

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- Obsolete Document:** A document that is no longer valid for use and has been replaced or archived.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, visual representation of the document control process.

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ISO 9001:2015 in Plain English Craig Cochran,2015-11-16 Just as he did with the bestselling ISO 9001 in Plain English Cochran has written a comprehensive yet easily understandable guide to ISO 9001 2015 ISO 9001 2015 in Plain English was written so that anyone at any level of the organization can get to the heart of the standard s requirements and how they apply to the organization quickly and simply This straightforward book is ideal for people who are new to ISO 9001 2015 experienced ISO coordinators who want to get more out of an established system as they transition to the new standard and for employees who just need a basic understanding of what ISO 9001 2015 is and how it applies to them Cochran explains each of ISO 9001 2015 s sections and clauses using real world examples and frequently asked questions [Process Improvement Essentials](#) James R. Persse, PhD,2006-09-14 Today technology has become too much a part of overall corporate success for its effectiveness to be left to chance The stakes are too high Fortunately the idea of quality management is being reinvigorated In the last decade process programs have become more and more prevalent And out of all the available options three have moved to the top of the chain These three are The 9001 2000 Quality Management Standard from the International Standards Organization The Capability Maturity Model Integration from the Software Engineering Institute and Six Sigma a methodology for improvement shaped by companies such as Motorola Honeywell and General Electric These recognized and proven quality programs are rising in popularity as more technology managers are looking for ways to help remove degrees of risk and uncertainty from their business equations and to introduce methods of predictability that better ensure success Process Improvement Essentials combines the foundation needed to understand process improvement theory with the best practices to help individuals implement process improvement initiatives in their organization The three leading programs ISO 9001 2000 CMMI and Six Sigma amidst the buzz and hype tend to get lumped together under a common label This book delivers a combined guide to all three programs compares their applicability and then sets the foundation for further exploration It s a one stop shop designed to give you a working orientation to what the field is all about

Product-Focused Software Process Improvement Muhammad Ali Babar,Matias Vierimaa,Markku Oivo,2010-06-16 On behalf of the PROFES Organizing Committee we are proud to present the proceedings of the 11 International Conference on Product Focused Software Process Improvement PROFES 2010 held in Limerick Ireland Since the first conference in 1999 the conference has established its place in the software engineering community as a respected conference that brings together participants from academia and industry The roots of PROFES are in professional software process improvement motivated by product and service quality needs The conference addresses both the solutions found in practice as well as relevant research results from academia To ensure that PROFES retains its high quality and focus on the most relevant research issues the conference has actively maintained close collaboration with industry and subsequently widened its scope to the research areas of collaborative and agile software development The main themes of this year s conference were Agile

and Lean Processes and Engineering Service Oriented Systems These two main themes enabled us to cover the contemporary software development demands and trends in a comprehensive manner and to tackle the most important current challenges identified by the software industry and software research community namely the shift of focus from products to services The technical program featured invited talks research papers and experience reports on the most relevant topics related to processes for developing software intensive services and products In addition a number of workshops and tutorials were hosted

ISO 9001:2000 International Organization for Standardization, International Trade Centre UNCTAD/GATT., 2005 This Workbook presents a set of questions checklists and planning guides to be used as a tool for streamlining the internal process of conformance to the ISO 9001 2000 standard by professional service firms in developing countries The Workbook provides an overview of ISO 9001 2000 as an international quality management framework focuses on internal decisions discussions and the planning needed in applying ISO 9001 2000 concept and for creating the necessary quality management system in a small service firm Publishing Agency International Trade Centre ITC

Healthcare Technology Management - A Systematic Approach Francis Hegarty, John Amooore, Paul Blackett, Justin McCarthy, Richard Scott, 2017-01-06 Healthcare Technology Management A Systematic Approach offers a comprehensive description of a method for providing safe and cost effective healthcare technology management HTM The approach is directed to enhancing the value benefit in relation to cost of the medical equipment assets of healthcare organizations to best support patients clinicians and other care providers as well as financial stakeholders The authors propose a management model based on interlinked strategic and operational quality cycles which when fully realized delivers a comprehensive and transparent methodology for implementing a HTM programme throughout a healthcare organization The approach proposes that HTM extends beyond managing the technology in isolation to include advancing patient care through supporting the application of the technology The book shows how to cost effectively manage medical equipment through its full life cycle from acquisition through operational use to disposal and to advance care adding value to the medical equipment assets for the benefit of patients and stakeholders This book will be of interest to practicing clinical engineers and to students and lecturers and includes self directed learning questions and case studies Clinicians Chief Executive Officers Directors of Finance and other hospital managers with responsibility for the governance of medical equipment will also find this book of interest and value

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Duffy, 2014-10-01 ASQ s Certified Quality Improvement Associate CQIA certification is designed to introduce the basics of quality to organizations and individuals not currently working within the field of quality This book and the Body of Knowledge

BOK it supports are intended to form a foundation for further study and application of proven quality principles and practices worldwide The book follows the CQIA BoK in both content and sequence The intent is that this book will serve as a guide to be used in preparation to take the CQIA examination given by ASQ Each chapter stands alone and the chapters may be read in any order Some material reaching beyond the content of the BoK has been added Supplemental reading suggestions are provided An online interactive sample exam and a paper and pencil sample can be found on the ASQ website <http://asq.org>

cert quality improvement associate prepare **ISO 9001:2000 for Small Businesses** Ray Tricker,2005 Small and medium sized companies face many challenges today including the demand by larger customers for ISO 9000 compliance Four years into the current version of ISO 9000 the new edition of this life saving book incorporates the hard won field experience of actually working with the standard Along with a thoroughly updated and customisable generic Quality Manual with audit checklists for developing a complete Quality Management System the book provides valuable advice on Compatibility and Inter Relationship between other Management Standards Basic Requirements to Set Up an Integrated Management System and The Eight Principles of Management among others *Laguna de Bay Environment Monitor* ,2013 **Total Quality Management** M.P. Poonia, S.C. Sharma, Total Quality Management TQM is an integrated approach in satisfying customer needs in totality on continuing basis through involvement of each and every employee of the organization making continuous improvement on one side and an appropriate cost effective technology on the other side It is a management philosophy for professional excellence that too through customer orientation With the rapid advancement in technology and awareness the users customers have become highly quality conscious and demands quality reliability and safety in product and service In view of this industries need to upgrade their quality continuously Product and service quality requires managerial technological and statistical concepts throughout all the major functions of an organization The concepts like strategic management competitive bench marking self managing teams getting it right first time zero defects employee empowerment are important as a move towards Total Quality Management TQM This book provides a fundamental and comprehensive coverage of Total Quality Management TQM in simple and easy to understand language The book is divided in to two parts Part I covers the principles and practices of TQM while part II covers the tools and technology of TQM The book covers the syllabi of various university and therefore should serve the needs of students of MBA and those of engineering technology and related disciplines The professionals too will find this book to be a valuable reference in the field *International Who's Who of Professional Management* Joseph A. Parker,Joe Parker,1999-11 **Vietnam Economic News** ,2002-05 **Annual Report** India. Ministry of Civil Aviation,2010 **Managing Globalization in Developing Countries and Transition Economies** Moses Kiggundu,2002-12-30 Examines the opportunities and challenges globalization offers to developing countries and transition economies *Genetic Engineering & Biotechnology News* ,2007 *ISO 9001 QMS Policies, Procedures, and Forms* ,2009 Collection of sample documents forms and checklists useful for setting up and running an ISO

9001 quality management system The forms can be customized to suit the user s business needs **The Times Index** ,2004
Indexes the Times Sunday times and magazine Times literary supplement Times educational supplement Times educational
supplement Scotland and the Times higher education supplement *Annual Report* India. Ministry of Textiles,2012 ISO
9001:2000 Quality Management System Design Jay J. Schlickman,2003 Provides a set of design rules for creating a quality
management system that will naturally translate into successful ISO 9001 2000 certification The book identifies the key
documentation components and supplies guidelines for outlining and writing the quality manual standard operating
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Table of Contents Ehqms Policy Document Iso 9001 Help Home

1. Understanding the eBook Ehqms Policy Document Iso 9001 Help Home
 - The Rise of Digital Reading Ehqms Policy Document Iso 9001 Help Home
 - Advantages of eBooks Over Traditional Books
2. Identifying Ehqms Policy Document Iso 9001 Help Home
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Ehqms Policy Document Iso 9001 Help Home
 - User-Friendly Interface
4. Exploring eBook Recommendations from Ehqms Policy Document Iso 9001 Help Home
 - Personalized Recommendations
 - Ehqms Policy Document Iso 9001 Help Home User Reviews and Ratings
 - Ehqms Policy Document Iso 9001 Help Home and Bestseller Lists
5. Accessing Ehqms Policy Document Iso 9001 Help Home Free and Paid eBooks
 - Ehqms Policy Document Iso 9001 Help Home Public Domain eBooks
 - Ehqms Policy Document Iso 9001 Help Home eBook Subscription Services

- Ehqms Policy Document Iso 9001 Help Home Budget-Friendly Options
- 6. Navigating Ehqms Policy Document Iso 9001 Help Home eBook Formats
 - ePub, PDF, MOBI, and More
 - Ehqms Policy Document Iso 9001 Help Home Compatibility with Devices
 - Ehqms Policy Document Iso 9001 Help Home Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Ehqms Policy Document Iso 9001 Help Home
 - Highlighting and Note-Taking Ehqms Policy Document Iso 9001 Help Home
 - Interactive Elements Ehqms Policy Document Iso 9001 Help Home
- 8. Staying Engaged with Ehqms Policy Document Iso 9001 Help Home
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Ehqms Policy Document Iso 9001 Help Home
- 9. Balancing eBooks and Physical Books Ehqms Policy Document Iso 9001 Help Home
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Ehqms Policy Document Iso 9001 Help Home
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Ehqms Policy Document Iso 9001 Help Home
 - Setting Reading Goals Ehqms Policy Document Iso 9001 Help Home
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Ehqms Policy Document Iso 9001 Help Home
 - Fact-Checking eBook Content of Ehqms Policy Document Iso 9001 Help Home
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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