**HOW TO PREPARE FOR COMPLIANCE
WITH ISO9001:2015**

**"A Design Model for an Organisation's Business
Management System"**

A Short Guide to a Simple Solution

Version: 2.2

14 February 2022

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INTRODUCTION

OBJECTIVE OF THE MODEL

To describe how an Organisation's ability to meet customer requirements should be managed, in a way that enables the requirements of ISO9001:2015 (and other management system standards) to be met.

BACKGROUND

The means by which an Organisation establishes its policies and objectives and manages its activities to implement those policies and to achieve those objectives is its "management system".

ISO 9001 has often been used (incorrectly) as a design model and not (as was intended) as an assessment standard for how the organisation manages its ability to meet customer requirements in relation to the quality of its goods and services.

As a consequence, many of the "management system descriptions" produced to meet "ISO requirements" merely reflect compliance with a particular standard rather than how the organisation achieves its objectives. See our: "**Guidance Notes on the Design Model for an Organisation's Business Management System"** document for more information and advice, including fundamental definitions and interpretation of terms – see
http://www.deethebusiness.co.uk/PP_Files/MgtSystemDesignModel/MgtSystemDesignGuidance.pdf.

APPLICATION

Management should review and refine how the Organisation currently operates as follows:

PREPARATION and PLANNING

SET THE SCENE

Identify those aspects of the Organisation's operations which may impact on its ability to meet customer requirements [such as business objectives, availability of resources, compliance requirements].

Clarify the business strategies to be followed.

Identify those parties ("stakeholders") which may have a beneficial interest in the Organisation's ability to meet customer requirements.

Clarify the Organisation's business objectives to be achieved and the relevant priorities.

Define the policies, values and principles to guide the Organisation in achieving its objectives.

Identify all legislative and compliance requirements relevant to its goods and services and to the processes needed to produce them.

CONSIDER THE FACTORS WHICH MAY INFLUENCE SUCCESS

Identify the (physical, financial, intellectual and human) resources required to achieve the objectives in a manner consistent with the policies.

Design processes to deliver outputs and outcomes which will achieve the Organisation's objectives and comply with its policies, values and principles, and identify how the processes inter-relate.

Identify the effect that operations may have on others (including the environment).

Identify the factors which may influence successful performance (and a compliant product).

Anticipate potential problems which may affect successful performance.

Anticipate internal and external changes that may affect how the business is managed and operated.

TAKE STEPS TO MANAGE SUCCESS

Ensure that there is a clear management and reporting structure for all staff and functions.

Allocate a suitably qualified senior person to be accountable for success in meeting customer requirements.

Set clear & measurable objectives, derived from the strategic direction of the Organisation and stakeholders' expectations, for how it will meet customer requirements.

Identify practical ways to measure and review success against objectives.

DEFINE AND MANAGE HOW WORK IS DONE (YOUR PROCESSES)

Establish accountability for the performance of each process.

Define the processes to the level of detail required for successful performance and to reflect the competence of those involved (RACI methodology is useful for identifying role involvements for each task).

Clarify roles and responsibilities for the performance of individual tasks.

Determine the competences and capabilities required for these roles and responsibilities.

Identify other likely outcomes from each process.

Take account of influences that may affect and shape how processes work.

Establish effective methods to enable the Organisation to review and improve each process.

Clarify responsibility for maintaining the system definition as the system develops and changes.

PUTTING PROCESSES INTO EFFECT (OPERATING)

PREPARE AND PLAN

Communicate the Organisation's business objectives, and the policies, values and principles to guide the Organisation in achieving the objectives, to all who need to know and ensure that they are applied where relevant.

Ensure that people involved in each process are competent (or are trained).

Provide information and support for staff and other stakeholders.

Ensure that required resources are available.

Balance the objectives of each process with other business objectives.

Ensure that factors and risks which can influence performance are monitored and managed.

Manage the outcomes from each process.

Measure processes in a way which is affordable and provides enough information to allow the Organisation to manage each process.

PRODUCE AND DELIVER

Ensure that customer and other stakeholder requirements are clear at the point at which they are to be implemented.

Anticipate requirements for product use and eventual disposal as appropriate.

Only accept work which the Organisation is capable of undertaking.

Communicate with customers at appropriate stages throughout production and delivery.

Establish evidence that provides assurance that the product meets requirements, and document this when required.

Verify that the product complies with requirements before delivery if possible.

Take appropriate action when problems arise.

Validate processes at appropriate intervals.

Ensure that product and process changes are controlled to ensure that they benefit the Organisation and satisfy the needs and expectations of stakeholders.

MANAGING RESOURCES

MANAGE PHYSICAL RESOURCES

Ensure that goods and services supplied to the Organisation are controlled by specifying requirements, checking, storing and using as appropriate.

Take care of customer property when under the control of the Organisation.

Control the receipt or creation, updating, issue and use of documents.

Control the receipt or creation, updating, retention and disposition of records.

Ensure that equipment used is maintained and is calibrated where necessary.

Ensure that the work environment is suitable for staff and others.

MANAGE PEOPLE AND RELATIONSHIPS

Recruit, deploy and promote individuals (whether employed or contracted) on the basis of their competence and potential in relation to the skills and knowledge required.

Make clear what is expected of individuals and hold them to account.

Ensure that people comply with legal requirements, industry regulations, organisational policies and professional codes.

Encourage and support learning and self development.

Establish and maintain an effective reporting and management structure.

Identify training requirements for staff, contractors and suppliers where necessary to support the Organisation's operations.

Arrange such training where required.

Maintain records of the competence and training of staff and of the suitability of contractors.

Keep staff and contractors informed of process performance, plans and developments when required.

Encourage and support staff to take responsibility for their own actions and to take decisions within agreed boundaries.

Encourage creativity and innovation where possible.

Encourage co-operation.

REVIEWING AND IMPROVING

REVIEW AND IMPROVE INDIVIDUAL PROCESSES

Understand the characteristics of individual processes and their inter-relationship.

Set and monitor priorities for review and improvement.

Review and improve process performance against objectives (according to priorities).

Review and improve the efficiency of the processes (according to priorities).

Ensure that people involved in the process continue to have the required competency.

Ensure that required resources are available.

Assess possible process changes for risk and potential return against potential investment cost.

Manage, communicate and measure the effect of changes in a process.

REVIEW AND IMPROVE THE OVERALL SYSTEM

Identify, record and communicate lessons learned and opportunities for improvement.

Review the continuing relevance of objectives against the Organisation's mission and stakeholder needs.

Monitor the quality of operations and progress against plans and take appropriate corrective action where necessary.

Identify systemic issues and trends and recognise their impact upon current and future work.

Take opportunities when they arise to achieve longer-term aims.

Revise the system as appropriate in response to internal and external changes.

Ensure that people are aware of forthcoming changes and how they will be affected.