

# 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- Obsolete Document:** A document that is no longer valid for use and has been replaced or archived.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 unaltered 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, lists, or logs.

- 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 Register: Visual representation of the document control process.

# Iso 9001 Document Control Procedure Example

**Susan K. Land, John W. Walz**



## **Iso 9001 Document Control Procedure Example:**

**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 **ISO 9001:2015 for Small Businesses** Ray Tricker, 2016-10-04 Small businesses face many challenges today including the increasing demand by larger companies for ISO 9001 compliance a challenging task for any organisation and in particular for a small business without quality assurance experts on its payroll Ray Tricker has already guided hundreds of businesses through to ISO accreditation and this sixth edition of his life saving ISO guide provides all you need to meet the new 2015 standards ISO 9001 2015 for Small Businesses helps you understand what the new standard is all about and how to achieve compliance in a cost effective way Covering all the major changes to the standards this book provides direct accessible and straightforward guidance This edition includes down to earth explanations to help you determine what you need to enable you to work in compliance with and or achieve certification to ISO 9001 2015 a contextual explanation of ISO 9001 within the structure of ISO 9000 family of standards a detailed description of the structure of ISO 9001 2015 and its compliance with Annex SL coverage of the new requirements for Risk Management and Risk Analysis a guide to the costs involved in implementing ISO 9001 2015 and advice on how to

control costs an example of a complete generic Quality Management System consisting of a Quality Manual plus a whole host of Quality Processes Quality Procedures and Work Instructions and access to a free software copy of these generic QMS files to give you a starting point from which to develop your own documentation This book is also supported with a complete bibliography containing abbreviations and acronyms as well as a glossary of terms This comprehensive text will provide you and your small business with a complete guide on your way to ISO compliance

**The ASQ Certified Reliability Engineer Handbook** Karen Hulting, Mary McShane-Vaughn, 2025-11-12 This updated handbook is ideal for working professionals who specialize in improving the reliability maintainability and safety of products systems and processes Organized according to the 2025 ASQ Certified Reliability Engineer CRE Body of Knowledge BoK the fourth edition of The ASQ Certified Reliability Engineer Handbook has been expanded to include new information tools and techniques Inside you ll find a comprehensive view of the role of a reliability engineer with a focus on the basics as well as the latest technology and applications used today Revised sections are also designed to expand the knowledge base of current CREs candidates preparing for the ASQ CRE certification exam and engineering students

**ISO 9001:2008 for Small Businesses** Ray Tricker, 2014-01-21 Small businesses face many challenges today including the increasing demand by larger companies for ISO compliance Compliance is a challenging task for any organisation and can often be time consuming and costly particularly for small businesses who are unlikely to have quality assurance experts on the payroll However it is still possible to achieve compliance without the need for expensive consultancy or training that takes you out of the office Ray Tricker has already guided hundreds of businesses through the challenge and this the 5th edition of his life saving ISO guide has been rewritten and refined following 5 years field use of working with the standard The one area that an organisation particularly a small business always wants to know is how much is it going to cost to implement and operate a QMS compliant with ISO 9001 2008 and is it going to be worth the trouble Due to popular demand Edition 5 now includes a brand new chapter on the cost of implementing ISO 9001 2008 This edition provides Relevant examples that put the concepts and requirements of the standard into a real life context Down to earth explanations to help you determine what you need to work in compliance with and or achieve certification to ISO 9001 2008 An example of a complete generic Quality Management System consisting of a Quality Manual plus a whole host of Quality Processes Quality Procedures and Work Instructions Access to a free software copy of this generic QMS files available from the author to give you a starting point from which to develop your own documentation ISO 9001 2008 is the most widely followed quality management standard and the rewards can be great opening up new business opportunities as well as bringing real improvements to your processes and outputs

**Guide to Quality Management Systems for the Food Industry** Ralph Early, 2012-12-06 Whenever I step into an aeroplane I cannot avoid considering the risks associated with flying Thoughts of mechanical failure pilot error and terrorist action fill my mind I try to reassure myself with statistics which tell me there is greater chance of injury crossing the road The moment the plane

takes off I am resigned to my fate placing faith in pilots who are highly qualified and superbly trained for the task of delivering me safely to my destination To be a passenger in an aeroplane is to express faith in the systems used by the airline It is to express a faith in the quality of the airline s organisation and the people who work within it The same is true of surgery Thoughts of mortality are difficult to avoid when facing the surgeon s knife However faith in the surgeon s training and skill faith in the anaesthetist and theatre technicians faith in the efficient resources and quality of the hospital all help to convince that there is little need to worry Apart from flying and surgery there are many facets of life which entail risk but knowing the risks we willingly place our confidence in others to deliver us safely In the consumption of food however few of us consider the risks Everyday if we are fortunate we eat food Food sustains and gives us pleasure Food supports our social interactions

**Essentials of Quality with Cases and Experiential Exercises** Victor E. Sower,2010-02-22 Thoroughly tested and used by students and proven to help students taking the American Society for Quality s Certified Quality Improvement Associate exam Essentials of Quality is highly accessible experiential and unique in its coverage of current quality management topics from creative and innovative improvements and approaches to today s economic environment to ways of developing metrics for measuring and evaluating programs With non academic reader friendly writing the text features many chapter exercise and cases that provide students with hands on experience *Complete Guide to ISO 14000*

Richard Barrett Clements,1996 This guide offers an overview of ISO 14000 a newly developed set of international standards for environmental management Their benefits and effects on a wide variety of companies are discussed **SHE**

**Management Systems for Small to Medium-sized Enterprises** Anders Jacobsson,2000 The production and use of chemicals frequently involves the handling of hazardous materials Experience built up by chemical manufacturers and users over many years has established methods of working which when correctly applied reduce the risks involved to acceptable levels Major companies in the process industries have found that the safety health and environmental aspects of their operations can be further improved if the individual procedures are integrated into a management system *Quality Manager's Complete Guide to ISO 9000* Richard B. Clements,1999 **Tietz Textbook of Clinical Chemistry and**

**Molecular Diagnostics - E-Book** Carl A. Burtis,Edward R. Ashwood,David E. Bruns,2011-12-16 As the definitive reference for clinical chemistry Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 5th Edition offers the most current and authoritative guidance on selecting performing and evaluating results of new and established laboratory tests Up to date encyclopedic coverage details everything you need to know including analytical criteria for the medical usefulness of laboratory procedures new approaches for establishing reference ranges variables that affect tests and results the impact of modern analytical tools on lab management and costs and applications of statistical methods In addition to updated content throughout this two color edition also features a new chapter on hemostasis and the latest advances in molecular diagnostics Section on Molecular Diagnostics and Genetics contains nine expanded chapters that focus on emerging issues and

techniques written by experts in field including Y M Dennis Lo Rossa W K Chiu Carl Wittwer Noriko Kusakawa Cindy Vnencak Jones Thomas Williams Victor Weedn Malek Kamoun Howard Baum Angela Caliendo Aaron Bossler Gwendolyn McMillin and Kojo S J Elenitoba Johnson Highly respected author team includes three editors who are well known in the clinical chemistry world Reference values in the appendix give you one location for comparing and evaluating test results NEW Two color design throughout highlights important features illustrations and content for a quick reference NEW Chapter on hemostasis provides you with all the information you need to accurately conduct this type of clinical testing NEW Six associate editors lend even more expertise and insight to the reference NEW Reorganized chapters ensure that only the most current information is included **ISO 9000 Quality Management System Design** Jay J. Schlickman,1998

**Integrating ISO 14001 Into a Quality Management System** Marilyn R. Block,I. Robert Marash,2002 This book encourages critical thinking about the similarities between ISO 14001 and the ISO 9001 QS 9000 quality standards and shares approaches used by various organizations through examples of documentation that have withstood the scrutiny of registrars *Implementing ISO 9001:2000* Tom Taormina,Keith Brewer,2002 ISO 9001 2000 A start to finish implementation guide to the newly updated ISO standard from two of the world s leading quality practitioners The realist s guide to ISO 9001 2000 internal audits choosing registrars ensuring customer focus measuring results and much more Dell s Asset Recovery Business ARB A start to finish ISO 9001 case study from the insiders who made it happen Moving ISO 9001 from cost center to profit center To maintain their ISO 9001 certifications organizations worldwide must upgrade to the brand new ISO 9001 2000 standard In this book two of the world s leading quality practitioners present the most realistic business focused guide to ISO 9001 2000 implementation The book s focus isn t on mere conformance it shows companies how ISO 9001 2000 can support their key strategic initiatives and how to move ISO 9001 2000 from cost center to profit center Tom Taormina and Keith Brewer cover every aspect of ISO 9001 2000 including the new process model the latest and most effective internal auditing techniques how to select a registrar how to reflect the new standard s requirements for customer focus and management involvement and much more In a start to finish ISO 9001 case study the authors show how Dell s Asset Recovery Business ARB has gone beyond mere compliance leveraging ISO 9001 2000 standards to build a fully integrated business management system that uses continuous improvement models to drive operational excellence and profitability *Understanding and Implementing ISO 9000:2000* David L. Goetsch,Stanley Davis,2002 As organizations that compete in the global marketplace seek to achieve peak performance worldclass quality and personnel improvement interest in ISO 9000 certification has gained worldwide momentum This practical resource and guide uses a step by step model to understanding the ISO 9000 2000 series of standards and explains how to use them in an organization Provides a detailed summary of similarities and differences between the earlier version and ISO 9000 2000 Features ISO INFO boxes throughout that show how material being discussed applies to an actual work setting Offers a Serialized Case Study after every chapter

that applies the information from a given chapter to how it was used in a real setting in which ISO 9000 registration was pursued the story unfolds with each new chapter showing the problems strategies mistakes and achievements of a company going through the registration process Ideal as a step by step how to guide for use in organizations that are interested in ISO 9000 registration

*The Certified Quality Manager Handbook* Duke Okes, Russ Westcott, 2001 Designed as a study aid for those preparing to take the Certified Quality Manager Examination administered by the American Society for Quality ASQ this book provides a thorough understanding of the principles terms and concepts of quality management The new second edition contains practical examples from many different industries and organizations including manufacturing health care government education and the service industries

*The Quality Auditor's Handbook* Don L. Freeman, 1997 The practical easy to use handbook for every quality auditor manager or trainer In this book leading ISO 9000 auditor and trainer Don Freeman gives you straight answers and practical tools for every step of the quality auditing process You ll learn how to successfully plan and conduct quality audits and report on their results And you ll discover proven solutions for the challenges faced by every quality auditor From start to finish The Quality Auditor's Handbook provides step by step methods tools matrices and forms that streamline the audit process Along the way you ll also learn the communications skills questioning listening and observation techniques that are essential to successful auditing The practices and tools you ll learn can be modified and used with any type of quality system auditing and for other types of auditing as well such as environmental auditing ISO 14000

**The Quality Systems Manual** Terence J. Hall, 1995-10-16 For the past four years a committee of professional interests representing industry academia consumers and governments has been meeting to develop a definitive standard to take Quality Systems into the 21st century In July 1994 ISO 9000 was announced to the world This is the ISO 9000 Family 9001 2 3 as it tends to be called There is now an even greater demand from companies to gain formal accreditation particularly since the standard has worldwide recognition The Quality Systems Manual is a detailed and definitive guide to the installation and maintenance of an ISO 9001 Quality System within a company It is an intensely practical guide laid out to follow the exact format of the 20 clauses of ISO 9001 It explains in plain English exactly how they should be applied to your business The official ISO 9001 paper provides only a slim seven page statement of the basic requirements that have to be met by a Quality System it supplies none of the required methodology It tells you what but not how The missing link between the rules and successful registration comes from knowing how to take the 20 clauses and apply them to everyday business situations This is where The Quality Systems Manual is so valuable It is relevant for every industry whether manufacturing or service and will be used by Quality Managers and those assigned to implement and maintain this new standard Because it is designed as a practical guide to enable companies to register there is a special section called Preparing for Assessment which covers all the nuances needed to optimise the chance of success when being formally assessed TickIT ISO 9000 3 the equivalent standard for software development is also examined in detail and shows

precisely how it integrates with ISO 9001 It has been calculated that a third of the cost a company incurs in achieving registration is spent on fees for consultants to help explain the rules and prepare for assessment For the cover price of The Quality Systems Manual you could buy yourself about one hour of a consultant s time      *Practical Support for ISO 9001 Software Project Documentation* Susan K. Land, John W. Walz, 2006-10-13 This book addresses how to meet the specific documentation requirements in support of the ISO 9001 software process definition documentation and improvement which is an integral part of every software engineering effort Provides a set of templates that support the documentation required for basic software project control and management The book provides specific support for organizations that are pursuing software process improvement efforts      **Understanding and Implementing ISO 9000 and ISO Standards** David L. Goetsch, Stanley Davis, 1998 Appropriate for courses based on the ISO 9000 series of quality standards as a supplemental text in courses dealing with Quality Management and Total Quality Management TQM and as a hands on guide for use in private sector organizations This practical teaching resource how to guide provides a step by step model for understanding the ISO 9000 family of standards and implementing the ISO 9001 standard in a total quality environment Interest in ISO 9000 certification is gaining momentum worldwide as organizations that compete in the global marketplace seek to achieve consistent peak performance world class quality and continual improvement of their processes products and management systems



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