



## I. Objective

To ensure that the Quality Manual, Procedures, Forms and other internally generated quality management system documents are under control. This includes creation, amendment, deletion, review, approval, maintenance and distribution.

## II. Scope

This procedure defines the actions and responsibilities of the Requester, Process Owners, Document Controller and Approving Authorities in the control of new, revised and deleted documents.

## III.

## Responsibilities

Requester,  
Process Owner

QMR

QMR

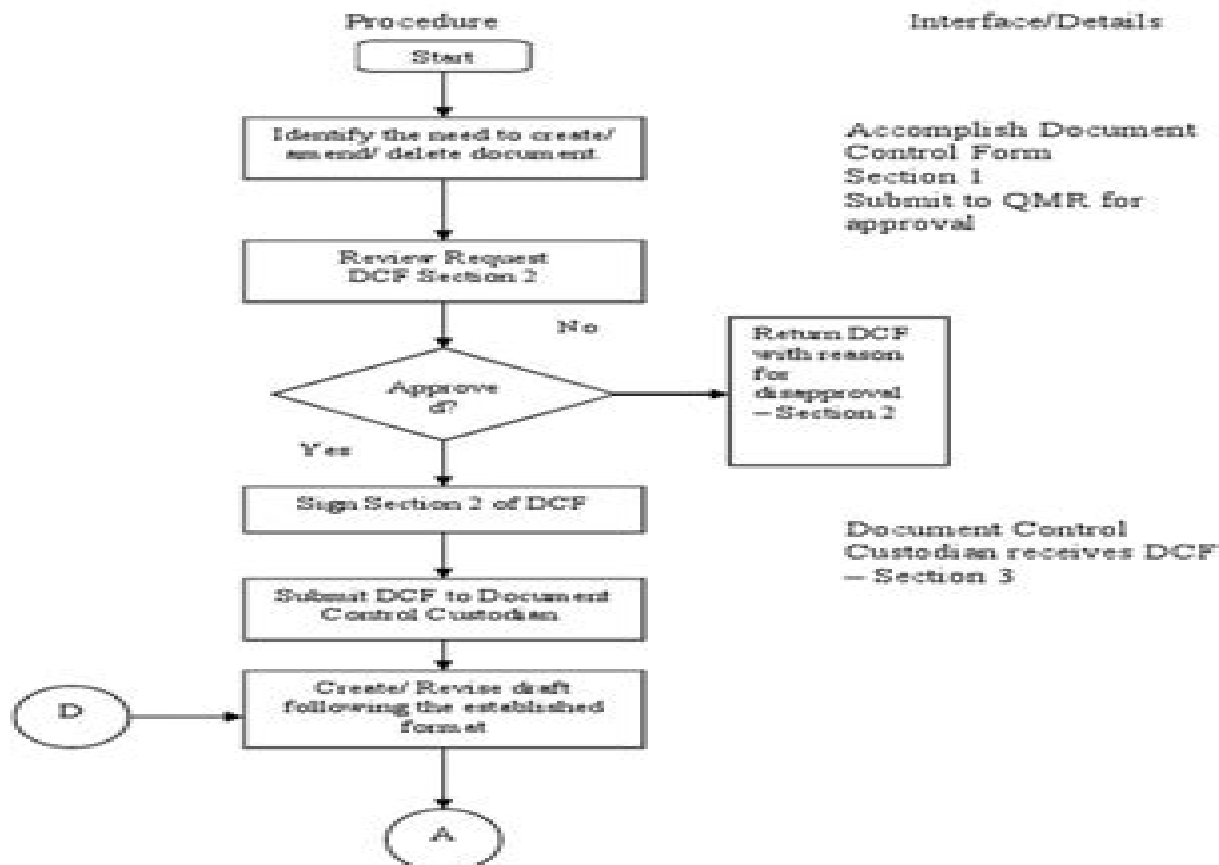
QMR

Document Control  
Custodian

Process Owner

## Procedure

## Interface/Details



Prepared by:

\_\_\_\_\_  
Quality Management Representative

Approved by:

\_\_\_\_\_  
Senior Manager / Top Management Representatives

# Sample Document Control Procedure

**Lingjun Ying**



## **Sample Document Control Procedure:**

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 *Document Control* Denise Robitaille, 2011-09 They re supposed to be useful tools but whether they re printouts computer files flowcharts or forms documents can often give more headaches than help And yet without them most organizations couldn t function ISO 9001 and other quality management systems place great emphasis on documents and for good reason Documents aren t individual stand alone elements of the management process They re interrelated formatted in different media and controlled by various and distinct functions Keeping critical information current and in the right hands requires more than just signing off on procedures Document control is essential but where should you begin Inside you ll find clear explanations about the document control process as well as practical solutions for creating organizing and maintaining documents including A discussion of different kinds of documents including electronic media and QMS requirements Identifying and defining responsibility Understanding the relationship between documents and records Tips for document writers Managing and maintaining documents Issues of accessibility Handling revisions and deviations Writing document control procedures 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 **Guidance Manual for**

**Collection of Samples During RCRA Inspections** Laura L. Gentile,1995      **Class A ERP Implementation** Donald H. Sheldon,2005-05-15 Class A ERP is often misunderstood and confused with software tools and implementations but is actually a management system for continuous improvement This book will resolve these myths by thoroughly describing the definition of Class A ERP and giving specifics for achieving Class A performance in a reasonable timeframe Examples from successes will be referenced to and the author will build a case for breaking the journey to world class performance into bite sized doable focus areas Class A ERP Implementation will help organizations set the stage for maximum effectiveness of both Lean strategies and Six Sigma and establish ERP disciplines as the prerequisite to success      **Guidelines for the establishment and management of seed testing laboratories** Food and Agriculture Organization of the United Nations ,International Seed Testing Association,2023-06-19 This Joint ISTA and FAO Handbook provides comprehensive guidelines for the setting up and managing of seed testing laboratories including those that cater to small and medium scale seed enterprises and farmers cooperatives which operate in low input production systems The adherence to the guidelines by seed testing laboratories results in the use of uniform procedures across the board thereby facilitating inter laboratory transferability of data This harmonization enhances confidence in seed quality assurance mechanisms The publication is an update of a previous one that was also jointly published by both organizations in 1969 and revised in 1979 and 1983 Its utility is enhanced by a set of new up to date information that builds upon existing data The Handbook provides guidance on the range of seed testing equipment procedures and management systems that have become available in the several decades since the previous editions Seed testing is a critical component of the seed value chain and is essential for the production of quality seeds i e seeds that are alive can germinate and produce vigorous seedlings are healthy and come from lots that meet set thresholds for genetic and analytical purity The Handbook covers all aspects of seed testing from laboratory design and equipment selection to sample preparation testing methods and data analysis Importantly the publication also addresses the challenges of testing seeds in low input systems and provides guidance on how to adapt procedures to these settings Therefore it serves as a reference material and training resource for everyone involved in seed quality assurance procedures in particular the personnel of seed testing laboratories and regulatory agencies seed producers and farmers The updated publication represents a significant improvement over previous guidelines as it incorporates advances in technology and provides guidance on a broader range of testing procedures The guidelines are designed to be adaptable to different contexts and seed types and include recommendations for quality management systems proficiency testing and inter laboratory comparisons which are essential for ensuring the accuracy and reliability of seed testing results      The Laboratory Quality Assurance System Thomas A. Ratliff,2005-02-25 Both the 17025 1999 standard and especially ANSI ISO ASQ 9001 2000 standard require that a laboratory document its procedures for obtaining reliable results The Laboratory Quality Assurance Manual details to the user how to a prepare a new laboratory quality assurance manual which will be appropriate to use as a

procedures manual for a particular laboratory a sales tool to attract potential customers a document that can be to answer regulatory questions and ultimately a tool to become a registered ISO 9001 2000 Lab and gain related certifications based on the standard The Laboratory Quality Assurance Manual Incorporates changes to ANSI ISO ASQ 9001 2000 pertaining to laboratories Provides blank forms used in preparing a quality manual Provides information on the interrelationship of ANSI ISO 17025 1999 and ANSI ISO ASQ 9001 2000     Developing a Successful Clinical Research Program Cara East,2018-08-08 This unique book is designed to help a medical team become a clinical research team It includes practical information and tips for the initial stages of clinical research building a team negotiating a contract developing a budget and writing and improving a patient consent Chapters describing the nuts and bolts of how to actually perform the study follow including patient recruiting and retention screening follow ups and handling monitor visits Finally there is discussion of the yearly reviews and disclosures and not just surviving but acing the all important Food and Drug Administration audit Clinical research moves medicine forward and is a necessary part of bringing any new therapy device or procedure into routine medical care However it can be costly and convoluted and the methodologies of clinical research are not widely standardized Decreasing some of the chaos present in American clinical research is the primary goal of this book The second goal is to improve the understanding and education of those who enter clinical research whether in the frontline work of the clinical research site in the middleman companies who have a high turnover rate at a research hospital or institution or at medical corporations that depend on good clinical research to bring their products to market The third reason is to standardize American clinical research and to remove some of the vagaries and inconsistencies in the field Practical and user friendly Developing a Successful Clinical Research Program fills a need for a clear guide to developing and improving a first class research program in any clinical setting     *Code of Federal Regulations* ,1988 Special edition of the Federal Register containing a codification of documents of general applicability and future effect with ancillaries     *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 Labora     **Best Practices for Environmental Project Teams** Stephen Massey,2011-08-16 Best Practices for Environmental Project Teams provides project managers and their teams government managers and regulatory agencies with practical guidelines for continuously improving performance Project managers and team members can pick from a variety of chapter topics stated as Actions to address existing skill gaps with practical tools and guidelines     Statement of Work for Organics Analysis Multi-media Multi-concentration ,1985     *Guidelines for Risk Based Process Safety* CCPS (Center for Chemical Process Safety),2011-11-30 Guidelines for Risk Based Process Safety provides guidelines for industries that manufacture consume or handle chemicals by focusing on new

ways to design correct or improve process safety management practices This new framework for thinking about process safety builds upon the original process safety management ideas published in the early 1990s integrates industry lessons learned over the intervening years utilizes applicable total quality principles i e plan do check act and organizes it in a way that will be useful to all organizations even those with relatively lower hazard activities throughout the life cycle of a company

**ISO 14001 Step by Step** Naeem Sadiq,Asif Hayat Khan,2019-01-22 This book provides practical advice on how to achieve compliance with ISO 14001 2015 the international standard for an EMS environmental management system With an EMS certified to ISO 14001 you can improve the efficiency of your business operations and fulfil compliance obligations while reassuring your employees clients and other stakeholders that you are monitoring your environmental impact This easy to follow guide takes a step by step approach and provides many sample documents to help you understand how to record and monitor your organisation s EMS processes Ideal for compliance managers IT and general managers environmental officers auditors and trainers this book will provide you with The confidence to plan and design an EMS Detailed descriptions of the ISO 14001 2015 requirements will give you a clear understanding of the standard even if you lack specialist knowledge or previous experience Guidance to build stakeholder support for your EMS Information on why it is important for an organisation to have an environmental policy and a sample communications procedure will help you to raise awareness of the benefits of implementing an EMS andAdvice on how to become an ISO 14001 certified organisation The book takes a step by step approach to implementing an ISO 14001 compliant EMS Key features A concise summary of the ISO 14001 2015 requirements and how you can meet them An overview of the documentation needed to achieve ISO 14001 2015 accreditation Sample documents to help you understand how to record and monitor your organisation s environmental management processes New for the second edition Updated for ISO 14001 2015 including terms definitions and references Revised approach to take into account requirements to address risks and opportunities Your practical guide to implementing an EMS that complies with ISO 14001 2015 buy this book today to get the help and guidance you need *Wiley*

*Practitioner's Guide to GAAS 2008* Michael J. Ramos,2007-12-04 The clearest easiest to use guide to understanding GAAS 2008 on themarket fully updated The 2008 edition includes Risk Assessment Standards effective for December 31 2007 Financial Statement Audits The only reference that offers the most comprehensive coverage of generally accepted auditing standards practices and procedures *Wiley Practitioner 2s Guide to GAAS 2008* explains and interprets the standards in clear easy to understand language Offering the accounting professional a clear accessible distillation of the official language of Statements on Standards for Attestation Engagements SSAEs and Statements on Standards for Accounting and Review Services SSARs this invaluable resource provides advice on exactly when and how to remain fully compliant with each Michael J Ramos Denver CO was an auditor with KPMG and now works as an author and consultant He is the author of *How to Comply with Sarbanes Oxley Section 404 Assessing the Effectiveness of Internal Control Second Edition* 0 471 74066 7

and The Sarbanes Oxley Section 404 Implementation Toolkit Practice Aids for Managers and Auditors 0 471 71225 6

**Wiley CPA Exam Review 2008** O. Ray Whittington, Patrick R. Delaney, 2007-12-04 Completely revised for the new computerized CPA Exam Published annually this comprehensive four volume study guide for the Certified Public Accountants CPA Exam arms readers with detailed outlines and study guidelines plus skill building problems and solutions that help them to identify focus and master the specific topics that need the most work Many of the practice questions are taken from previous exams and care is taken to ensure that they cover all the information candidates need to pass the CPA Exam Broken down into four volumes Regulation Auditing and Attestation Financial Accounting and Reporting and Business Environment and Concepts these top CPA Exam review study guides worldwide provide More than 2 700 practice questions Complete information on the new simulation questions A unique modular structure that divides content into self contained study modules AICPA content requirements and three times as many examples as other study guides "Code of Massachusetts regulations, 2015" ,2015 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 *The Massachusetts register* ,1991-09-13 "Code of Massachusetts regulations, 2007" ,2007 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020 "Code of Massachusetts regulations, 2014" ,2014 Archival snapshot of entire looseleaf Code of Massachusetts Regulations held by the Social Law Library of Massachusetts as of January 2020

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