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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@fablesssemi.com](mailto:any.name@fablesssemi.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.fablesssemi.com](http://www.fablesssemi.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

**Yi-Tong Ma**



## **Iso 9000document 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 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 **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 **Textbook**

**of Assisted Reproductive Techniques** David K. Gardner, Ariel Weissman, Colin M. Howles, Zeev Shoham, 2023-12-13 Established as the definitive reference for the IVF clinic the sixth edition has been extensively revised with the addition of several important new contributions on clinical topics including The use of digitalization and precision medicine in the IVF clinic The environment and reproduction The use of gonadotropin releasing hormone agonists and the efficiency of IVF Controlled ovarian stimulation for freeze all cycles Immunology in ART Home monitoring of ART cycles Luteal phase support in ART The POSEIDON stratification of low prognosis patients in ART Controlled ovarian stimulation for low responder patients Adjuvants for poor responders Innovative therapies in diminished ovarian reserve and primary ovarian insufficiency patients and Fertility options for transgender and nonbinary individuals As previously methods protocols and techniques of choice are presented by IVF pioneers and eminent international experts *ISO 9001: 2000 for Small Businesses* Ray Tricker, 2012-09-10 Review of previous edition This will be of particular importance to companies that act as suppliers to larger multinational organisations whose original specifications may not translate readily into local practice Quality Today Small and medium sized companies face many challenges today not least that their larger institutional and multinational customers make demands that are difficult to meet for an organisation with limited resources One such demand is ISO 9000 compliance Fully revised and updated ISO 9001 2000 for Small Businesses explains the new requirements of ISO 9001 2000 and helps businesses draw up a quality plan that will allow them to meet the challenges of the market place For engineers and managers in small and medium sized companies and also in service industries and user groups the text will serve as a essential guide to the most important new developments in quality assurance *Enterprise Process Mapping* Charles G. Cobb, 2004-06-30 Many books on process mapping are oriented around a traditional manufacturing process control

environment The methodology and tools in this book are applicable to any company in any industry that is interested in developing a much more integrated systems approach to management to dramatically improve their business The author's previous book From Quality to Business Excellence A Systems Approach to Management explains the philosophy behind this approach This book provides the how to for achieving that level of visualization with a unique combination of theory and tools showing you how to implement enterprise process mapping in a way that will yield significant business value for your organization nl Comply with quality standards such as ISO 9001 2000 and regulatory requirements such as Sarbanes Oxley Develop a unifying view of how an overall business works as a system Implement a very high impact well integrated and cross functional systems approach to managing all aspects of the business Understand how all processes and tasks within the organization contribute to achieving the company's overall business goals Provide a foundation for a systematic and proactive approach to business process improvement that will result in real and tangible improvements in cost and effectiveness

**ISO 9001:2015 Internal Audits Made Easy** Ann W. Phillips, 2015-09-21 Implementing the requirements of ISO 9001 can be a daunting task for many organizations In an attempt to develop a system that will pass the registration audit we are tempted to establish processes with the primary purpose of conforming to the requirements of ISO 9001 In doing so however it is easy to lose sight of the primary intent of the standard to continually improve the effectiveness of the quality management system QMS implemented at our organization This book is intended to help managers quality professionals internal audit coordinators and internal auditors implement a practical internal audit process that meets the requirements of ISO 9001 2015 while adding significant measurable value to the organization The tools techniques and step by step guidelines provided in this book can also be used by those organizations that have a well established internal audit process but are looking for easy ways to make that process more effective

**Using ISO 9001 in Healthcare** James M. Levett, Robert G. Burney, 2010-11-19 Healthcare providers deal with quality concepts and tools on a regular basis but the idea of a quality system or quality management system QMS is not a familiar term Most are familiar with control charts Lean the PDCA cycle Six Sigma and the Baldrige criteria but ISO 9001 is not usually recognized and most have no experience with a systematic program to implement quality objectives within an organization This book explains the overall value of an ISO 9001 based QMS its value in implementing a quality culture within an organization using other quality tools within the ISO framework clinical integration accreditation and performance improvement Several case studies of ISO implementation in healthcare organizations are described including a large multi specialty group a community hospital and hospital system and the State Department Medical Unit in D C

**The ISO 9001:2015 Implementation Handbook** Milton P. Dentch, 2016-08-17 The handbook is structured to guide organizations new to ISO 9001 through the process necessary to connect their current practices to the requirements of ISO 9001 2015 For organizations already certified to ISO 9001 it advises how to use your upgrade to ISO 9001 2015 as an opportunity to rebuild your QMS into a helpful asset in managing

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