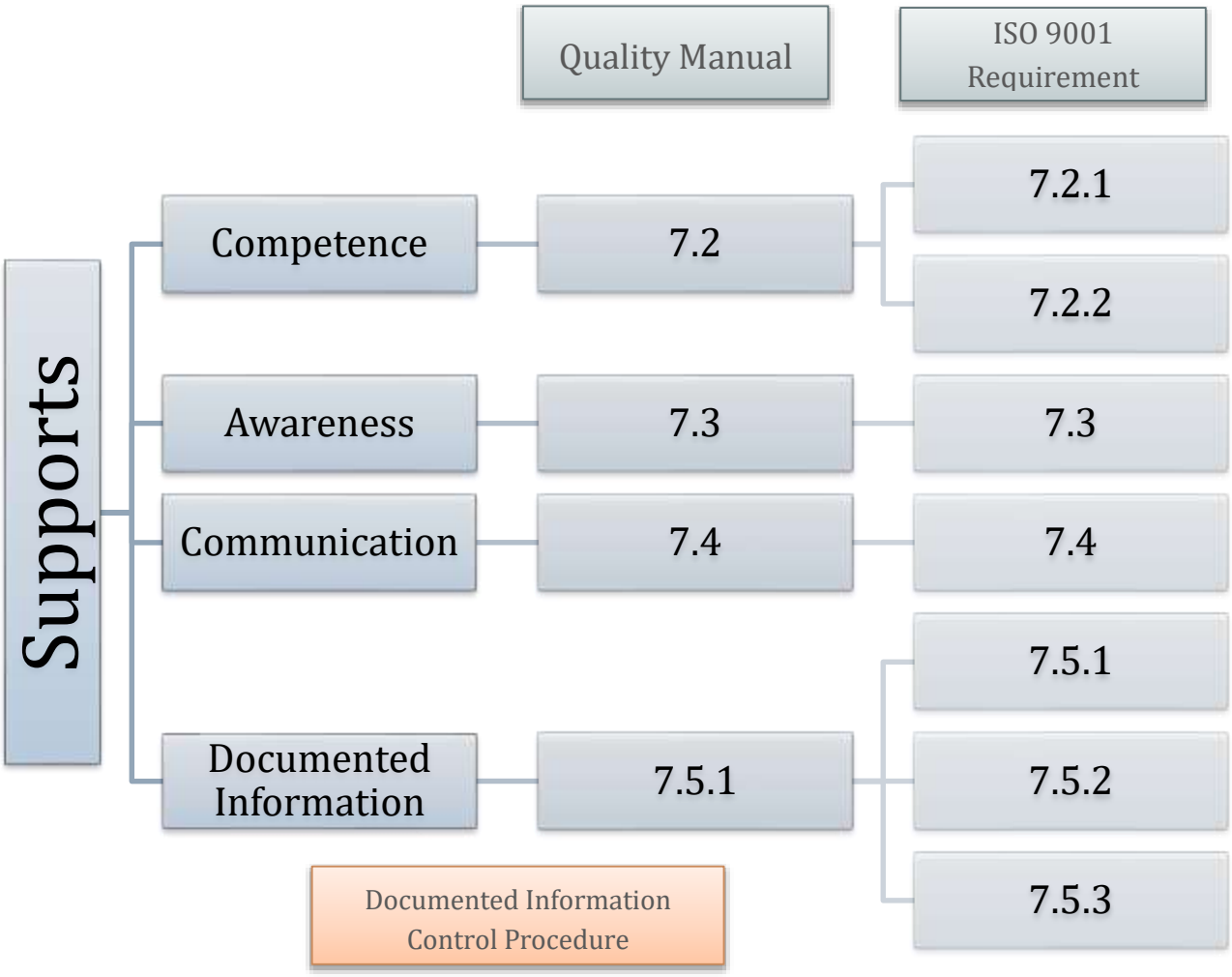


Full Name Company Sdn. Bhd

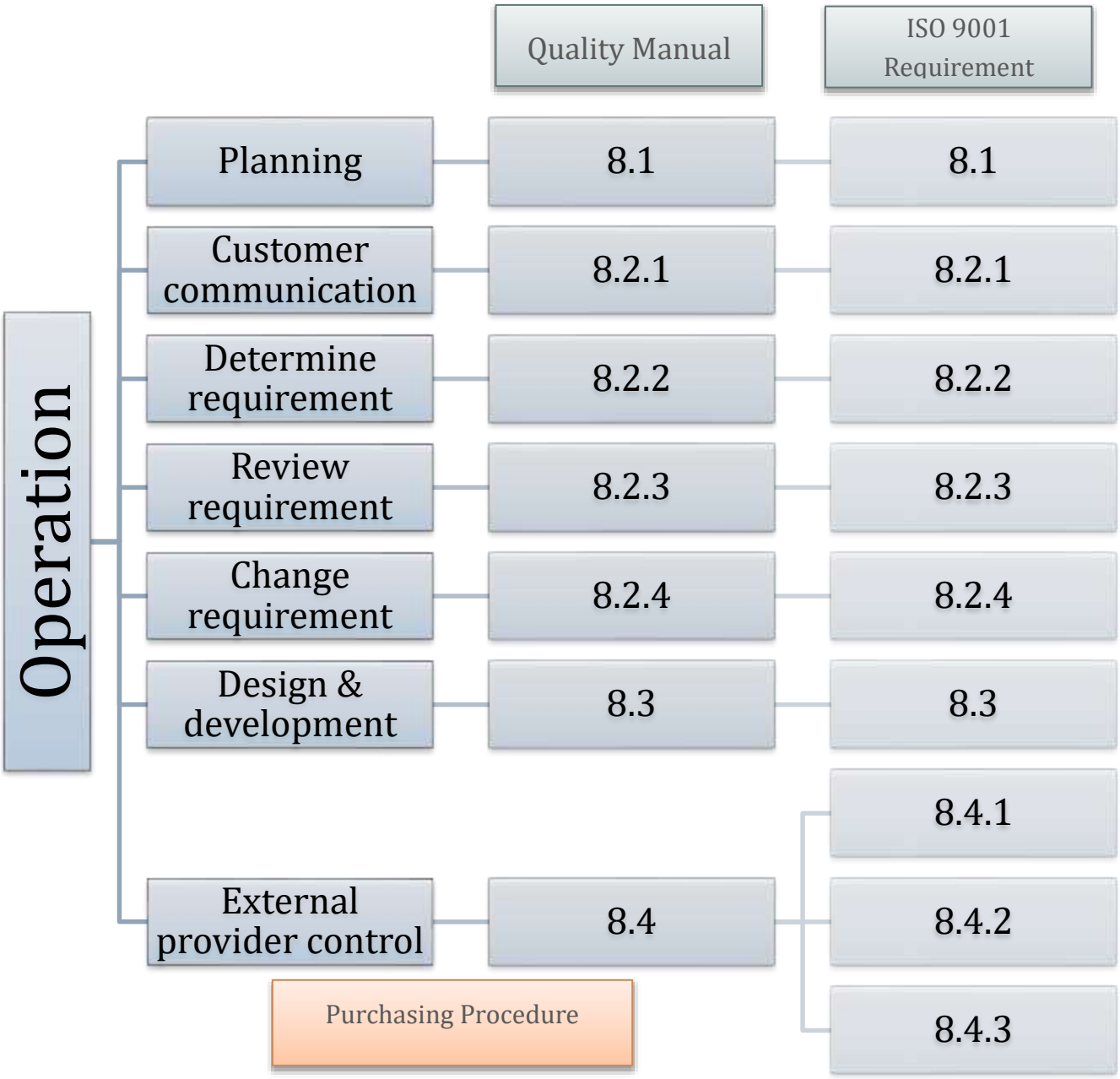




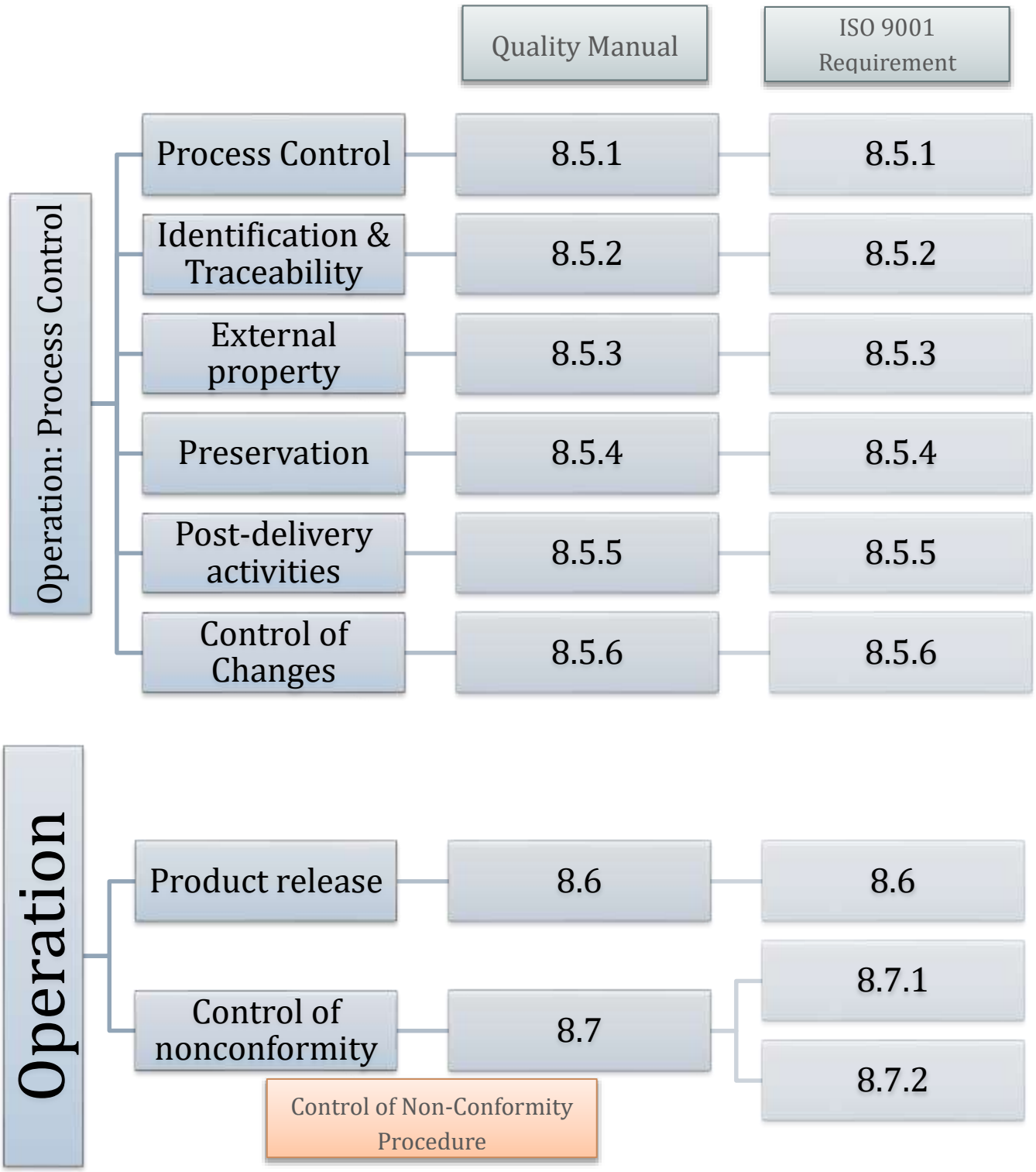
Full Name Company Sdn. Bhd



Full Name Company Sdn. Bhd



Full Name Company Sdn. Bhd

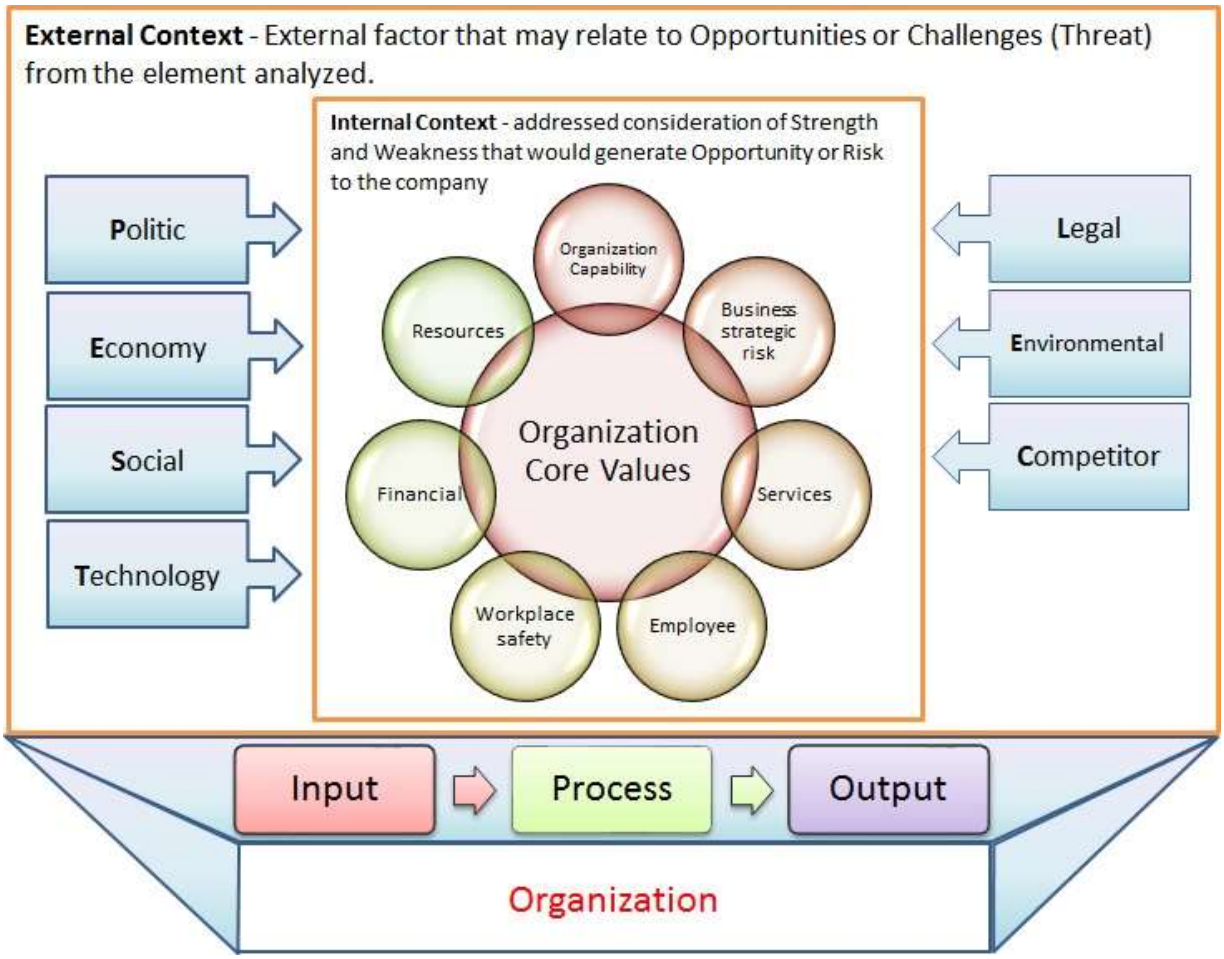


4. ORGANIZATIONAL CONTEXT OF FULL NAME COMPANY SDN. BHD.

4.1 Understanding the context of the Short Name

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

Internal and external issue of **Short Name** can be displayed from below diagram;



Information of these issued has been demonstrated by the Risk Analysis document. Realization of the Risk Analysis will follow according to section 6.1 Risk Management of this Quality Manual

Short Name shall monitor and review the Risk Analysis document to ensure prevention of the negative impact to **Short Name** business and consequences of the issues will not jeopardize the opportunity of **Short Name** in this industy

Notes;

1. Issues can include positive and negative factors or conditions for consideration
2. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
3. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

Any changes in external and internal issues that are relevant to the quality management system, the input shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 4.1, Understanding the organization and its context of ISO 9001

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the **Short Name**'s ability to consistently provide best services that meet customer and applicable statutory and regulatory requirements, the top management of **Short Name** shall determine:

a) the interested parties that are relevant to the quality management system implemented within **Short Name**
b) 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 information of the interested parties demonstrated by the List of Stakeholders. The organization shall monitor and review this document to maintain the compliance of needs of interested parties and their relevant requirements.

Note: This section is addressed to meet the requirement of clause 4.2, Understanding the needs and expectations of interested parties of ISO 9001

4.3 Scope of Quality Management System

The top management of **Short Name** shall determine the boundaries and applicability of the quality management system to establish its scope for certification.

Consideration is important for **Short Name** before determining the scope of certification

a) the external and internal issues referred to in clause 4.1 Understanding the organization and its context of the ISO 9001 standard

b) the requirements of relevant interested parties referred to in clause 4.2 Understanding the needs and expectations of interested parties of the ISO 9001 standard
c) the products and services of **Short Name.**
d) **Short Name** shall apply all the requirements of ISO 9001 if applicable within the determined scope of quality management system.

Therefore the scope of certification to be justified for **Full Name Company Sdn. Bhd.** (**Short Name**) is;

Provision of Project Management for Construction of Building and Civil Works

To run their activities at below site address;

Kuala Terengganu, Terengganu, Malaysia

By stating the abovementioned scope, justification is also being provided to determine any requirement of ISO 9001 Standard that Short Name is not applicable to the scope of quality management system.

Short Name confirmed that the following elements are not applicable and does not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction;

Clause: XXXXXX

Clause: XXXXXX

Note: This section is addressed to meet the requirement of clause 4.3, Determining the scope of the quality management system of ISO 9001

4.4 Quality Management System and determined processes

The top management of **Short Name** shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001.

Short Name has determined the processes needed for the quality management system and its application throughout the company as follows:

PROCESS TABLE

PROCESS & APPLICATION	REFERENCE
determined inputs required and the outputs expected from the processes; determined sequence and interaction of the processes;	Business Process Mapping and Project Management Process Sequence
determine and apply the criteria and methods	Datermination of process is through Quality Manual; 1. Clause 8.1 Project Planning,

	2. Clause 8.2. Requirement for products and services, and 3. Clause 8.4 Control of externally provided processes, products and services Application of process is demonstrated by clause 8.5 Provision of construction project management
monitoring, measurements and related performance indicators needed to ensure the effective operation and control of these processes;	KPI Monitoring (Application of this shall follow as per clause 6.2 Quality Objective of this Quality Manual)
determine the resources needed for these processes and ensure their availability	Refer to clause 7.1 Resource of this Quality Manual
assign the responsibilities and authorities for these processes	Refer to clause 5.3 Organizational Roles, Responsibility and Authorities
address the risks and opportunities as determined in accordance with the requirements of 6.1 of the standard	Refer to Risk Analysis document (Application of this shall follow as per clause 6.1 Risk Management of this Quality Manual)
evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;	Refer to 1. Internal Audit Procedure 2. **Error! Reference source not found.** and, 3. Management Review (as defined in clause 9.3 Management Review of this Quality Manual) Where applicable, the change needed shall follow according to Documented Information Control Procedure
improve the processes and the quality management system.	Refer to; 1. KPI Monitoring, 2. Corrective Action Procedure, and, 3. Management Review (as defined in clause 9.3 Management Review of this Quality Manual)

All abovementioned documented information shall be maintained and controlled through Documented Information Control Procedure

Note: This section is addressed to meet the requirement of clause 4.4, Quality management system and its processesof ISO 9001

5 LEADERSHIP AND COMMITMENT

Top management of **Short Name** shall demonstrate leadership and commitment with respect to the quality management system through;

5.1 General responsibilities

a) taking accountability for the effectiveness of the quality management system
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Top management of **Short Name** shall demonstrate leadership and commitment with respect to customer focus by:

COMMITMENT TABLE

COMMITMENT	REFERENCE
customer requirements are determined, understood and consistently met	Refer to clause 8.2. Requirement for products and services of this Quality Manual
applicable statutory and regulatory requirements are determined, understood and consistently met	Legal Register List and Evaluation
the risks and opportunities that can affect conformity of products and services	Risk Analysis document
ability to enhance customer satisfaction are determined and addressed and maintaining to focus for enhancing customer satisfaction	Clause 9.1.2 Customer satisfaction of this Quality Manual

Note: This section is addressed to meet the requirement of clause 5.1 Leadership and Commitment of ISO 9001

5.2 Quality Policy

Top management of **Short Name** established, implemented and maintained a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction
b) provides a framework for setting quality objectives
c) includes a commitment to satisfy applicable requirements
d) includes a commitment to continual improvement of the quality management system.

The Quality Policy statement of **Full Name Company Sdn. Bhd.** is;

Full Name Company Sdn. Bhd. strives to be the leading and professional master builder in achieving customer satisfaction by:

1. ***Providing excellent standard of quality construction services which exceeds customer requirements***

2. ***Continuously monitor and fulfill customer required project deadline.***

And we are committed to continuously improve the effectiveness of our services by implementing and complying to all requirements required by ISO9001 standard

This quality policy shall be:

a) maintained as documented information; and controlled through clause 7.5 Documented Information of this Quality Manual
b) communicated, understood and applied within the organization; through clause 7.3 Awareness of this Quality Manual
c) available to relevant interested parties, as appropriate.

Note: This section is addressed to meet the requirement of clause 5.2.1 Developing the Quality Policy of ISO 9001

5.3 Organizational Roles, Responsibility and Authorities

Top management of **Short Name** shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. The structure of the organization can be demonstrated by the Organization Chart

Top management of **Short Name** shall assign the responsibility and authority for executing the below tasks:

RESPONSIBILITY TABLE

TASK	HOW TO ACHIEVE IT?	PERSON-IN-CHARGE
ensuring that the quality management system conforms to the requirements of ISO 9001 Standard	1. Internal Audit (refer to clause 9.2 Internal Audit of this Quality Manual and 2. Management review as per clause 9.3 Management Review of this Quality Manual Awareness of every staff through clause 7.3 Awareness of this Quality Manual	QMR
ensuring that the processes are delivering their intended outputs;	1. Business Process Mapping, 2. Project Management Process Sequence 3. Clause 8.1 Project Planning of this Quality Manual 4. Clause 8.5.1 Project management control of this Quality Manual	QMR
Reporting on the performance of the quality management system	1. KPI, 2. Internal Audit process as per 9.2 Internal Audit of this Quality Manual 3. Management review as per Clause 9.3 Management Review of this Quality Manual	QMR
Reporting on opportunities for improvement (see 10.1), in particular to top management of **Short Name**	Refer to Quality Manual 1. Clause 10.2 Nonconformity and corrective action, and 2. Clause 10.3 Continual Improvement	QMR
ensuring the promotion of customer focus throughout **Short Name**	Refer to Quality Manual; 1. Clause 5.1 General responsibilities 2. Clause 7.3 Awareness	QMR

ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented	According to Documented Information Control Procedure	Document Controller

Note: This section is addressed to meet the requirement of 5.3 Organizational Roles, Responsibility and Authorities of ISO 9001

6 MANAGEMENT OF RISKS AND QUALITY OBJECTIVES

6.1 Risk Management

When planning for the QMS, **Short Name** had considered the issues addressed in clause 4.1 of the standard and the requirements addressed in clause 4.2 of the standard.

This also in line with the aspect described in clause 4.1 Understanding the context of the Short Name of this Quality Manual for **Short Name** where the internal and external issues shall be addressed. While, the expectation of interested parties as in clause 4.2 of this Quality Manual (Understanding the needs and expectations of interested parties) to incorporate with relevant issues to ensure their interaction does not give a negative effect to the construction project management executed by the company.

Therefore, determination to the risks and opportunities is needed to:

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

The planning of risk management has concerned on the following aspects;

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.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. Where appropriate, it should follow according to Corrective Action Procedure

In the context of **Short Name**, risk management shall taking into account on the following aspects

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

Reference: Risk Analysis Document

In conformance with clause 4.4, Quality Management System and determined processes of this Quality Manual, documented information of risk management shall be established, implemented and maintained. The requirement of Documented Information Control Procedure is followed

The effectiveness of actions taken to address risks and opportunities shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of 6.1 Action to address risks and opportunities of ISO 9001

6.2 Quality Objective

Short Name established quality objectives at relevant functions, levels and processes needed for the QMS.

The quality objectives shall:

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

The planning how to achieve quality objectives, **Short Name** shall determine:

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

Reference: KPI monitoring

In conformance with clause 4.4, Quality Management System and determined processes of this Quality Manual, documented information of Quality Objectives shall be established, implemented and maintained. The requirement of Documented Information Control Procedure is regulated.

Note: This section is addressed to meet the requirement of 6.2 Quality Objectives and planning to achieve them of ISO 9001

6.3 Planning of changes

When **Short Name** determines the need for changes to the QMS, the changes shall be carried out in a planned manner (according to clause 4.4 of the standard).

It shall consider:

a) the purpose of the changes and their potential consequences; (see clause 6.1.1 and 6.1.2 of this Quality Manual)
b) the integrity of the quality management system; see clause 7.5.1 of this Quality Manual
c) the availability of resources; see clause 7.1.1 of this Quality Manual

Where the changes is applied, it shall follow according to Documented Information Control Procedure

Note: This section is addressed to meet the requirement of 6.3 Planning of changes of ISO 9001

7 SUPPORT

7.1 Resource

7.1.1 General

Short Name shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS.

Determination shall include:

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

The adequacy of resources laid down in this Quality Manual through clause 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 **Short Name**as it required by clause 9.3 Management Review of this Quality Manual

7.1.2 People

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

Determination of qualified personnel will be addressed in clause 7.2 Competence of this Quality Manual

Note: This section is addressed to meet the requirement of clause 7.1.2 People, of ISO 9001

7.1.3 Infrastructure

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

Determination of Infrastructure within **Short Name** is including:

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

All abovementioned infrastructure shall be appropriately maintained in order to facilitate towards positive outcome and to ensure the smoothness of process control as it defined in clause 8.5.1 Project management control of this Quality Manual

Note: This section is addressed to meet the requirement of clause 7.1.3 Infrastructure of ISO 9001

7.1.4 Environment for the operation of processes

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

A suitable environment within **Short Name** 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 abovementioned factors can be associated with the elements defined in section 6.1 Risk Management.

The maintenance of environment is also important to ensure the smoothness of process control as it defined in clause 8.5.1 Project management control of this Quality Manual

Note: This section is addressed to meet the requirement of clause 7.1.4 Environment for the operation of processes of ISO 9001

7.1.5 Monitoring and measuring resources

Short Name shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Therefore, **Short Name** will ensure that the resources provided:

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

Evidence of fitness for purpose of the monitoring and measurement resources shall retain as documented information and controlled according to Documented Information Control Procedure

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
b) identified in order to determine their status;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

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

Important Note: Construction project is executed by appointed subcontractor. Therefore, verification and calibration of measurement equipment should be responsible under subcontractor's duty. Short Name shall ensure the maintenance of the process to ensure conformity to the quality management system.

Note: This section is addressed to meet the requirement of clause 7.1.5 Monitoring and measuring resources of ISO 9001

7.1.6 Organizational Knowledge

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

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

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

Organizational knowledge is knowledge specific to demonstrate conformity to positive outcome of **Short Name** scope of certification as addressed in section 4.3 of this Quality Manual.

Organizational knowledge can gained by experience. It is information that 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 clause 7.2 Competence of this Quality Manual

Note: This section is addressed to meet the requirement of clause 7.1.6 Organizational Knowledge of ISO 9001

7.2 Competence

7.2.1 Determination of competence

a) The personnel / function competency can be determined from respective Job Description or JD. JD elaborates qualification needed 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 also important to ensure the smoothness of process control as it defined in clause 8.5.1 Project management control of this Quality Manual
c) Consideration of competency may associate the subjects addressed in this Quality Manual through following clause;
    a. Clause 5.3 Organizational Roles, Responsibility and Authorities
    b. Clause 7.1.2 People
    c. Clause 7.1.6 Organizational Knowledge
    d. Clause 7.3 Awareness
d) Competency determined when issue being raised from Control of Non-Conformity Procedure

7.2.2 Maintaining the competency

a) Job Description of key functions will describe based from education, experience and related skill
b) Skill of function may defined 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 the personnel attended the training.
d) Update JD as necessary
e) Retain appropriate documented information and comply with Documented Information Control Procedure

Note: This section is addressed to meet the requirement of clause 7.2 Competence, of ISO 9001

7.3 Awareness

Short Name shall ensure 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 should be conducted and process should follow according to section 7.2 Competence of this Quality Manual.

Note: This section is addressed to meet the requirement of clause 7.3 Awareness, of ISO 9001

7.4 Communication

Short Name shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;
e) who communicates.

7.4.1 Importance of effective communication

It is important for company to take into account for internal and external communication input from interested parties to ensure that message from them will be managed in proper way

7.4.2 Communication approach

COMMUNICATION TOOLS

WHO?	TOOLS	RECEIVER
Employee	Email, Memo, CAR, Notice Board	Employee / customer / stakeholder
Customer	Email, written official letter/notice	Employee
Stakeholders	Email, written official letter/notice	Employee

Maintenance of communication tools shall follow according to section 7.1.3 Infrastructure of this Quality Manual

The sign of fail communication may possible cause the following cases to be occurred;

a) Complaint from customer or stakeholder
b) Output does not able to achieve the intended result(s) of its quality management system.
c) The process is not delivering their intended outputs;

Where appropriate, the problem solving should follow according to Control of Non-Conformity Procedure and Corrective Action

Note: This section is addressed to meet the requirement of clause 7.4 Communication, of ISO 9001

7.5 Documented Information

Top Management of **Short Name** shall ensure the quality management system shall include:

a) documented information required by ISO 9001;

b) documented information determined by **Short Name** as being necessary for the effectiveness of the quality management system.

Therefore, **Short Name** has determined the necessary documented information to be applied within the organization as follows;

DOCUMENTED INFORMATION (TABLE 1)

MANAGEMENT DOCUMENT	RESOURCES	OPERATION
Quality Policy	Monitoring and measurement document	Operational Planning document
Quality Objectives	Competency document	Service requirement review
		Control of external provider
		Process control document
		Identification and traceability document
		Customer property document
		Process changed document
		Release of service document
		Service nonconformity

DOCUMENTED INFORMATION (TABLE 2)

DESIGN AND DEVELOPMENT	MONITORING & EVALUATION	IMPROVEMENT
Design input	Performance monitoring	Nonconformity and corrective action
Design control	Internal Audit	
Design output	Management Review	
Design change		

Control of documented information shall follow according to Documented Information Control Procedure

Note: This section is addressed to meet the requirement of clause 7.5 Documented Information, of ISO 9001

8. OPERATION

8.1 Project Planning

Short Name shall plan, implement and control the processes;

1. as defined in clause 4.4 Quality Management System and determined processes of this Quality Manual that needed to meet the requirements for the provision of scope of which **Short Name** being certified (Provision of Project Management for Construction of Building and Civil Works), and
2. to implement the actions determined in clause 6 of this Quality Manual (Management of Risks and Quality Objectives) , by following table;

QMS PLANNING TABLE

DESCRIPTION	REALIZATION
a). determining the requirements for the products and services	Refer to clause 8.2. Requirement for products and services of this Quality Manual
b). establishing criteria for: **1. the processes;** **2. the acceptance of products and services** **c). implementing control of the processes in accordance with the criteria**	Refer to 1. Business Process Mapping to overview the process criteria, 2. Clause 8.4 Control of externally provided processes, products and services of Quality Manual for purchasing activities or if outsourced process is applicable 3. Clause 8.5.1 Project management control of this Quality Manual for operational control process, and 4. Clause 8.6 Release of products and services of this Quality Manual for handing over process
d). determining the resources needed to achieve conformity to the product and service requirements	Refer to; 1. Clause 7.1 Resource of this Quality Manual 2. If outsourced processes or external provided process are applied, clause 8.4 Control of externally provided processes, products and services of this Quality Manual shall be refered.
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.**	Control of documented information shall according to clause 7.5 Documented Information

All abovementioned activity shall be maintained in order to ensure;

1. The output of this planning remain suitable for **Short Name**'s operations.
2. Ability of the planning adequately controlled and consequences of unintended changed can be reviewed so that action can be taken to mitigate any adverse effects, as necessary

Note: This section is addressed to meet the requirement of clause 8.1 Operational planning and control, of ISO 9001

8.2. Requirement for products and services

8.2.1 Customer communication

Communication with customers shall follow according to clause 7.4 Communication of this Quality Manual in order to ensure the smoothness of the following process

a) providing information relating to products and services; during tendering / bidding process
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, Whenever receive complaints from customer solution process shall follow according to clause 10.2 Nonconformity and corrective action of this Quality Manual
d) handling or controlling customer property, if applicable. (Refer to clause 8.5.3 Property belonging to customers or external providers of this Quality Manual for details)
e) establishing specific requirements for contingency actions, when relevant.

Note: This section is addressed to meet the requirement of clause 8.2.1 Customer communication, of ISO 9001

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 shall ensure that:

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

Note: This section is addressed to meet the requirement of clause 8.2.2 Determining the requirements related to products and services, of ISO 9001

8.2.3 Review of requirements related to products and services

Short Name shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. **Short Name** shall conduct a review before committing to supply products and services to a customer, to include:

REVIEW REQUIREMENT	
DESCRIPTION OF REQUIREMENT	SOURCE
requirements specified by the customer, including the requirements for delivery and post-delivery activities;	Contract Document
requirements not stated by the customer, but necessary for the specified or intended use, when known;	Legal Requirement
requirements specified by the organization;	As per clause 8. Operation of this Quality Manual
statutory and regulatory requirements applicable to the products and services;	As per contract document As per Risk Analysis
contracts or order requirements differing from those previously expressed.	As per contract document

Who shall ensure that contracts or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the authorized person before acceptance, when it is the case of customer does not provide a documented statement of their requirements.

Documented information, shall be control according to clause 7.5 Documented Information of this Quality Manual as applicable when:

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

Note: This section is addressed to meet the requirement of clause 8.2.3 Review of requirements related to products and services, of ISO 9001

8.2.4 Changes to requirements for products and services

Who shall ensure that relevant documented information shall follow clause 7.5 Documented Information for the amendment process.

Also, the team member shall aware of the changed requirements, when the requirements for products and services are changed according to clause 7.4 Communication of this Quality Manual

Where applicable, the process shall follow according to Documented Information Control Procedure

Note: This section is addressed to meet the requirement of clause 8.2.4 Changes to requirements for products and services, of ISO 9001

8.3 Design and development of products and services

Top management of **Short Name** decided the design and development process does not applied within the organization. Once project successfully awarded, the designing process will be outsourced to third party. Therefore, the control process to ensure conformity shall follow according to clause 8.4 Control of externally provided processes, products and services of this Quality Manual.

8.4 Control of externally provided processes, products and services

Short Name shall ensure that externally provided processes, products and services or commonly known as purchasing process conform to requirements.

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

Control of externally provided process are including

a) Datermination of purchasing control including slection, 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

Detail of externally provided process control should refer to Purchasing Procedure

Result of performance of external provider shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 8.4 Control of externally provided processes, products and services, of ISO 9001

8.5 Provision of construction project management

8.5.1 Project management control

Short Name shall implement the provision of project management under controlled conditions.

Controlled conditions of process control is as follows:

PROCESS CONTROL TABLE	
DESCRIPTION	REFERENCE

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** **2) be performed;** **3) the results to be achieved;**	Process Control Procedure
b) the availability and use of suitable monitoring and measuring resources;	Process Control Procedure and clause 7.1.5 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;	Process Control Procedure
d) the use of suitable infrastructure and environment for the operation of processes;	Refer to; 7.1.3 Infrastructure 7.1.4 Environment for the operation of processes
e) the appointment of competent persons, including any required qualification;	Refer to; 7.2 Competence
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;	Process Control Procedure
g) the implementation of actions to prevent human error;	Risk Analysis Corrective Action Procedure
h) the implementation of release, delivery and post-delivery activities.	Process Control Procedure

Note: This section is addressed to meet the requirement of clause 8.5.1 Control of production and service provision, of ISO 9001

8.5.2 Identification and traceability

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

That is including the control of;

1. Identification of status of outputs with respect to monitoring and measurement requirements throughout production and service provision as defined in 8.5.1 Project management control

The unique identification of the outputs when traceability is a requirements through the process defined in clause

2. 8.2.2 Determining the requirements related to products and services and clause 8.2.3 Review of requirements related to products and services of this Quality Manual.

To maintain the identification and traceability by retaining the documented information according to Documented Information Control Procedure.

Note: This section is addressed to meet the requirement of clause 8.5.2 Identification and traceability, of ISO 9001

8.5.3 Property belonging to customers or external providers

Short Name shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

Short Name shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the designated personnel 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.

Note: This section is addressed to meet the requirement of clause 8.5.3 Property belonging to customers or external providers, of ISO 9001

8.5.4 Preservation

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

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Note: This section is addressed to meet the requirement of clause 8.5.4 Preservation, of ISO 9001

8.5.5 Post-delivery activities

Short Name shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, consideration has been made through below information:

TABLE HEADING	
DESCRIPTION	REFERENCE
a) statutory and regulatory requirements	Legal Register
b) the potential undesired consequences associated with its products and services	Risk Analysis and Clause 8.7 Control of Nonconforming output of this Quality Manual
c) the nature, use and intended lifetime of its products and services	Warranty claim, claimable period
d) customer requirements	Refer to clause 8.2.2 Determining the requirements related to products and services
e) **customer feedback**	Refer to Quality Manual; 1. Clause 8.2.1 Customer communication 2. Clause 9.1.2 Customer satisfaction 3. Clause 10.2 Nonconformity and corrective action

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.

Note: This section is addressed to meet the requirement of clause 8.5.5 Post-delivery activities, of ISO 9001

8.5.6 Control of changes

Short Name shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

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

Where the changes are applied, Documented Information Control Procedure must follow to comply.

Note: This section is addressed to meet the requirement of clause 8.5.6 Control of changes, of ISO 9001

8.6 Release of products and services

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

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed in accordance with clause 8.5.1 Project management control of this Quality Manual.

The control of product to be released is also applied to the product supplied by the external provider with direct delivery to customer as defined in Purchasing Procedure

Any abnormality which does not meet with requirement from customer, resolution should be made through clause 8.7 Control of Nonconforming output of this Quality Manual where, the the product only can be released unless obtained approval by a determined authority and, as applicable, by the customer.

The record of released product shall be retained as documented information in accordance with Documented Information Control Procedure to ensure;

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

Note: This section is addressed to meet the requirement of clause 8.6 Release of products and services, of ISO 9001

8.7 Control of Nonconforming output

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

Short Name 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 ways of dealing with nonconforming outputs must be according to one or more of the following measures:

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.

The organization shall retain documented information that:

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

Control of nonconforming outputs shall follow according to Control of Non-Conformity Procedure

Information on nonconformities shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 8.7 Control of nonconforming outputs, of ISO 9001

9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Short Name shall

1. Determine:
   a) what needs to be monitored and measured;
   b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
   c) when the monitoring and measuring shall be performed;
   d) when the results from monitoring and measurement shall be analysed 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 Documented Information Control Procedure

Note: This section is addressed to meet the requirement of clause 9.1.1 General of Monitoring, measurement, analysis and evaluation of ISO 9001

9.1.2 Customer satisfaction

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

Method of evaluation should refer to clause 9.1.3 Analysis and evaluation of this Quality Manual

Result of monitoring activity shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 9.1.2 Customer satisfaction of Monitoring, measurement, analysis and evaluation of ISO 9001

9.1.3 Analysis and evaluation

Short Name shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used in accordance with below table;

EVALUATION ANALYSIS

WHAT	METHOD OF MONITORING & EVALUATION	FREQUENCY OF MONITORING (DATA COLLECTION)	FREQUENCY OF ANALYSIS ON RESULT
a) conformity of products and services;	KPI	Monthly	Quarterly
b) customer satisfaction	Customer Satisfaction evaluation	Annually	Annually
c) Performance and effectiveness of the quality management system	KPI	Monthly	Quarterly
d) Effectiveness of quality management system planning	Internal Audit	Annually	Annually
e) the effectiveness of actions taken to address risks and opportunities;	1. Internal Audit, and 2. Clause 10.2 Nonconformity and corrective action	Annually Monthly	Annually Monthly
f) the performance of external providers;	Supplier evaluation	Annually	Annually
g) Needs for improvements to the quality management system.	Management Review	Annually	Annually

Result of analysis and evaluation shall be reviewed by top management of **Short Name**as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 9.1.3 Analysis and evaluation of ISO 9001

9.2 Internal Audit

Short Name shall conduct internal audits **at least by 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 shall include;

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

Details of internal audit activities shall follow according to Internal Audit Procedure

Result of internal audit activity shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 9.2 Internal Audit of ISO 9001

9.3 Management Review

9.3.1 General

Top management of **Short Name**shall review the organization's quality management system, **at least by annually**, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of **Short Name**.

9.3.2 Management Review Inputs

The management of **Short Name** review shall be planned and carried out taking into consideration:

INPUT OF MANAGEMENT REVIEW	
INPUT	SOURCE
a) the status of actions from previous management reviews;	Previous year meeting minutes of management review

b) changes in external and internal issues that are relevant to the quality management system;	7.5 Documented Information
c) information on the performance and effectiveness of the quality management system, including trends in:	
1. **customer satisfaction**	
2. **Customer complaint**	
3. **feedback from relevant interested parties;** **i. Notice from authorities** **ii. Letter from interested parties**	
4. **the extent to which quality objectives have been met**	
5. **process performance and conformity of products and services;**	
6. **nonconformities and corrective actions;**	
7. **monitoring and measurement results;**	
1. **audit results;** **i. Internal audit** **ii. External audit**	
8. **the performance of external providers**	
9. **The adequacy of resources;**	
10. **the effectiveness of actions taken to address risks and opportunities (see 6.1);**	
11. **opportunities for improvement.**	

9.3.3 Management Review Outputs

The outputs of the management review shall include decisions and actions related to:

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

Documented information of Management Review outputs shall be retained as an evidence of the results of management reviews

Note: This section is addressed to meet the requirement of clause 9.3 Management Review of ISO 9001

10. IMPROVEMENT

10.1 General

Short Nameshall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

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

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

The input of opportunity for improvement shall be reviewed by top management of **Short Name**as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 10.1 General of improvement of ISO 9001

10.2 Nonconformity and corrective action

When a nonconformity occurs, including any arising from complaints, the designated personnel shall:

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

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

<who> shall retain documented information as evidence of:

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

Details of step measures for taking action on nonconformity shall follow according to Corrective Action Procedure

Information on nonconformities and corrective action shall be reviewed by top management of **Short Name**as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 10.2 Nonconformity and corrective action of ISO 9001

10.3 Continual Improvement

The organization of **Short Name** shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The consideration shall be taken based from following inputs

a) Results of analysis and evaluation as defined in clause 9.1.3 Analysis and evaluation of this Quality Manual, and
b) The outputs from management review as defined in clause 9.3.3 Management Review Outputs

Based from inputs from the abovementioned, top management of **Short Name** has to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

The input of opportunity for improvement shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

Note: This section is addressed to meet the requirement of clause 10.3 Continual Improvement of ISO 9001

Documented Information Control Procedure

Document Ref. No.: P-DC-0

REVISION HISTORY

NO. PINDAAN	TARIKH	KETERANGAN PINDAAN	PEGAWAI
0	13-Sep-15	Versi awalan dilancarkan	

GENERAL REQUIREMENT

This procedure provides guideline to extent information explained in clause 7.5 Documented Information of the Quality Manual.

The requirement requirement is also enable to provide conformity to clause 7.5 Documented Information of ISO 9001:2015 Standard Requirement.

Type of Documented information applied in **Short Name**is as follows;

a) **Information type 1**: Instruction or guideline document such as manual, procedure, work instruction, flow chart and others.
b) **Information type 2**: Blank format
c) **Information type 3**: Filled-up document such as record.

COMMON DEFINITION USED

The definitions addressed are mainly refer to IS0 9000:2015

RESPONSIBILITY AND AUTHORITY

DOCUMENTED INFORMATION CONTROL PROCESS

New Creation of Document

1 Document that required to be controlled is as defined in clause clause 7.5 Documented Information of the Quality Manual. It applies to documented information **type 1** and **type 2**.

2 Any new document proposal must be approved by QMR. Endorsement will be made Managing Director where necessary

3 Approved document shall be listed in the Document Master List

4 Revision history should be determined through;

a) Revision history table at front page of document (e.g. procedure or work instruction)
b) Address in the footer of the document in case of form, checklist or other similar type of document

5 Document will consider as official once being formated in PDF version and retained by QMR.

6 Document shall be controlled as section Management of Controlled Document of this procedure

Amendment of Existing Document

1 Any proposal of revision to the existing document must through QMR. It applies to documented information **type 1** and **type 2**.

2 Those changes made for the form, old version of document need to be cleared first before use of revised document. Where applicable, Document Controller or QMR has authority to stop the usage of old document if reflected to the quality service conformity.

3 Revision history as determined in #4 of section New Creation of Document shall be updated

Management of Controlled Document

1 Control requirement for document is covered for internal and external document.

2 Master Copy shall be in soft copy, protected in PDF file and retained by QMR.

3 Copy of document is allowed but shall obtain approval from QMR before issuance.

4 Original soft copy only kept by the Document Controller for reference or to be used upon requires for changed.

5 Maintenance of soft copy should be in appropriate manner and back-up system should be activated through external hard disc or USB drive or other appropriate methods

6 No hard copy is allowed. However, **QMR** will justify the method of distribution if hard copy of controlled document is really need and does not against **Short Name**'s integrity of quality management system.

7 Distributed copies shall be indicated with CONTROLLED in red on the first page of Revision History.

8 Any controlled document need to be distributed to the third party, it shall be approved by QMR and indicated with UNCONTROLLED

Management of Controlled Records

This section is applied to documented information **type 3.**

Identification and traceability of Records

1 All records shall be filed in sequence and/or dated to allow easy identification and retrieval.

2 Unique identification of the version used is generated as described in #3 and #4 of section New Creation of Document of this procedure.

3 Unique identification for referring to the product, services or output of **Short Name**can refer to clause 8.5.2 Identification and traceability of the Quality Manual

4 QMR shall be responsible to maintain the List of Records. If any changes to the list of their records, the list shall be updated accordingly.

5 Records should be kept at the designated location to ensure the traceability and person in charge is defined

Storage, Protection and Retention

1 All records shall be stored and maintained and retrievable by the respective functions.

2 Record's legibility must be preserved.

3 Records shall be stored in hard copy and/or soft copy as appropriate. For non-critical records, storage in normal file cabinet is sufficient. For critical records, if any, the records shall be protected from potential fire, theft, unauthorized removal and other damage.

4 Also, critical records on electronic media shall be secured from inadvertent deletion, computer viruses and corruption of files; hard copies shall be produced and kept at a different location / area.

5 Records on soft copy shall be backed-up and back-up records shall be protected accordingly from damage or loss.

6 All records shall be retained for a minimum period as specified in the List of Records. Designated person shall be responsible to establish the retention period.

Retrieval and Disposal

1 All records shall be made available for inspection by management committee or as requested by the interested parties.

2 The records shall be stored in such a way that they are readily retrievable for review. For any request for records by external parties,

3 Records only can be disposed once obtained approval from QMR

4 Records shall be disposed-off by any suitable means. Confidential records shall be disposed-off by shredding.

DOCUMENTED INFORMATION

1. KLJKLJ
2. JNJKJK
3.

Internal Audit Procedure

Document Ref. No.: P-IA-0

REVISION HISTORY

NO. PINDAAN	TARIKH	KETERANGAN PINDAAN	PEGAWAI
0	13-Sep-15	Versi awal dilancarkan	

GENERAL REQUIREMENT

This procedure provides guideline to extent information explained in clause XXXXXXXXXXXXXXX of the Quality Manual.

The requirement requirement is also enable to provide conformity to clause xxxxxxxxxxxxxx of ISO 9001:2015 Standard Requirement.

COMMON DEFINITION USED

The definitions addressed are mainly refer to IS0 9000:2015

Conformity	Measurement	Outsource	Provider
Effectiveness	Nonconformity	Performance	Supplier
Monitoring	Output	Product	Verification

RESPONSIBILITY AND AUTHORITY

SELECTION OF AUDITORS

1 QMR shall nominate an Internal Auditor;
2 Selected auditor should be complied with one of the following criteria
   a) Experienced and/or trained in ISO 9001.
   b) Third party appointed and recognized by the Top Management with proven of competency qualification.
   c) Where necessary, training will be arranged for internal auditor to assure their competency. The process shall follow as per 7.2 Competence of the Quality Manual

PRE-AUDIT ACTIVITY

1. Lead auditor will prepare the Audit Plan.

2. The Audit Plan should define the audit criteria, scope and process need to be audited.

3. Determination of audit intensity
   a. All active projects shall be audited.
   b. If there is no active project is running, scope of audit may focus on adequacy of QMS process (such as Organizational Context of Full Name Company Sdn. Bhd., Leadership and commitment, Management of Risks and Quality Objectives, section 7 Support, section 9. Performance Evaluation and section 10. Improvement, or,

c. If QMR identified that there is no project is running and no change in QMS implementation, he has authority to decide the necessity of internal audit to be conducted due with circumstances reason should be determined.

4. Lead Auditor has to ensure the selection of auditors is meeting the objectivity and impartiality of the audit process.

5. Lead auditor will organize the auditors which not audit their own work.

6. Audit Plan will be distribute to the auditor prior assessment conducted

DURING AUDIT ACTIVITY

1 Auditor will conduct audit as per Audit Plan

2 Audit tools need to be used;

a. Audit Checklist

b. ISO 9001 Standard, where necessary

3 Audit Method
   a. Based from records
   (It shall consistently meet with Documented Information Control Procedure)
   b. Cross reference with the procedure and work instruction
   (It shall consistently maintained as per clause 8. Operation of Quality Manual)
   c. Observation of process to meet with clause 8. Operation of Quality Manual.
   d. Interview to the process owner to obtain input for justifying the effectiveness of process defined in Quality Manual in clause 7 Support, 7.1 Resource, 7.2 Competence, 7.3 Awareness and 7.4 Communication.

4 All findings should be recorded down to the Audit Checklist.

5 Classification of findings;

a. Comply and fulfill with the ISO 9001 Requirement and company QMS established (Quality Manual and procedures).
b. Observation or OFI
c. NC: Non-compliance with the with the ISO 9001 Requirement and company QMS established (Quality Manual and procedures)

6 Next to do for the findings;

a. All OFI should be listed in the Audit Summary for Lead Auditor take further action

b. Any NC, Auditor should follow action determined in the Corrective Action Procedure and submit to Lead Auditor

POST-AUDIT ACTIVITIES

1 Lead Auditor compile the OFI and keep as an input for management review to meet with clause 9.3 Management Review of Quality Manual.

2 <CPAR> form will issue to the respective parties and should follow with Corrective Action Procedure.

DOCUMENTED INFORMATION

4. KLJKLJ
5. JNJKJK
6.

Full Name Company Sdn. Bhd

Purchasing Procedure

Document Ref. No.: P-MR-0

REVISION HISTORY

NO. PINDAAN	TARIKH	KETERANGAN PINDAAN	PEGAWAI
0	13-Sep-15	Versi awal dilancarkan	

GENERAL REQUIREMENT

This procedure provides guideline to extent information explained in clause 8.4 Control of externally provided processes, products and services of the Quality Manual.

The requirement requirement is also enable to provide conformity to clause 8.4 Control of externally provided processes, products and services of ISO 9001:2015 Standard Requirement.

COMMON DEFINITION USED

The definitions addressed are mainly refer to IS0 9000:2015

Conformity	Measurement	Outsource	Provider
Effectiveness	Nonconformity	Performance	Supplier
Monitoring	Output	Product	Verification

RESPONSIBILITY AND AUTHORITY

EXPECTED OUTPUT OF PURCHASING PROCESS / OUTSOURCED PROCESS

This define the capability of provider to supply products or services to meet;

Customer, statutory and regulatory requirement as addressed in

a) 8.2.2 Determining the requirements related to products and services of Quality Manual
b) Where applicable when the product is supplied directly to customer, it must conform to clause 8.6 Release of products and services of the Quality Manual
c) Where suppliers are responsible on the nature, use and intended lifetime of its products and services, clause 8.5.5 Post-delivery activities of Quality Manual may applied.

PURCHASING PROCESS CONTROL

1. External provider or supplier are eligible to supply their product if;
   a) The processes, products and services to be provided meet with control requirement specified in clause 8.5.1 Project management control;
   b) Satisfying the approval of:
      a. products and services;
      b. methods, processes and equipment;
      c. the release of products and services;
   c) Where customer requirement about competency is addressed, information about qualification of persons shall be demonstrated;

d) Able to interact with the designated person of Short Nameaccording to clause 7.4 Communication of Quality Manual

2. Supplier shall be evaluated before they can registred as an Approved Supplier

3. Purchasing process shall comply with the following;
   a) Purchasing request?
   b) Purchase Order?
   c) Payment voucher?

4. All purchased product or provided services must be verified before acceptance. It should be done by designated personnel.

5. Result of verification;
   a) Acceptance product shall be stamped with??
   b) Any abnormality shall refer to Control of Non-Conformity Procedure

6. Where required and stated in any document, verification or validation activities by **Short Name**or customer, intends to perform at the external providers' premises.

OUTSOURCED PROCESS CONTROL

1. Outsource process may covered;
   a. Design and development of the building
   b. Construction activity
2. Subcontractor shall comply with the element described in section Expected output of purchasing process / outsourced process of this procedure.
3. There is also compliance to #1 and #2 of Purchasing process control shall be demonstrated
4. Subcontractor must execute the project according to Project Control Procedure
5. Designated person will monitor the operation run by the subcontractor
6. Any nonconformity of output detected, the further process shall refer to Control of Non-Conformity Procedure

EXTERNAL PROVIDER PERFORMANCE MONITORING

1. All active external provider including supplier / subcontractor shall be evaluated through;
   a. Annual basis for supplier.
   b. For outsourced process, the subcontractor shall be evaluated once the job is completed.
2. Active supplier /subcontractor can be determined through;

a. Carry out work on current construction project. Or,
b. Any single purchase with worth exceeded that RM5,000

3. Additional monitoring for subcontractor of construction activity through;
   a. Input from meeting with clients
   b. Customer complaint input from Corrective Action Procedure
4. Result of external provider performance shall be reviewed as an input of managmenet review as required by the clause 9.3.2 Management Review Inputs of Quality Manual

DOCUMENTED INFORMATION

7. KLJKLJ
8. JNJKJK
9.

Full Name Company Sdn. Bhd

Control of Non-Conformity Procedure

DOCUMENT REF. NO.: P-NC-0

REVISION HISTORY

NO. PINDAAN	TARIKH	KETERANGAN PINDAAN	PEGAWAI
0	13-Sep-15	Versi awal dilancarkan	

CONTROL OF NON-CONFORMITY PROCEDURE

Full Name Company Sdn. Bhd

GENERAL REQUIREMENT

This procedure provides guideline to extent information explained in clause 8.7 Control of Nonconforming output of the Quality Manual.

The requirement is also enable to provide conformity to clause 8.7 Control of nonconforming outputs of ISO 9001:2015 Standard Requirement.

COMMON DEFINITION USED

The definitions addressed are mainly refer to IS0 9000:2015

Complaint	Correction	Quality	Defect
Concession	Supplier	Release	Corrective action
Conformity	Verification	Requirement	Nonconformity

RESPONSIBILITY AND AUTHORITY

IDENTIFICATION OF NON-CONFORMITY

Nonconformity of output in the construction activity can be identified throughout one or combination of following occurrence;

a) Inappropriate planning as described in clause 8.1 Project Planning of this Quality Manual
b) Defect detected by the personnel during construction where it does not meet with specification as defined in clause 8.5.1 Project management control of this Quality Manual
c) Absence of competent person if it is required by the clause 7.2 Competence of this Quality Manual
d) Defective purchased material or out of specification material as defined in clause 8.4 Control of externally provided processes, products and services of this Quality Manual caused by supplier.
e) Other potential undesired consequences associated with services (example; measurement faulty caused by unfit measurement instrument as per clause 7.1.5 Monitoring and measuring resources of Quality Manual)
f) Customer complaint
g) Complaint received during warranty period

CONTROL OF NONCONFORMITY

1. Whenever nonconformity is detected;

a) Nonconformity with regard to the facility or material or physical property, the On-Hold tag must be placed to the defect unit accordingly.
b) If related to the human resources, proceed to the clause 7.2 Competence of Quality Manual.

c) Review possibility of occurrence due to weaknesses of communication factor as described in clause 7.4 Communication of Quality Manual

2. The nonconformity shall be reviewed by <who> for disposition, which may be any of the following;
   c) Hold or must not to be used, or
   d) Concession by authorized person

3. The concession of nonconformity is not accepted for concession if high impact to the quality issues or jeopardize the company reputation as defined in Risk Analysis.

4. Results of the review shall be recorded by <who> on the CPAR form

5. The <who> shall be responsible to review the nature and seriousness of nonconformity.

6. For nonconforming condition that have been accepted by concession when regulatory requirements are met. The record of the identity of the person(s) authorizing the concession shall be maintained.

7. If action will be taken other than decision stated in #2, the non-conformity shall be corrected. <who> will verify the measures taken before release non-conformance status.

8. <who> will decide whether the issuance of CAR form, the nonconformity need further investigation throughout the Corrective Action Procedure or used as record purpose only.

9. For purchased material/part which are found defective or out of specification, OE or HRA shall arrange to return the item to the supplier for replacement or further action. CPAR form should be issued.

10. Any defective purchased material requested for concession, the process should follow step as described in the #9.

11. Top management will decide for necessity to inform the nonconformity depends on the severity of the issues.

12. QMR shall maintain CPAR status log.

13. Status of CAR shall be highlighted for management review meeting.

DOCUMENTED INFORMATION

10. KLJKLJ
11. JNJKJK
12.

Full Name Company Sdn. Bhd

Corrective Action Procedure

Quality Manual

Document Ref. No.: P-CA-0

REVISION HISTORY

NO. PINDAAN	TARIKH	KETERANGAN PINDAAN	PEGAWAI
0	13-Sep-15	Versi awal dilancarkan	

CORRECTIVE ACTION PROCEDURE

Full Name Company Sdn. Bhd

GENERAL REQUIREMENT

This procedure provides guideline to extent information explained in clause 10.2 Nonconformity and corrective action of the Quality Manual.

The requirement requirement is also enable to provide conformity to clause 10.2 Nonconformity and corrective action of ISO 9001:2015 Standard Requirement.

COMMON DEFINITION USED

The definitions addressed are mainly refer to IS0 9000:2015

RESPONSIBILITY AND AUTHORITY

IDENTIFICATION OF NON-CONFORMITY OCCURRENCE

1 Identification of non-conformity can be defined as following inputs;

a) Nonconformity of output in the project occurred as per Control of Non-Conformity Procedure
b) Nonconformity raised during Internal Audit as per Internal Audit Procedure
c) Customer complaint through evidence from documented information as in clause 8.5 Provision of construction project management of Quality Manual. E.g. Work Progress Report, Inspection Report etc.
d) Valid feedback received from interested parties associated with the risk to the project conformity defined as per clause 6.1 Risk Management of the Quality Manual.

2 All nonconformity received shall be validated first before further measure can be taken.

CORRECTIVE ACTION

1. Whenever nonconformity is confirmed, <who> shall verify and record the nonconformity in the <name of record> form.

2. Where required, <who> shall than call respective person and arrange for meeting. Input of meeting then will be used in determining root caused and measures need to be taken.

3. The root cause of the problem shall be determined and a suitable solution to the nonconformity shall be initiated.

4. Evaluations of the nonconformities shall indicate what corrective actions to take to eliminate the root causes of the nonconformities or potential nonconformities.

5. The personnel responsible in providing and implementing the corrective action shall complete the <CPAR or other name of form> with the following information :-

    a. Action Proposed to prevent recurrence so as action taken to rectify the problem.

    b. Date which the corrective action shall be completed.

    c. Where appropriate, analysis and support data is necessary to address the potential occurrence of problem.

6. QMR shall verify that the corrective actions are taken and are effective.

7. Where come into situation of corrective action taken being being reported other than <CPAR> such as PQP, CAR format from customer etc., the tracking of documented information shall be demonstrated.

8. If the action taken is not effective in resolving the problem, QMR shall bring it to the attention of the relevant party concerned and another corrective action plan may be initiated.

9. If there any <CPAR> is unable to close within the dateline given, QMR should get feedback from the relevant parties and stating the valid reason of unclosed issue.

10. At time, the action implemented may result in changes of affected documents; any amendment of document shall follow according to Documented Information Control Procedure.

11. The trends in nonconformities and corrective actions shall be reviewed by top management of **Short Name** as it required by clause 9.3 Management Review of this Quality Manual

DOCUMENTED INFORMATION

13. KLJKLJ
14. JNJKJK
15.

Full Name Company Sdn. Bhd

Appendix

PROCESS MAPPING & INTERACTION

Document Ref. No.: D-PM-0

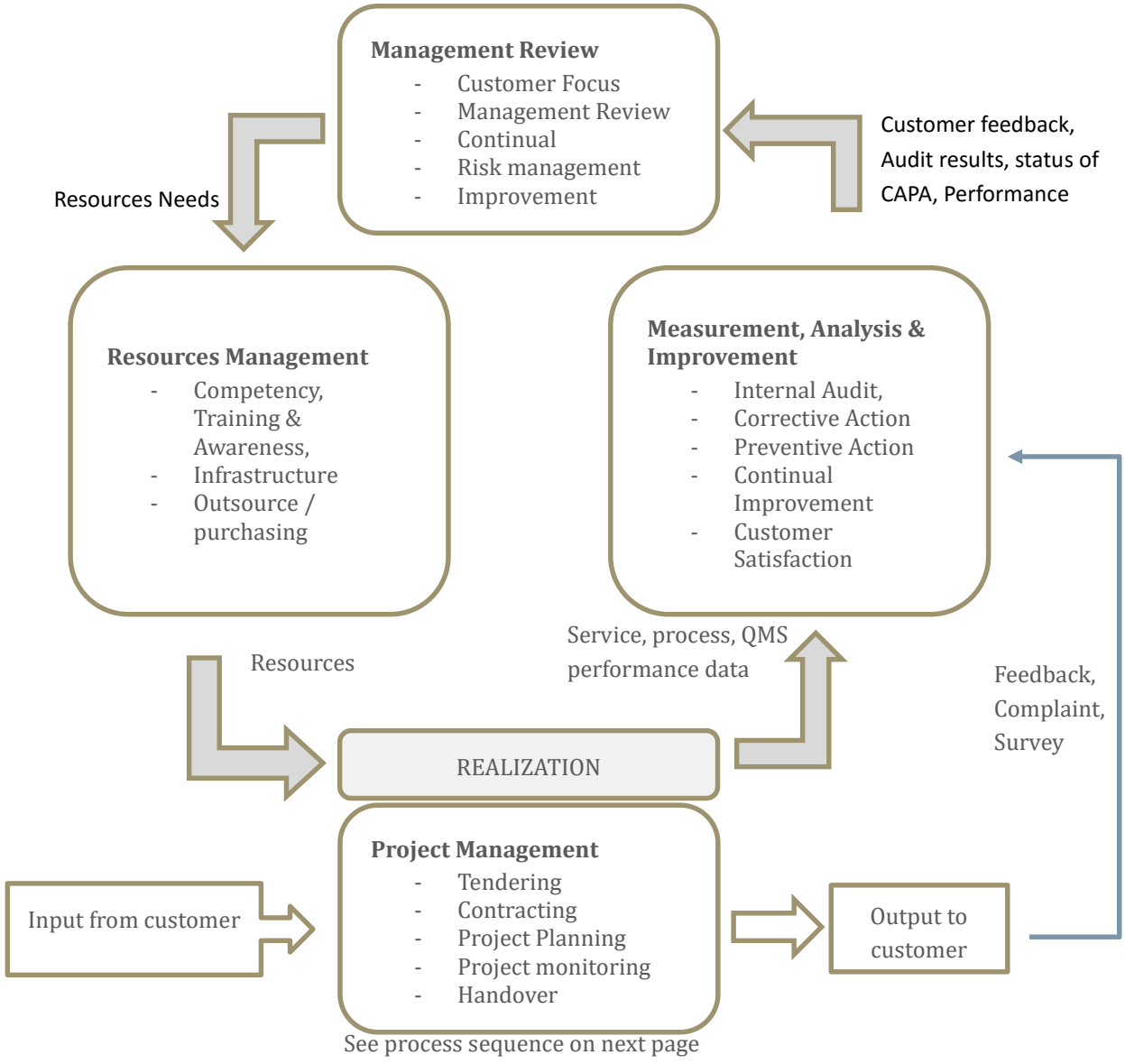
REVISION HISTORY

REF NO	DATE	DESCRIPTION	AUTHORITY
0			

Full Name Company Sdn. Bhd

Business Process Mapping

This document is explained on the requirement stated in clause 4.4 Quality Management System and determined processes of the Quality Manual.



Project Management Process Sequence

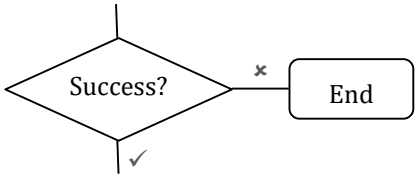
This document is explained on the requirement stated in clause Quality Management System and determined processes of the Quality Manual.

Receive Offer Input: Newspaper, direct invitation

- Output:
- Decision for tendering

Tendering Input: Top management decision & set direction

- Output:
- Prepare for Bill of Quantity
- Tender submission



Contracting Input: Letter of Award

- Output:
- Contract document stamped
- Technical documents

Project Planning Input: Contract document, technical drawing

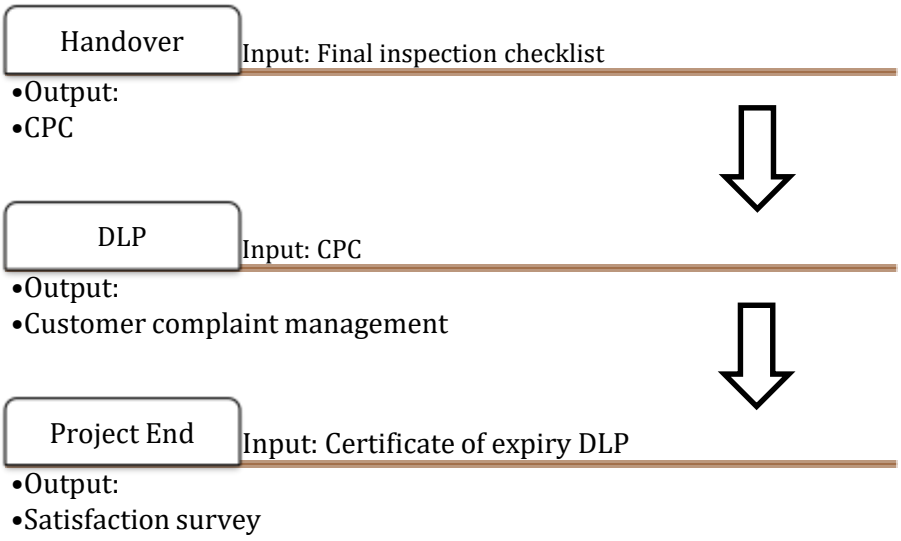
- Output:
- Selection of sub-contractor
- Issue LA to sub-con
- PQP

Project Input: PQP

- Output:
- Construction control, Inspection & Test
- Work Progress
- Final inspection

APPENDIX

Full Name Company Sdn. Bhd



Detail of process and operation has been elaborated in clause 8. Operation of the Quality Manual

DOCUMENTED INFORMATION MASTERLIST

Full Name Company Sdn. Bhd

RISK AND OPPORTUNITIES

Document Ref. No.: D-RM-0

REVISION HISTORY

REF NO	DATE	DESCRIPTION	AUTHORITY
0			

Full Name Company Sdn. Bhd

Risk Analysis Document

This document is explained on the requirement stated in clause 6.1 Risk Management of the Quality Manual.

RISK MANAGEMENT PLANNING: EXTERNAL

STAKEHOLDER	ISSUE	EXPECTATION	RISK	ACTION
CIDB	Legal compliance	Validity of license	Cannot run business	
PSV (certification body)	ISO 9001 Certification	Remain certified	Not able to renew CIDB under G7 class	Annual assessment to be conducted
Consultant	Design & development of project	Meet with specification as per Contract document	Customemer complaint	Purchasing Procedure
Subcontractor	Project execution	Project execution under control condition	Customemer complaint Project delay	8.5.1 Project management control 8.4 Control of externally provided processes, products and services
Local authority	Legal compliance	Meet with the local authority requirement	Stop work	
JKKP	Legal compliance	Meet with safety requirement	Stop work if there incident occurrence	

APPENDIX

Full Name Company Sdn. Bhd

RISK MANAGEMENT PLANNING: INTERNAL

SUBJECT	ISSUE	EXPECTATION	RISK	ACTION
Employee	Knowledge	To be competent	Not able to deliver a good job	Clause 7.2 Competence of Quality Manual
	Workmanship	Process execution as per work schedule	Project delay	Recruitment
Work environment	Maintenance of workplace	Provide good facility and infrastructure	Inadequate work performance	Clause 7.1.4 Environment for the operation of processes of Quality Manual
Infrastructure	Facility to execute the process	Up-to-date	Communication breakdown	Clause 7.1.3 Infrastructure of Quality Manual

Management System Committee

NAME TITLE	NAME TITLE	NAME TITLE
		
Tel [Telephone] **Fax** [Fax] [Email Address]	**Tel** [Telephone] **Fax** [Fax] [Email Address]	**Tel** [Telephone] **Fax** [Fax] [Email Address]

Organization

Full Name Company Sdn. Bhd.
Kuala Terengganu, Terengganu, Malaysia
Tel 03 - 78051140
Fax 03 - 78043811
http:/www.mdyongpeng.gov.my

replace with
LOGO

Appendiks

Standard Requirement of ISO9001:2015

KANDUNGAN PIAWAIAN

1. SCOPE

This International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) 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.

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

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

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

2. NORMATIVE REFERENCES

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

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

3. TERMS AND DEFINITIONS

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

4. CONTEXT OF THE ORGANIZATION

Quality Manual

4.1 Understanding the organization and its context

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

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

Go to Quality Manual (Section: Understanding the context of the Short Name)

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
6.3		
7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
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8.2	8.2.1	A.2
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	8.2.3	
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	8.3.2	
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8.4	8.4.1	A.8
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4.2 Understanding the needs and expectations of interested parties

Quality Manual

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

c) the interested parties that are relevant to the quality management system;

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

The organization shall monitor and review information about these interested parties and their relevant requirements

Go to Quality Manual (Section: Understanding the needs and expectations of interested parties **)**

4.3 Determining the scope of the quality management system

Quality Manual

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

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

Go to Quality Manual (Scope registered: Provision of Project Management for Construction of Building and Civil Works**)**

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
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6.1	6.1.1	A.4
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4.4 Quality management system and its processes

4.4.1 System establishment…

Quality Manual

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

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

4.4.2 Neccessity…

To the extent necessary, the organization shall:

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

Go to Quality Manual (Section: Quality Management System and determined processes)

5. LEADERSHIP

5.1 Leadership and Commitment

Quality Manual

5.1.1 General

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

a) taking accountability for the effectiveness of the quality management system
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
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d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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

See Annex A

5.1.2 Customer focus

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

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained.

Go to Quality Manual (Section: General responsibilities)

5.2 Policy

5.2.1 Developing the Quality Policy

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

e) is appropriate to the purpose and context of the organization and supports its strategic direction
f) provides a framework for setting quality objectives
g) includes a commitment to satisfy applicable requirements
h) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The quality policy shall:

d) be available and be maintained as documented information;
e) be communicated, understood and applied within the organization;

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
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f) be available to relevant interested parties, as appropriate.

Go to Quality Manual (Section 5.2 Quality Policy)

5.3 Organizational Roles, Responsibility and Authorities

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

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
d) ensuring the promotion of customer focus throughout the organization;
e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Go to Quality Manual (Section 5.3 Organizational Roles, Responsibility and Authorities)

6. PLANNING

6.1 Action to address risks and opportunities

6.1.1 Consideration…

When planning for the quality management system, 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 that need to be addressed to:

e) give assurance that the quality management system can achieve its intended result(s);
f) enhance desirable effects;
g) prevent, or reduce, undesired effects;
h) achieve improvement.

6.1.2 Organization shall…

The organization shall plan

c) actions to address these risks and opportunities;
d) how to:
   3) integrate and implement the actions into its quality management system processes (see 4.4);
   4) evaluate the effectiveness of these actions.

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
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	7.1.5	
	7.1.6	A.7
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7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
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8.2	8.2.1	A.2
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10.3		

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

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

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

Go to Quality Manual (Section 6.1 Risk Management)

6.2 Quality Objectives and planning to achieve them

6.2.1 Establishment…

The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

h) be consistent with the quality policy;
i) be measurable;
j) take into account applicable requirements;
k) be relevant to conformity of products and services and to enhancement of customer satisfaction;
l) be monitored;
m) be communicated;
n) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 Determination…

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

f) what will be done;
g) what resources will be required;
h) who will be responsible;
i) when it will be completed;
j) how the results will be evaluated.

Go to Quality Manual (Section 6.2 Quality Objective)

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
6.3		
7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
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8.2	8.2.1	A.2
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	8.2.3	
	8.2.4	
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	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
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8.7	8.7.1	
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	9.1.2	
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9.2	9.2.1	
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9.3		
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6.3 Planning of changes

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

The organization shall consider:

d) the purpose of the changes and their potential consequences;
e) the integrity of the quality management system;
f) the availability of resources;
g) the allocation or reallocation of responsibilities and authorities.

7. SUPPORT

7.1 Resources

7.1.1 General

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

The organization shall consider:

c) the capabilities of, and constraints on, existing internal resources;
d) what needs to be obtained from external providers

7.1.2 People

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

7.1.3 Infrastructure

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

NOTE Infrastructure can include:

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

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
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5.2	5.2.1	
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6.1	6.1.1	A.4
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6.2	6.2.1	
	6.2.2	
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	7.1.6	A.7
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	7.5.3	
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	8.2.3	
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7.1.4 Environment for the operation of processes

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

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

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

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

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

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

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

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

d) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
e) identified in order to determine their status;
f) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

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

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
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	7.1.6	A.7
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7.1.6 Organizational knowledge

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

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

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

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

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

7.2 Competence

The organization shall:

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

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

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

e) the quality policy;
f) relevant quality objectives;
g) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
h) the implications of not conforming with the quality management system requirements

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
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7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

f) on what it will communicate;
g) when to communicate;
h) with whom to communicate;
i) how to communicate;
j) who communicates.

7.5 Documented Information

7.5.1 General

The organization's quality management system shall include:

c) documented information required by this International Standard;
d) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

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

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and Updating

When creating and updating documented information, the organization 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 Control to ensure…

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 Item to address…

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

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
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	7.5.3	
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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.

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

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

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

8. OPERATION

8.1 Operational planning and control

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

b) determining the requirements for the products and services;
c) establishing criteria for:
    1. the processes;
    2. the acceptance of products and services;
d) determining the resources needed to achieve conformity to the product and service requirements;
e) implementing control of the processes in accordance with the criteria;
f) 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.

NOTE "Keeping" implies both the maintaining and the retaining of documented information.

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

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

The organization shall ensure that outsourced processes are controlled (see 8.4).

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
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6.1	6.1.1	A.4
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	7.1.6	A.7
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8.2. Requirement for products and services

8.2.1 Customer communication

Communication with customers shall include:

f) providing information relating to products and services;
g) handling enquiries, contracts or orders, including changes;
h) obtaining customer feedback relating to products and services, including customer complaints;
i) handling or controlling customer property;
j) establishing specific requirements for contingency actions, when relevant.

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 organization shall ensure that:

c) the requirements for the products and services are defined, including:
    1) any applicable statutory and regulatory requirements;
    2) those considered necessary by the organization;
d) the organization can meet the claims for the products and services it offers.

8.2.3 Review of requirements related to products and services

8.2.3.1 ensure has ability…

The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements specified by the organization;
d) statutory and regulatory requirements applicable to the products and services;
e) contracts or order requirements differing from those previously expressed.

The organization shall ensure that contracts or order requirements differing from those previously defined are resolved.

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

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material.

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
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8.2.3.2 Retain documented information

The organization shall retain documented information, as applicable:

c) on the results of the review;
d) on any new requirements for the products and services

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;
b) the required process stages, including applicable design and development review;
c) the required design and development verification and validation activities;
d) the responsibilities and authorities involved in the design and development process;
e) the internal and external resource needs for the design and development of products and services
f) the need to control interfaces between persons involved in the design and development process;
g) the need for involvement of customers and users in the design and development process;
h) the requirements for subsequent provision of products and services;
i) the level of control expected for the design and development process by customers and other relevant interested parties;
j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
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a) functional and performance requirements;
b) information derived from previous similar design and development activities;
c) statutory and regulatory requirements;
d) standards or codes of practice that the organization has committed to implement;
e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;
b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the input requirements;
b) are adequate for the subsequent processes for the provision of products and services;
c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
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7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
8.1		
8.2	8.2.1	A.2
	8.2.2	
	8.2.3	
	8.2.4	
8.3	8.3.1	
	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
8.5	8.5.1	
	8.5.2	
	8.5.3	
	8.5.4	
	8.5.5	
	8.5.6	
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8.7	8.7.1	
	8.7.2	
9.1	9.1.1	
	9.1.2	
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	9.2.2	
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10.2	10.2.1	
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8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;
b) products and services are provided directly to the customer (s) by external providers on behalf of the organization;
c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

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

The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
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	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
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6.2	6.2.1	
	6.2.2	
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	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
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7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
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	8.2.3	
	8.2.4	
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	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
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b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) take into consideration:
    1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
    2) the effectiveness of the controls applied by the external provides;
d) determine the verification, or other activities, necessary to ensure that the externally provided processs, products and services meet requirements.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;
b) the approval of:
    1) products and services;
    2) methods, processes and equipment;
    3) the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with the organization;
e) control and monitoring of the external providers' performance to be applied by the organization;
f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and service Provision

8.5.1 Control of production and service provision

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

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:
    1) the characteristics of the products to be produced, the services to be provided, or the activities
    2) be performed;
    3) 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;

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
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5.2	5.2.1	
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6.1	6.1.1	A.4
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	7.1.6	A.7
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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

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

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirements, and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

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

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization 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

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

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities

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

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
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5.2	5.2.1	
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5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
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	7.1.6	A.7
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7.5	7.5.1	A.6
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	7.5.3	
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In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

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

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

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

8.6 Release of products and services

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

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

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

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

8.7 Control of nonconforming outputs

8.7.1 identify and control...

The organization shall ensure that outputs that 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

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
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5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
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	7.1.6	A.7
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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:

e) correction;
f) segregation, containment, return or suspension of provision of products and services;
g) informing the customer;
h) obtaining authorization for acceptance under concession.

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

8.7.2 Retain documented information…

The organization shall retain documented information that:

e) describes the nonconformity;
f) describes the actions taken;
g) describes any concessions obtained;
h) identifies the authority deciding the action in respect of the nonconformity

9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

Quality Manual

9.1.1 General

The organization shall determine:

e) what needs to be monitored and measured;
f) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
g) when the monitoring and measuring shall be performed;
h) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

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

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
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5.2	5.2.1	
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5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
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	7.1.6	A.7
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7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
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8.2	8.2.1	A.2
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9.1.2 Customer satisfaction

Quality Manual

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

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

9.1.3 Analysis and evaluation

Quality Manual

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal Audit

Quality Manual

9.2.1 Performing an internal audit…

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

c) conforms to
    1) the organization's own requirements for its quality management system;
    2) the requirements of this International Standard;
d) is effectively implemented and maintained.

9.2.2 Execution…

Organization shall;

g) plan, establish, implement and maintain an audit programme(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;
h) define the audit criteria and scope for each audit;

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
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6.1	6.1.1	A.4
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i) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
j) ensure that the results of the audits are reported to relevant management;
k) take appropriate correction and corrective actions without undue delay
l) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.3 Management Review

Quality Manual

9.3.1 General

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

9.3.2 Management Review Inputs

The management review shall be planned and carried out taking into consideration:

1. the status of actions from previous management reviews;
2. changes in external and internal issues that are relevant to the quality management system;
3. 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;
4. the adequacy of resources;
5. the effectiveness of actions taken to address risks and opportunities (see 6.1);
6. opportunities for improvement.

9.3.3 Management Review Outputs

The outputs of the management review shall include decisions and actions related to:

d) opportunities for improvement;
e) any need for changes to the quality management system;
f) resource needs.

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

Standard Clause		
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4.3		A.5
4.4	4.4.1	A.4
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10. IMPROVEMENT

10.1 General

Quality Manual

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

These shall include:

d) improving products and services to meet requirements as well as to address future needs and expectations;
e) correcting, preventing or reducing undesired effects;
f) improving the performance and effectiveness of the quality management system.

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

10.2 Nonconformity and corrective action

Quality Manual

10.2.1 When a nonconformity occurs...

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

g) react to the nonconformity and, as applicable:
    1) take action to control and correct it;
    2) deal with the consequences;
h) 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 analysing the nonconformity;
    2) determining the causes of the nonconformity;
    3) determining if similar nonconformities exist, or could potentially occur;
i) implement any action needed;
j) review the effectiveness of any corrective action taken;
k) update risks and opportunities determined during planning, if necessary;
l) make changes to the quality management system, if necessary.

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

10.2.2 Retain documented information

The organization shall retain documented information as evidence of:

c) the nature of the nonconformities and any subsequent actions taken;
d) the results of any corrective action.

Standard Clause		
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	7.5.3	
8.1		
8.2	8.2.1	A.2
	8.2.2	
	8.2.3	
	8.2.4	
8.3	8.3.1	
	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
8.5	8.5.1	
	8.5.2	
	8.5.3	
	8.5.4	
	8.5.5	
	8.5.6	
8.6		
8.7	8.7.1	
	8.7.2	
9.1	9.1.1	
	9.1.2	
	9.1.3	
9.2	9.2.1	
	9.2.2	
9.3		
10.1		
10.2	10.2.1	
	10.2.2	
10.3		

10.3 Continual Improvement

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

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

ANNEX A (INFORMATIVE): CLARIFICATION OF NEW STRUCTURE, TERMINOLOGY AND CONCEPTS

A.1 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider").

Table A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
6.3		
7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
8.1		
8.2	8.2.1	A.2
	8.2.2	
	8.2.3	
	8.2.4	
8.3	8.3.1	
	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
8.5	8.5.1	
	8.5.2	
	8.5.3	
	8.5.4	
	8.5.5	
	8.5.6	
8.6		
8.7	8.7.1	
	8.7.2	
9.1	9.1.1	
	9.1.2	
	9.1.3	
9.2	9.2.1	
	9.2.2	
9.3		
10.1		
10.2	10.2.1	
	10.2.2	
10.3		

TABLE A.1 — MAJOR DIFFERENCES IN TERMINOLOGY BETWEEN ISO 9001:2008 & ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management Representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

A.2 Products and services

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International Standard uses "products and services". The term "products and services" includes all output categories (hardware, services, software and processed materials).

The specific inclusion of "services" is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

A.3 Understanding the needs and expectations of interested parties

Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties.

However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

A.4 Risk Based Thinking

The concept of risk-based thinking has been implicit in previous editions of this International Standard, e.g. through requirements for planning, review and improvement. This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or subclause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities.

Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for its application of risk based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

A.5 Applicability

This International Standard does not refer to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
6.3		
7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
8.1		
8.2	8.2.1	A.2
	8.2.2	
	8.2.3	
	8.2.4	
8.3	8.3.1	
	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
8.5	8.5.1	
	8.5.2	
	8.5.3	
	8.5.4	
	8.5.5	
	8.5.6	
8.6		
8.7	8.7.1	
	8.7.2	
9.1	9.1.1	
	9.1.2	
	9.1.3	
9.2	9.2.1	
	9.2.2	
9.3		
10.1		
10.2	10.2.1	
	10.2.2	
10.3		

A.6 Documented information

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organization shall monitor and review the information about these external and internal issues"), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

A.7 Organizational knowledge

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g.

— through staff turnover;

— failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g.

— learning from experience;

— mentoring;

— benchmarking.

A.8 Control of externally provided processes, products and services

All forms of externally provided processes, products and services are addressed in 8.4, e.g. whether through:

a) purchasing from a supplier;
b) an arrangement with an associate company;

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
6.3		
7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
8.1		
8.2	8.2.1	A.2
	8.2.2	
	8.2.3	
	8.2.4	
8.3	8.3.1	
	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
8.5	8.5.1	
	8.5.2	
	8.5.3	
	8.5.4	
	8.5.5	
	8.5.6	
8.6		
8.7	8.7.1	
	8.7.2	
9.1	9.1.1	
	9.1.2	
	9.1.3	
9.2	9.2.1	
	9.2.2	
9.3		
10.1		
10.2	10.2.1	
	10.2.2	
10.3		

c) outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the processes, products and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services.

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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.

See 9.2.2

Standard Clause		
4.1		A.4
4.2		A.3
4.3		A.5
4.4	4.4.1	A.4
	4.4.2	
5.1	5.1.1	
	5.1.2	
5.2	5.2.1	
	5.2.2	
5.3		
6.1	6.1.1	A.4
	6.1.2	
6.2	6.2.1	
	6.2.2	
6.3		
7.1	7.1.1	
	7.1.2	
	7.1.3	
	7.1.4	
	7.1.5	
	7.1.6	A.7
7.2		
7.3		
7.4		
7.5	7.5.1	A.6
	7.5.2	
	7.5.3	
8.1		
8.2	8.2.1	A.2
	8.2.2	
	8.2.3	
	8.2.4	
8.3	8.3.1	
	8.3.2	
	8.3.3	
	8.3.4	
	8.3.5	
	8.3.6	
8.4	8.4.1	A.8
	8.4.2	
	8.4.3	
8.5	8.5.1	
	8.5.2	
	8.5.3	
	8.5.4	
	8.5.5	
	8.5.6	
8.6		
8.7	8.7.1	
	8.7.2	
9.1	9.1.1	
	9.1.2	
	9.1.3	
9.2	9.2.1	
	9.2.2	
9.3		
10.1		
10.2	10.2.1	
	10.2.2	
10.3		

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 (or programme) 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.

See 9.2.2

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.

See 8.3.5, 8.5.1,

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.

See 7.2, 7.5.1,

Complaint

In the context 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.

See 8.2.1, 10.2.1

Link to Procedure

- Control of Non-Conformity Procedure

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.

See 8.7.1, 8.7.2

Link to Procedure

- Control of Non-Conformity Procedure

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.

See 1 , 4.3, 7.1.3, 7.1.4, 7.1.5.1, 7.1.6, 7.5.3.2, 8.1, 8.3.6, 8.5.2, 8.5.4, 8.5.6, 8.6, 8.7.1, 9.1.3, 9.3.2, ANNEX 2, ANNEX 5, ANNEX 6, ANNEX 7,

Link to Procedure

- Control of Non-Conformity Procedure

Context of the organization

An organization's context is its business environment. It includes all of 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 includes all of the needs and expectations of interested parties, as well as its social, cultural, legal, technological, regulatory, and competitive environment. An organization's internal context includes its values, culture, knowledge, and performance. ISO 9001 2015 expects you to consider your organization's internal and external context when you define the scope of its QMS and when you plan it's design and development.

See 5.2.1

Continual improvement

Continual improvement is a set of recurring activities that are carried out in order 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.

See 5.2.1, 7.1.1, 10.1, 10.3

Contract

A contract is a binding agreement between two or more parties.

See 8.2.1, 8.2.3.1

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.

See 8.7.1, 9.2.2, 10.1

Link to Procedure

- Control of Non-Conformity Procedure

Corrective action

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

See 9.2.2, 9.3.2, 10.1, 10.2.2

Link to Procedure

- Control of Non-Conformity Procedure

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.

See 1 , 4.2, 5.1.2, 5.3, 6.1.2, 7.1.6, 8.2.1, 8.2.2, 8.2.3.1 8.3.2, 8.4.1, 8.4.2, 8.4.3, 8.5.3, 8.5.5, 8.6, 8.7.1, 9.1.2, 10.1,

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.

See, 1 , 4.3, 5.1.2, 6.2.1, 9.1.3, 9.3.2, 10.1

Data

The term data is defined as any facts about an object.

See 9.1.3

Defect

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

Link to Procedure

- Control of Non-Conformity Procedure

Design and development

Design and development is a process (or a set of processes) that uses resources to transform general input requirements for an object into specific output requirements. 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.

See 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6

Determination

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

See 4.1, 4.2, 4.3, 4.4, 5.1.2, 6.1.1, 6.2.2, 6.3, 7.1.1, 7.1.2, 7.1.3, 7.1.4, 7.1.5.1, 7.1.5.2, 7.1.6, 7.2, 7.4, 7.5.1, 7.5.3.2, 8.1, 8.3.3, 8.3.4, 8.4.1, 8.4.2, 9.1.1, 9.1.2, 10.1, 10.2.1, 10.3

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).

See 4.3, 4.4.2, 5.2.2, 6.2.1, 7.1.5.1, 7.1.5.2, 7.2, 7.5.1, 7.5.2, 7.5.3.1, 7.5.3.2, 8.1, 8.2.3.2, 8.2.4, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.5.1, 8.5.2, 8.5.3, 8.5.6, 8.6, 8.7.2, 9.1.1, 9.2.2, 9.3.3, 10.2.2

Effectiveness

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

See 5.1.1, 6.1.2, 7.2, 7.3, 7.5.1, 8.4.2, 9.1.1, 9.1.3, 9.3.1, 9.3.2, 10.1, 10.2.1, 10.3

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.

See 8.2.1, 8.5.5, 9.1.2, 9.3.2

Function

A function is a role that is performed by a unit of an organization.

See 6.2.1

Improvement

Improvement is a set of activities that organizations carry out in order 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.

See 1 , 5.1.1, 5.2.1, 5.3, 6.1.1, 7.1.1, 7.1.6, 9.1.3, 9.3.2, 9.3.3, 10.1, 10.3

Information

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

See 4.1, 4.2, 7.1.3, 7.1.6, 8.2.1, 8.2.3.1, 8.3.3, 9.1.2, 9.1.3, 9.2.1, 9.3.2

Information system

In the context 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 in order to function.

According to ISO 9001, section 7.1.3, the term infrastructure can include buildings, equipment, utilities, and technologies (both hardware and software).

See 7.1.3, 8.5.1

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.

See 10.1

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.

See 4.2, 4.3, 5.2.2, 8.3.2, 9.3.2

Involvement

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

See 8.3.2

Knowledge

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

See 4.1, 7.1.6

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, the term management does not refer to people. It refers to what managers do.

See 5.1.1, 9.2.2

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 needed to ensure 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.

See

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

See 4.4.1, 7.1.5.1, 7.1.5.2, 8.3.5, 8.5.1, 8.5.2, 9.1.1, 9.1.3, 9.3.2

Monitoring

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

See 4.4.1, 7.1.5.1, 8.3.5, 8.4.1, 8.5.1, 8.5.2, 9.1.1, 9.1.2, 9.1.3, 9.3.2

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.

See 8.7.1, 8.7.2, 9.3.2, 10.2.1, 10.2.2

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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 as a whole 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.

See 7.1.6

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).

See 4.4.1, 5.3, 8.1, 8.3.4, 8.3.5, 8.4.2, 8.5.1, 8.5.2, 8.5.4, 8.7.1, 9.3.3, 10.3

Outsource

When an organization makes an arrangement with an outside organizsation 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 inhouse. While an outsourced organization is beyond the scope of your QMS, the outsourced process or function itself falls within your scope.

Performance

According to ISO, the term performance refers to a measurable result. It refers to the measurable results that activities, processes, products, services, systems and organizations are able to achieve. Whenever they perform well it means that acceptable results are being achieved and whenever they perform poorly, unacceptable results are achieved.

See 4.1, 4.4.1, 5.3, 7.2, 7.3, 8.3.3, 8.4.1, 8.4.3, 9.1.1, 9.1.3, 9.3.2, 10.1

Performance indicator

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

See 4.4.1

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.

See 4.4.1, 4.4.2, 5.1.1, 5.3, 6.1.2, 6.2.1, 7.1.2, 7.1.3, 7.1.4, 7.1.6, 7.5.1, 8.1, 8.3.1, 8.3.2, 8.3.4, 8.3.5, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 9.2.2, 9.3.2,

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.

See 5.1.1,

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.

According to 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).

See 4.2, 4.3, 5.1.2, 6.1.2, 6.2.1, 7.1.3, 7.1.4, 7.1.5.1, 7.1.6, 7.5.1, 7.5.3.2, 8.1, 8.2.1, 8.2.2, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 8.5.2, 8.5.3, 8.5.5, 8.6, 8.7.1, 9.1.2, 9.1.3, 9.3.2, 10.1

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.

See 7.1.1, 7.1.6, 8.4.1, 8.4.2, 8.4.3, 8.5.3, 9.1.3, 9.3.2

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. So 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.

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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.

See 5.1.1

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 needed to ensure 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.

See 4.1, 4.2 4.3, 4.4.1, 5.1.1, 5.2.1, 5.3, 6.1.1, 6.1.2, 6.2.1, 6.3, 7.1.1, 7.1.2, 7.2, 7.3, 7.4, 7.5.1, 7.5.3.1, 7.5.3.2, 8.4.2, 9.1.1, 9.1.3, 9.2.1, 9.3.1, 9.3.2, 9.3.3, 10.1, 10.2.1, 10.3

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.

See 5.1.1, 5.2.1, 6.2.1, 6.2.2, 7.3 , 9.3.2,

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.

See 5.1.1, 5.2.1, 5.2.2, 6.2.1 & 7.3

Regulatory requirement

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

See 4.2, 5.1.2, 8.2.2, 8.2.3.1, 8.3.3, 8.4.2, 8.5.5

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.

See 8.4.3, 8.5.1, 8.6

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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.

See 4.2, 4.3, 4.4.1, 5.1.1, 5.1.2, 5.2.1, 5.3, 6.1.1, 6.2.1, 7.1.5.1, 7.1.5.2, 7.3, 8.1, 8.2.1, 8.2.2, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.4.2, 8.4.3, 8.5.2,, 8.5.4, 8.5.5, 8.5.6, 8.6, 8.7.1, 9.2.1, 9.2.2, 10.1

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Review

A review is an activity. Its purpose is to figure out how well the thing being reviewed is capable of achieving 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.

See 4.1, 4.2, 7.5.2, 8.1, 8.2.3.1, 8.2.3.2, 8.3.2, 8.3.4, 8.5.6, 9.1.2, 9.3.1, 9.3.2, 9.3.3, 10.2.1, 10.3

Risk

According to ISO 9000, risk 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 according to 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 of risk management, uncertainty exists whenever the knowledge or understanding of an event, consequence, or likelihood is inadequate or incomplete. While this definition argues that risk can be positive as well as negative, a note acknowledges that "the term risk is sometimes used when there is only the possibility of negative consequences".

See 4.4.1, 5.1.2, 6.1.1, 6.1.2, 9.1.3, 9.3.2, 10.2.1

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.

See 5.1.1

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).

See See 4.2, 4.3, 5.1.2, 6.1.2, 6.2.1, 7.1.3, 7.1.4, 7.1.5.1, 7.1.6, 7.5.1, 7.5.3.2, 8.1, 8.2.1, 8.2.2, 8.2.3.1, 8.2.3.2, 8.2.4, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 8.5.2, 8.5.3, 8.5.5, 8.6, 8.7.1, 9.1.2, 9.1.3, 9.3.2, 10.1

Statutory requirement

A statutory requirement is defined by a legislative body and is obligatory. Strategy A strategy is a plan for achieving an objective.

See 4.2, 5.1.2, 8.2.2, 8.2.3.1, 8.3.3, 8.4.2, 8.5.5

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.

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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 needed to ensure 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.

See 5.1.1, 5.1.2, 5.2.1, 5.3, 9.3.1

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.

See 7.1.5.2, 8.5.2, 8.6

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.

See 8.3.2, 8.3.4, 8.4.2, 8.4.3, 8.5.1

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.

See 7.1.5.2, 8.3.2, 8.3.4, 8.4.2, 8.4.3, 8.7.1

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