
Quality Procedure ISO 9001: 2008 – Control of Documents

1 Purpose

FablessSemi Inc¹ 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 2nd, 2009
Name and Title of Approver: Any Name (Director)
Date of Approval: April 21st, 2009

This Quality Procedure was written and published by **Any Name** of FablessSemi Inc. Please contact 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 www.cognidox.com	PW	PW

4 Related Documents

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

¹ FablessSemi Inc is a fictional company. The domain www.fablesssemi.com is registered and controlled by Cognidox Limited (www.cognidox.com) as a demonstration of its document control software.

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**ASTM International, American Society
for Testing and Materials**

A red circular graphic with a gradient, appearing as a partial circle or a thick arc, located to the right of the ASTM text box.

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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 *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 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 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 **Document Control** Denise Robitaille,2005-03 *Implementing Quality in Laboratory Policies and Processes* Donnell R. Christian Jr.,Stephanie Drilling,2009-11-24 In order to gain accreditation every laboratory must have a superior quality assurance program The keys to a successful program are the operational and technical manuals and associated documents which define the program and its various components Written by experts with global experience in setting up laboratories *Implementing Quality in Laboratory Policies and Processes Using Templates* Project Management and Six Sigma provides templates for the various policies procedures and forms that should be contained in the quality assurance operational and technical manuals of a laboratory seeking accreditation Templates for the entire project life cycle The book begins with a general introduction and overview of quality assurance and then moves on to cover implementation strategies It contains best practices and templates for the project management of the design and implementation of the laboratory operational and technical manuals required to establish a quality assurance program The templates span the entire project life cycle from initiation to planning to execution to monitoring and finally to closure The book also examines how Six Sigma concepts can be used to optimize laboratories and contains templates that cover administrative issues quality assurance sample control and health and safety issues In addition there is a section of criteria files that relate the individual document templates to specific accreditation criterion Addresses the standards of ISO 17025 The results of any laboratory examination have the potential to be presented in court and can ultimately affect the life and liberty of the parties involved Therefore a stringent quality assurance program including well documented policies and a procedure manual is essential Ensuring that laboratories meet the standards of ISO 17025 this volume is a critical component of any laboratory s accreditation process **Laboratory Quality Manager - The Comprehensive Guide** DEAN STRATTON,101-01-01 Unlock the essential roadmap to excellence in laboratory quality management with *Laboratory Quality Manager The Comprehensive Guide* Designed for both emerging and experienced professionals this book delivers an in depth practical and inspiring exploration of quality assurance within the modern laboratory environment Discover how to build and sustain robust Quality Management Systems QMS aligned with ISO IEC 17025 CLIA and GLP standards Each chapter blends regulatory knowledge real world case studies and hypothetical scenarios that illuminate key concepts from root cause analysis to continuous improvement Learn how to design effective documentation systems manage internal audits lead accreditation preparations and foster a culture of scientific integrity and accountability This guide also explores advanced topics such as digital transformation in laboratories risk based thinking and

quality metrics for performance optimization Whether you manage a clinical research or industrial lab this resource equips you with actionable strategies to enhance precision compliance and credibility Perfect for laboratory managers quality officers auditors and students in laboratory sciences this comprehensive manual empowers readers to not only meet regulatory expectations but to elevate their lab s reputation for excellence Elevate your leadership master compliance and redefine quality one system at a time **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 procedures work instructions forms and records Two case studies illustrate the upgrade and recertification of a corporation from ISO 9001 1994 to ISO 9001 2000 and the creation of a company s first quality management system The author is an auditor certified by the ASQ ANSI registrar accreditation board Annotation copyrighted by Book News Inc Portland OR **Common Sense Implementation Of Qms In The Clinical Laboratory: A Software Guided Approach** Masahiko Amano,Robert Bredt,Mark A Colby,Trent Freeman,2019-10-23 This book explains how SaaS works and lists and describes many common misconceptions and pitfalls that laboratories have about implementing Quality Management Systems QMS By walking the reader through all ISO 15189 Standards and describing each in detail we can show how to implement them in common sense and meaningful ways This book demonstrates to clinical laboratories how to combine the rigor of international standards with the inherent benefits of contemporary cloud based software systems so that they can involve the entire laboratory in making quality a shared habit [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 [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 [Encyclopedia of Forensic Sciences](#) ,2012-12-28 Forensic science includes all aspects of investigating a crime including chemistry biology and physics and also incorporates countless other specialties Today the service offered under the guise of forensic science includes specialties from virtually all aspects of modern science medicine engineering mathematics and technology The Encyclopedia of Forensic Sciences Second Edition Four Volume Set is a reference source that will inform both the crime scene worker and the laboratory worker of each other s protocols procedures and limitations Written by leading scientists in each area every article is peer reviewed to establish clarity

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ISO 9000 for the Chemical Process Industry Helen Gillespie, Helen Davys Gillespie, 1998 Gillespie includes all the necessary procedures for documenting and implementing the process detailed information on preparing for registration and audit case studies and interviews with executives in industry

The Memory Jogger 9000/2000 Robert W. Peach, Bill Peach, Diane S. Ritter, 2000 Guide your organization quickly easily and effectively through the ISO 9001 2000 registration process This convenient reference guide is designed to help your organization follow its course toward ISO registration from preparation to implementation and maintenance with additional discussion about further improvement choices Because the registration process will affect everyone in your organization The Memory Jogger 9000 2000 is designed for use by every member of your company not just the few people responsible for guiding the implementation process Each clause is separated into sections describing what the clause is why it should be done how it should be done and what is new in ISO 9001 2000 Examples of quality documents and quality records are included to illustrate ways to comply with ISO requirements

Total Quality Management in the Chemical Industry G. R. Turner, R. P. Hadfield, Society of Chemical Industry (Great Britain), 1994 Total Quality in the Chemical Industry relates first hand experiences of both successes and the difficulties encountered in following the Total Quality philosophy It is complementary to existing how to guides illustrating the way this philosophy works in actual practice The book begins with a brief introduction to the subject and goes on to describe real examples of the implementation of total quality management in industry in both manufacturing and research The bulk of the papers cover developments in the chemical industry but other industries are represented as well and the companies featured in the examples are widely recognized as being leaders in Total Quality Management TQM TQM is currently under criticism as being another management philosophy which fails to deliver yet this book shows that success can be gained and that the potential rewards are well worth the effort Total Quality Management in the Chemical Industry is essential reading for managers section leaders and safety professionals in the

chemical industry and in most manufacturing industries as well **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 **ISO 14001 Implementation Manual** Gayle Woodside,Patrick Aurricho,Jeanne Yturri,1998-05-22 This one stop sourcebook provides all the information procedures and guidance needed for ISO 14001 implementation Packed with checklists figures templates tables and example programs the book enables environmental health and safety EMS in accordance with ISO 14001 Designed for easy access and portability this unique tool covers all 18 elements of the standard explaining how to implement each in a cost effective practical way 50 illus Ironmaking Conference Proceedings ,1993 **Quality Systems Update** ,1996 *Annual Book of ASTM Standards* ASTM International,American Society for Testing and Materials,2003 *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

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