

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- Obsolete Document:** A document that is no longer valid for use and has been replaced or archived.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 this 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 noted on the original, with reminders sent to prompt review before the review date expires.

4.3 Revision Status

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

7. Security and Access Control

7.1 Access Control

Documents should be accessible only to authorized personnel. The 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 ensure authenticity and integrity, documents must be protected using digital signatures, checksums, or other controls of a document management system. The section also outlines measures to prevent accidental deletion or modification.

8. Training and Awareness

Personnel must be trained on the importance of document control and their role in the system. The 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 section details the audit process, including frequency, audit roles, and corrective actions required upon non-compliance or gaps identified.

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 product standard 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: Provides a detailed log of all revisions made to a document.
- Document Control Checklist: Visual representation of the document control process.

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Joseph F. Dyro



Iso 900document 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 **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 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 **Mastering ISO 9001**

Cybellium, Take control of your quality management system with ease and confidence In the globally connected world of today quality standards matter more than ever Whether you re an experienced quality manager or new to the field Kris Hermans Mastering ISO9001 provides a comprehensive guide to understanding implementing and optimizing the ISO 9001 standard This book demystifies the complexities of ISO 9001 making it accessible and practical for businesses of all sizes Hermans breaks down the standard s core components into manageable sections guiding you step by step through the process of building an effective quality management system In Mastering ISO9001 you will learn to Understand the structure and requirements of the ISO 9001 standard Implement the standard effectively in your organization Identify opportunities for continuous improvement Prepare for and manage ISO 9001 audits Utilize ISO 9001 as a tool for enhancing customer satisfaction and business performance

How to Audit Document Control System Based on ISO 9001 Folarin Omojoye,2021-06-23 How to Audit Document Control System based on ISO 9001 2015 Document Control Audit is one of the most difficult system audits to perform Some organizations are unaware of the relevant document control requirements that must be met let alone how to conduct a meaningful audit on their document control system Unfortunately ISO 9001 does not and cannot show any organization the how to because it is a book for all You know what that means a framework that is one size fits all In plain English the author of this book demonstrates how to assess the compliance of any document control system with the requirements of the ISO 9001 standard This book is divided into seven chapters and three appendices as follows Chapter 1 What is Document Control Audit and What Are the Different Types Chapter 2 Glossary of Abbreviations and Terms Chapter 3 Benefits of Document Control Audit Chapter 4 Principles of a Document Control Audit Chapter 5 Sources of Document Control Audit Criteria Chapter 6 Audit checks based on the ISO 9001 2015 Clause 7 5 Chapter 7 Approach to a Document Control Audit Appendix A Section 4 2 3 Control of Documents excerpts from ISO 9001 2008 Appendix B Framework for Document Control Audit Interview Questions Appendix C Sample Document Control System Audit Report I hope this book will be an essential tool in your audit arsenal

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

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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 *Texas Instruments Technical Journal* ,1992 Quality Systems Update ,1997 **IEEE International Engineering Management Conference** ,1994 *Tappi Journal* ,1994 **The Management and Control of Quality** James Robert Evans,William M. Lindsay,1996 This text continues to provide a managerially oriented integrated view of the issues involved in total quality management The Third Edition is strongly influenced by the Malcolm Baldrige National Quality Award criteria New chapters have been added on current topics such as customer focus leadership and strategic planning measurement and information management and quality management evaluation and assessment Updating of all chapters ensures complete and timely coverage Transactions of the American Nuclear Society American Nuclear Society,1993 **Conference Proceedings** Society of Plastics Engineers. Technical Conference,1993 Export Today ,1996

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