

# QMS ISO 9001 Document Control Plan Template – Example

## QMS ISO 9001 Document Control Plan

Company Name		Date
Prepared by	Reviewed by	Approved by

### 1. Purpose

This section defines the purpose of the Document Control Plan, which is to establish a procedure for the management, control, and revision of all documents relevant to the Quality Management System (QMS) to ensure that they remain current, approved, and properly maintained. The purpose is also to comply with ISO 9001 requirements for document control.

Text

### 2. Scope

This section outlines the types of documents covered by the Document Control Plan, including policies, procedures, work instructions, forms, manuals, and external documents relevant to the QMS. The scope defines which departments or processes are subject to document control and the applicability of the control system across the organization.

Text

### 3. Definitions

- Document:** Any written, electronic, or digital information used within the QMS.
- Revision:** A formal change made to an existing document.
- Obsolete Document:** A document that is no longer valid for use and has been replaced or archived.
- Document Owner:** The individual responsible for ensuring that a document is up-to-date, accurate, and compliant.

### 4. Responsibilities

Defines the key roles in the document control process:

- Document Owner:** Responsible for drafting, revising, and maintaining the document.
- Document Controller:** Ensures that documents are properly stored, distributed, and updated.
- Approving Authority:** The individual(s) responsible for approving the document before it is released for use.
- Users:** Personnel who must follow the procedures defined in controlled documents.

### 5. Document Control Procedure

#### 5.1 Document Creation and Identification

All documents must be clearly identified with a unique document number, title, version number, issue date, and department or function to which they pertain. Each new document or form must follow a structured naming convention for traceability and control.

#### 5.2 Document Review and Revision

Prior to approval, all documents must undergo a thorough review process. This includes verifying the accuracy, completeness, and relevance of the content, ensuring compliance with applicable standards or regulatory requirements. The document should also be revised periodically to remain current.

#### 5.3 Document Approval

Documents must be formally approved by the relevant authority before being released for use. Each approval must be documented with the name of the approver(s), date of approval, and signature (digital or handwritten). No document may be issued without the approval.

#### 5.4 Document Distribution

Once approved, documents must be distributed to relevant personnel. Distribution methods may include electronic dissemination (e.g., through a document management system) or physical copies. The distribution list must be maintained, ensuring only the latest version of the document is in use.

#### 5.5 Document Revision

Whenever a change is made to a document, a new revision number is assigned. The revision history should clearly state the reason for the revision, date of the change, and the approving authority. All superseded versions must be archived to avoid confusion.

#### 5.6 Document Storage and Accessibility

All controlled documents must be securely stored, whether in a digital or physical format. The document control system must ensure that documents are easily accessible to authorized personnel and protected from damage, loss, or unauthorized changes. Secure backup procedures should be in place for electronic documents.

#### 5.7 Document Retention and Archiving

There must be a defined retention period for each document type based on its relevance, regulatory requirements, or company policy. After this period, documents are archived or disposed of securely. Archived documents must remain accessible for auditing or reference purposes.

#### 5.8 Obsolete Documents

Obsolete or superseded documents must be clearly marked and removed from active use to prevent accidental use. They should be archived or disposed of in accordance with the retention policy. Obsolete documents may only be accessed for historical purposes or audits.

### 6. Document Control Register

#### 6.1 Register Content

The Document Control Register is a log that tracks all controlled documents, including document number, title, revision number, date of issue, owner, next review date, and status (active or obsolete). It provides a centralized, up-to-date overview of all documents under control.

#### 4.2 Review Schedule

Each document must have a scheduled review date to ensure its continued relevance and accuracy. The schedule should be listed on the digital, web-enabled or e-printed version before the version date issue.

#### 4.3 Revision Status

The revision status of each document (Open, Closed, or Under Review) is tracked in the document control register. This provides transparency on the current state of document updates and engineering history.

#### 7. Security and Access Control

##### 7.1 Access Control

Documents should be accessible only to authorized personnel. This section defines security measures, such as password-protected files, restricted access to sensitive documents, and controlled physical storage for paper documents.

##### 7.2 Document Integrity

To prevent unauthorized changes, documents must be protected using digital signatures, hashcodes, or other controls in a document management system. This section also outlines measures to detect accidental deletion or modification.

#### 8. Training and Awareness

Personnel must be trained on the importance of document control and their role in the system. This section outlines the training requirements for document users, owners, and controllers. Training records must be maintained as part of the QMS.

Text

#### 9. Auditing and Compliance

Regular internal audits should be conducted to verify that document control procedures are being followed. The audit scope includes audit planning, audit execution, audit risks, and corrective actions required upon non-compliance, and closure.

Text

#### 10. References

Include references to relevant ISO 9001 clauses, company policies, or other documents that are applicable to the document control process. This may include alignment with the project plan and any common standards or regulations.

Text

#### 11. Appendices

Appendices may include sample forms, such as:

- Document Review Form, used to record the review and approval process.
- Revision History Form, provided as a detailed log of all revisions made to a document.
- Document Control Register, used for dissemination of the document control process.

# Iso 900document Control

**Wayne Lam, Sten Peeters**



## **Iso 9000document Control:**

*How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements* Stephanie L. Skipper, 2015-10-14 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system

**Environmental and Quality Systems Integration** William C. Culley, 2019-09-17 Global competition corporate downsizing and corporate restructuring have forced many firms to reevaluate their operating methods Today corporations must do more with less while still watching the bottom line and improving profitability ISO 14000 and ISO 9000 because of their similar management system requirements and auditing procedures are g Document Control Denise Robitaille, 2011-09 They re supposed to be useful tools but whether they re printouts computer files flowcharts or forms documents can often give more headaches than help And yet without them most organizations couldn t function ISO 9001 and other quality management systems place great emphasis on documents and for good reason Documents aren t individual stand alone elements of the management process They re interrelated formatted in different media and controlled by various and distinct functions Keeping critical information current and in the right hands requires more than just signing off on procedures Document control is essential but where should you begin Inside you ll find clear explanations about the document control process as well as practical solutions for creating organizing and maintaining documents including A discussion of different kinds of documents including electronic media and QMS requirements Identifying and defining responsibility Understanding the relationship between documents and records Tips for document writers Managing and maintaining documents Issues of accessibility Handling revisions and deviations Writing document control procedures

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**The ASQ Metrology Handbook** Heather A. Wade,2023-01-04 The ever changing fields of science and technology have made huge leaps thanks in part to improvements in measurements Without metrology these areas may not have experienced exponential growth Developed by experts in the field as a comprehensive and practical reference The ASQ Metrology Handbook Third Edition provides a foundation for understanding metrology as well as calibration principles and practices This handbook is ideal for not only metrology professionals but also calibration professionals including calibration technicians and technologists quality professionals workers in testing laboratories consultants and instructors Whether you are entering a new phase of your career field investing in your own continuous improvement journey training your fellow calibration practitioners or preparing for ASQ s Certified Calibration Technician CCT exam this handbook provides the information guidance and knowledge to help you achieve your goals New to this Third Edition A thorough explanation of ISO IEC 17025 2017 The 2019 Redefinition of the International System of Units Updated and expanded chapters including information about training and competency software validation statistics decision rules and risk uncertainty in measurement mass and weighing force and chemical and biological measurements and uncertainties

**Software Quality Assurance: Principles and Practice** Dr.M.Kameswari,Dr.P.Getchial Pon Packiavathi, Dr. N.Deena,Dr.R.Srinivasan, Dr.G.Stephen,2023-11-09 Dr M Kameswari Associate Professor Head School of Advanced Sciences Department of Mathematics Kalasalingam Academy of Research and Education Krishnankoil Srivilliputhur Tamil Nadu India Dr P Getchial Pon Packiavathi Assistant Professor Department of Mathematics V V Vanniaperumal College for Women Virudhunagar Tamil Nadu India Dr N Deena Assistant Professor Department of Mathematics Saraswathi Narayanan College Perungudi Madurai Tamil Nadu India Dr R Srinivasan Associate Professor Department of Computer Science SLS MAVMM Ayira Vaisyar College Madurai Tamil Nadu India Dr G Stephen Assistant Librarian St Xavier s University Kolkata West Bengal India

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**Integrating QS-9000 with Your Automotive Quality System** D. H. Stamatis,1999 This detailed reference was the first of its kind to discuss the requirements for QS 9000 certification Written for automotive suppliers and manufacturers responsible for developing a quality strategy for achieving high quality standards this book serves as an overview and critical interpretation of the ISO 9000 quality standards and the QS 9000 requirements In this revised and expanded edition to his best selling book *Integrating QS 9000 with Your Automotive Quality System* D H Stamatis explains the changes to the QS 9000 requirements the author also introduces some issues regarding the applicability of audits and auditors to the industry perspective Two new chapters dealing with auditors and auditing have been added to address concerns most often expressed by those involved with an evaluation A new chapter discusses the environmental impacts relating to QS 9000 and the role ISO 14000 plays in the QS 9000 arena the VDA 6 German requirement is also introduced You ll find a full quality manual QM to demonstrate how a QM can be written in a paragraph format combining the elements with the subelements of the standard Two revised appendices offer an overview of the production part approval process PPAP and the advanced product quality planning process APQP **IS Manager's Guide to Implementing and Managing Internet Technology** Richard

Barrett Clements,1999 *The IS Manager s Guide to Implementing and Managing Internet Technology* is a practical sourcebook designed to help IS managers incorporate the Internet intranet into their company s business operations It shows how to define an agenda develop an overall electronic strategy and policy that will generate high return on investment determine and cost justify who in the organization should be given access to the Internet and present an effective business plan Coverage includes developing a policy and implementation strategy for conducting business on the Internet Internet marketing Inter and intranet architecture key web technologies and electronic solutions to a variety of company problems

IEEE International Engineering Management Conference ,1994      **Texas Instruments Technical Journal** ,1992

Preparation for ISO 9000 Certification at Kolar Machines, Inc., Ithaca, NY Wayne Lam,Sten Peeters,1996      **Quality Systems Update** ,1997      *The Consultant* ,1999      *The International Construction Law Review* ,2000      **Transactions of the American Nuclear Society** American Nuclear Society,1993      **A Practical Field Guide for AS9100** Erik V. Myhrberg,Dawn Holly Crabtree,2006 What separates this field guide from most other books on AS9100 are the flowcharts showing the steps to be taken in implementing a QMS to meet subclause requirements and the process control tips that assist the reader to meet the intent of AS9100 and gain competitive advantage Jacket

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