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## Quality Procedure ISO 9001: 2008 – Control of Documents

### 1 Purpose

FablessSemi Inc<sup>1</sup> controls all documents that are required by our Quality Management System (QMS).

The purpose of this procedure is to define the process and responsibilities to ensure that internal documents, external and customer-supplied documents (standards, specifications, procedures, etc.), and data within FablessSemi Inc are controlled.

### 2 Scope

The requirements of this procedure apply to all drawings, procedures, work instructions, forms, etc. used within the QMS that affect the quality of products or services at FablessSemi Inc.

### 3 Revision History

#### 3.1.1 Approval

This Quality Procedure has been approved for use throughout FablessSemi Inc:

**Date of Initial Version:** February 2<sup>nd</sup>, 2009  
**Name and Title of Approver:** Any Name (Director)  
**Date of Approval:** April 21<sup>st</sup>, 2009

This Quality Procedure was written and published by **Any Name** of FablessSemi Inc. Please contact [any.name@fabless-semi.com](mailto:any.name@fabless-semi.com) with questions, comments and improvement ideas.

#### 3.1.2 Revision History

The following revisions have been made to this procedure since its initial publication:

Revision Date	List of Changes	Author	Approval
02/02/09	First draft	PW	
10/03/09	Incorporated review comments from the QA team and up-issued	PW	
21/04/09	Issued as an example document and published to the Extranet Library at <a href="http://www.cognidox.com">www.cognidox.com</a>	PW	PW

### 4 Related Documents

All references to ISO 9001 in this procedure refer to the requirements of ISO 9001:2008.

<sup>1</sup> FablessSemi Inc is a fictional company. The domain [www.fabless-semi.com](http://www.fabless-semi.com) is registered and controlled by Cognidox Limited ([www.cognidox.com](http://www.cognidox.com)) as a demonstration of its document control software.

# Iso 900document Control Procedure Example

**Ray Tricker**



## **Iso 900document 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 9001compliance 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 Word 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 *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 *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 Kusukawa 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

**Integrated Circuit Metrology, Inspection, and Process Control**, 1994 **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

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

**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

ISO 9000 Roy M. Chiulli, 2001 If you are switching from using MIL Q 9858 to ISO 9000 and don't want to become an ISO 9000 expert this book is for you Easily read in an hour or two the book provides managers and engineers with a quick basic understanding of these important international standards

*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

**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 ISO 9000 Implementation and Assessment: A Guide to Developing and Evaluating Quality Management Systems ,1996

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

*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 **ISO 9000 for Software Developers** Charles H. Schmauch, 1994 Software Software Engineering ISO 9000 and the Service Sector James L. Lamprecht, 1994

**International Process Safety Management Conference and Workshop** ,1993 The proceedings of the conference and

workshop held in San Francisco September 1993 comprise 25 papers two workshops and 12 posters Among the paper topics planning guidelines for acute risk management the Canadian chemical industry experience a review of the role of cost benefit analysis as a

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