

**Statutory and Regulatory**

**Requirements Procedure**

ISO9001 Toolkit Version 1

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| **Implementation Guidance****(The header page and this section must be removed from final version of the document)** |
| **Purpose of this document**This document sets out how the applicable statutory and regulatory requirements relevant to the QMS, and our approach to meet them, will be identified, documented and kept up to date. |
| **Areas of the standard addressed**The following areas of the ISO9001 standard are addressed by this document:5 Leadership5.1 Leadership and commitment5.1.2 Customer focus |
| **General Guidance**The specifics of the procedure will depend upon the statutory and regulatory environment in which your organization operates.You may well need to obtain legal advice, either from your internal legal team or an external law firm about which laws affect your business operations. If you operate in more than one country then local advice will need to be sought from each country individually.This template procedure defines the steps need at a fairly high level. You will need to add more organization-specific detail to ensure it represents a useful procedure that reflects the way you have decide to approach this area.  |
| **Review Frequency**We would recommend that this document is reviewed as part of an annual exercise. |
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| --- | --- |
| **Document Ref.** | **QMS-DOC-05-6** |
| **Version:** | **1** |
| **Dated:** | **[Insert date]** |
| **Document Author:** |  |
| **Document Owner:** |  |

**Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Revision Author** | **Summary of Changes** |
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# Introduction

 has implemented a Quality Management System (QMS) in line with the ISO9001 international standard for quality management systems.

In creating and maintaining a QMS it is vital that a full understanding is gained of the various statutory and regulatory requirements that apply to [Organization Name] and its business. This will ensure that the organization continues to meet its obligations and its board of directors and other stakeholders are not exposed to the risk of criminal prosecution or corporate liability.

The purpose of this procedure is to document how such requirements are identified and incorporated into the QMS and how updates to the requirements are handled.

# Statutory and Regulatory Requirements Procedure

The procedure for identifying, documenting and maintaining statutory and regulatory requirements is summarised in the diagram below. Each step is expanded upon in the following sections.



*Figure 1 – Statutory and regulatory requirements procedure*

## Identify Requirement

[Organization Name] relies upon the following internal teams and external bodies to identify statutory and regulatory requirements that are relevant to its business:

|  |  |  |
| --- | --- | --- |
| **Team/organization** | **Areas Covered** | **Method of Communication** |
| Legal department | Laws relevant to countries and industries involved | Email alertsQuarterly meetings |
| External legal advisers | Laws relevant to countries and industries involved | WebinarsNewslettersMeetings on specific topics |
| Governance, Risk and Compliance team | Regulatory framework and requirementsRegulatory reporting | Email alertsQuarterly meetings |
| Industry body | Laws, regulations and other issues relevant to our industry | SeminarsAnnual Conference |
| Regulatory Authority | Regulatory framework and requirementsRegulatory reporting | Official communicationsBriefing events |
| Professional associations | General statutory and regulatory issues | National and regional meetingsNewslettersTraining |
| National and regional business groups | General statutory and regulatory issues | National and regional meetingsNewslettersTraining |

*Table 1 - Sources of requirements*

[Include all real or potential sources of advice in the above table]

In general [Organization Name] will rely upon the appropriate team or external body to provide an interpretation of the relevant parts of the item under consideration. This may be in the form of briefing papers, presentation materials or other media.

Where necessary, the Quality Manager shall obtain full copies of the relevant source material (such as legislation or regulatory announcements) for reference purposes. These may be in hardcopy or electronic form.

## Assess Implications

The Quality Manager is responsible for ensuring that a full assessment of the implications of the relevant items for the QMS is carried out. This will be based upon qualified advice from the relevant sources listed in Table 1.

The assessment will include the following aspects:

* Degree of change to the QMS and its associated policies, procedures, forms and plans needed to meet the requirement
* Urgency of meeting the requirement
* Consequences of not meeting the requirement
* Available options for meeting the requirement

## Document Requirements

Once assessed, the relevant requirements will be documented at a high level as part of the QMS within the document *QMS Context, Requirements and Scope*. All changes to this document will be recorded in accordance with the QMS documentation procedures.

Details of the requirements will be documented in the *Statutory and Regulatory Requirements* spreadsheet. These details will include:

* Source of the requirement
* Type of requirement – legislative, regulatory, other
* Details of the requirement, at an appropriate level
* Link(s) to more detailed specification of the requirement, where relevant e.g. legislative documents, regulations, contracts
* Owner of the requirement
* The legal scope of the requirement e.g. which country’s law applies
* Dates the requirement applies from and to

Where needed, confirmation of the interpretation of the requirement will be obtained from a relevant source e.g. the organization legal department.

## Define Approach to Meeting Requirements

Where immediate changes are needed to the QMS as a result of a new or changed requirement these will be incorporated as soon as possible and revisions issued to all recipients of the relevant policies and procedures. Otherwise the change will be considered at the next annual review of the QMS.

Details of the approach to be taken will be added to the *Statutory and Regulatory Requirements* spreadsheet along with links to relevant documentation, where appropriate.

## Review and Update

New requirements and changes to existing requirements will be discussed at regular review meetings with internal departments, particularly:

* Legal department
* Governance, Risk and Compliance team
* Business Management

All relevant requirements will be re-assessed on at least an annual basis as part of the QMS annual review. Appropriate advice will be obtained at this point to ensure that all changes have been captured.

Any new or changed requirements identified as part of the review process will be handled in accordance with this procedure and appropriate updates made.