



Standard Operating Procedure Document Control

Page 1 of 18
ECN #:
Effective:

SOP 4-002

Revision: 1

1.0 Purpose

- 1.1 The purpose of this procedure is to provide a system for editing, issuing, and controlling documents deemed as necessary by GMP requirements and company management.

2.0 Scope

- 2.1 Company documents are maintained under document control as described by this procedure.
- 2.2 This procedure will also apply to business procedures and other documents not required by GMP's but deemed necessary by the company management. All documents that are required by GMP and management are to be maintained under formal document control.

3.0 Applicable Documents

- 3.1 SOP 4-001 Engineering Change Notice
- 3.2 SOP 4-003 Records Retention Procedure
- 3.3 SOP 4-006 Specification Format Procedure
- 3.4 QMSM Quality Management System Manual
- 3.5 Attachment A: Engineering Change Notice Checklist
- 3.6 Attachment B: Notification and Receipt Sheet
- 3.7 Attachment C: Document Distribution Sheet

4.0 Definitions

- 4.1 Approval Cycle: That period in the life of an ECN from the time that it is placed into the review process to the time that the last required approval signature has been obtained.
- 4.2 Device Master Record (DMR): A compilation of records containing, but not limited to, the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, packaging requirements and labeling of a finished device.
- 4.3 Document Control System: The Document Control System deployed at the company is a paper-based system, which utilizes some on-line tools found on the company's intranet. Examples of these tools are email and shared folders with varied security features.
- 4.4 Document: Any manual or electronic record of a text or graphics image that represents a drawing, parts list, Bill of Material, purchasing specification, process specification, assembly procedure, test or inspection procedure, business procedure, etc., relating to products processed or administrated under the control of the company's Document Control Department.

Examples Of Document Control Procedure

Donald H. Sheldon



Examples Of Document Control Procedure:

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

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 going to be implemented together. Implementing ISO/IEC 17025:2017 Bhavan (Bob)

Mehta,2019-02-21 The focus of this book is to demystify the requirements delineated within ISO IEC 17025 2017 while providing a road map for organizations wishing to receive accreditation for their laboratories AS9100 ISO 9001 2015 and ISO 13485 2016 are standards that have been created to support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system QMS for many diverse industries Similar to these recognized QMS standards ISO IEC 17025 2017 for laboratory accreditation serves a unique purpose It is not unusual for laboratories to retain dual certification in ISO 9001 2015 and ISO IEC 17025 2017 However ISO IEC 17025 2017 contains requirements specific to the laboratory environment that are not addressed by ISO 9001 2015 This book highlights those differences between ISO 9001 2015 and ISO IEC 17025 2017 while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO IEC 17025 2017 For those currently or formerly accredited to the 2005 version of ISO IEC 17025 an appendix outlines the changes between the 2005 and 2017 versions of the standard Implementing ISO/IEC 17025:2017, Second Edition Bob Mehta,2019-02-21 The focus of this book is to demystify the requirements delineated within ISO IEC 17025 2017 while providing a road map for organizations wishing to receive accreditation for their laboratories AS9100 ISO 9001 2015 and ISO 13485 2016 are standards that have been created to support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system QMS for many diverse industries Similar to these recognized QMS standards ISO IEC 17025 2017 for laboratory accreditation serves a unique purpose It is not unusual for laboratories to retain dual certification in ISO 9001 2015 and ISO IEC 17025 2017 However ISO IEC 17025 2017 contains requirements specific to the laboratory environment that are not addressed by ISO 9001 2015 This book highlights those differences between ISO 9001 2015 and ISO IEC 17025 2017 while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO IEC 17025 2017 For those currently or formerly accredited to the 2005 version of ISO IEC 17025 an appendix outlines the changes between the 2005 and 2017 versions of the standard **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 and Advice 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

Achieving Inventory Accuracy Donald H. Sheldon, 2004-07-15 This book is a step by step guide to achieving inventory record accuracy in a manufacturing retail or distribution facility Starting at day one the author outlines the necessary elements of procedure and discipline necessary for good sustainable process The result is 95 % perfect inventory balances with minimal cycle counting required for on going maintenance The book includes special aids such as Gantt charts cycle count process parameters and process celebration points Donald H Sheldon is certified at the Fellow level by APICS as CFPIM and as CIRM

Developing and Managing Engineering Procedures Phillip A. Cloud, 2001-01-16 This book provides hands on techniques for writing engineering procedures to achieve ISO 9000 compliance It is designed for individuals responsible for writing these procedures in any industry Readers will find actual examples of clearly written compliant engineering procedures ready to adapt to your own industry and your own particular needs and use immediately It answers virtually all your procedure writing questions Procedure writers will gain a general understanding of engineering documentation principles and how to apply them to their own situations Simple diagrams and other graphics illustrate key ideas giving a bird s eye view of what is coming next The intent of the book is to familiarize the reader with the essential elements and concepts of engineering procedure development and management and show how to apply these concepts to their own specific applications The author emphasizes engineering principles and tools that are common to all engineering disciplines with examples for their use Step by step procedures shown for each document format enable readers to apply each format to their own engineering documentation programs quickly and easily The book provides a fingertip reference that covers the entire engineering procedure process using the latest technology for engineering documentation systems

Accounting Policies and Procedures Manual Steven M. Bragg, 2012-06-19 Now in a fifth edition Accounting Policies and Procedures Manual A Blueprint for Running an Effective and Efficient Department is a how to guide on creating an effective and efficient accounting department policies and procedures manual Written by Steven Bragg the foremost authority in accounting and controllership issues the new edition includes A new complimentary Web site providing readers with the foundation for creating or enhancing their accounting department policies and procedures manual More coverage of

accounting procedures including inventory billing cash receipts pricing order entry credit collections sales returns capital budgeting cash forecasting payroll and closing the books Accounting Policies and Procedures Manual is the tool every accounting department needs to regularize and systematize its procedures to match the best in the industry *Guidance Manual for Collection of Samples During RCRA Inspections* Laura L. Gentile,1995 **Mastering and Managing the FDA Maze** Gordon Harnack,2014-07-18 The number of FDA regulations and the agency s increased expectations is staggering and their content tedious creating a regulated industry need for compliance insight and appropriate detail This book is the reference needed to successfully navigate through the FDA maze The target audiences for this desk reference include Regulatory professionals who know their responsibility to keep their firm s employees trained and competent on FDA device regulations and who need a preliminary desk reference that can be used throughout their enterprise to help train and ensure compliance Neophytes who know nothing about FDA but need a resource that provides both broad and specific information in sufficient detail to be useful Beginners who know a little about FDA need to know more and need a reference tool to help them be more effective and productive on the job Intermediates who knows enough about FDA to know they need to know more and who need a reference tool that provides them with both more basics and executable detail Busy managers who need to know regulatory requirements and FDA expectations in order to manage compliance in their specific activity Busy executives CEOs COOs and operations managers whom FDA holds responsible for all regulatory compliance who also need a desk reference with specific information to quickly assess regulatory compliance identify potential noncompliance and review corrective preventive and compliance actions Wiley Practitioner's Guide to GAAS 2019 Joanne M. Flood,2019-07-30 The definitive reference for clarified standards application and compliance fully updated for 2019 The Wiley Practitioner s Guide to GAAS 2019 is the comprehensive and user friendly guide to Generally Accepted Auditing Standards Fully updated to reflect all new standards practices and statements including Statements on Standards for Accounting and Review Services SSARS and Statements on Standards for Attestation Engagements SSAE this essential resource offers practitioners a clear and complete reference in a single volume This book provides complete coverage of relevant areas including audit planning and documentation audit evaluation and evidence examination and review engagements and more to help auditors interpret and apply current auditing standards while maintaining full compliance with GAAS General auditing standards are subject to frequent updates and divergent interpretations yet practitioners need to keep pace with the latest changes if compliance is to be maintained Employing a logical organizational structure this guide defines and interprets each clarified standard and explains its relation to the engagement process Practice notes checklists questionnaires and relevant real world examples demonstrate how each section is applied This indispensable resource provides in depth guidance on GAAS interpretation application and compliance to help you Identify and apply each auditing SSAE and SSARS section Understand new requirements in clarified attestation standards Access technical alerts interpretation summaries and individual section

descriptions and definitions Employ techniques to maintain compliance with each standard The Wiley Practitioner's Guide to GAAS 2019 provides auditing professionals with the expert guidance and up to date information necessary to save you time streamline your workload and maximize your job performance *Wiley Practitioner's Guide to GAAS 2017* Joanne M. Flood, 2017-02-15 The clearest easiest to use guide to understanding all the clarified standards including the new attestation standards fully updated This comprehensive guide to understanding Generally Accepted Auditing Standards GAAS is not just about auditing It addresses the toughest part of an accountant's job identifying interpreting and applying the many audit attest review compilation and preparation standards relevant to a particular engagement Wiley Practitioner's Guide to GAAS 2017 offers a clear and accessible distillation of the official language of GAAS Statements on Standards for Attestation Engagements SSAEs and Statements on Standards for Accounting and Review Services SSARs as well as advice on exactly how to remain fully compliant with each Wiley Practitioner's Guide to GAAS 2017 is organized according to the logical arrangement of the clarified standards presenting each section individually and explaining how it is related to the engagement process Guidance is offered on the entire process in the form of practice notes checklists questionnaires and real world examples illustrating how the fundamental requirements of each section are applied Other key features include A brief identification of each auditing SSAE and SSARS section with effective dates and tips on how to apply it Highlights of new requirements in the clarified attestation standards Concise listing and descriptions of each section's specific mandates including definitions Easy to read capsule summary of interpretations plus selected technical alerts Helpful techniques for remaining compliant with each standard New in GAAS 2017 In 2016 the AICPA's Auditing Standards Board completed a major stage of its clarity project and issued SSAE No 18 The new guidance is effective for reports dated May 1 2017 SSAE No 18 replaces the attestation standards introducing major new requirements that will change practice In this transition year guidance on the extant attestation standards is also included Wiley Practitioner's Guide to GAAS 2017 is completely updated to reflect all the clarified standards and provide valuable implementation information **Wiley Practitioner's Guide to GAAS 2010** Steven M. Bragg, 2009-10-22 Your clearest easiest to use guide to understanding GAAS 2010 on the market fully updated This latest resource to understanding GAAS addresses the toughest part of your job identifying interpreting and applying the many audit attest review and compilation standards relevant to a particular engagement Wiley Practitioner's Guide to GAAS 2010 offers you A brief identification of each SAS SSAE and SSARS with its effective date and tips on when to apply it A convenient and comprehensive glossary of official definitions which are usually scattered throughout a standard Behind the scenes explanations of the reasons for each pronouncement and brief explanations of the basic ideas of the section Concise listing and descriptions of each standard's specific mandates Easy to read capsule summary of interpretations plus selected AICPA practice alerts and advisories Helpful techniques for remaining compliant with each standard Examples and illustrations for testing internal controls The only GAAS reference organized according to your actual

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Implementing ISO/IEC 17025:2005 Bhavan "Bob" Mehta,2013-04-16 The purpose of this book is to demystify the requirements delineated within ISO IEC 17025 2005 while providing a road map for organizations that wish to receive maintain accreditation for their laboratories AS9100 ISO 9001 and ISO 13485 are standards that support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system QMS for diverse industries Although similar to these recognized QMS standards ISO IEC 17025 serves a unique purpose laboratory accreditation It is not unusual for laboratories to retain dual certification to ISO 9001 and ISO IEC 17025

Wiley Practitioner's Guide to GAAS 2015 Joanne M. Flood,2015-02-26 The all in one guide to the latest auditing standards with clear explanations and more Wiley Practitioner s Guide to GAAS 2015 offers the most comprehensive coverage of auditing standards practices and procedures clarifying complex guidelines in clear easy to understand language Each statement is presented individually with explanations and practice notes that highlight main ideas and mandates giving practitioners a clearer understanding of SAS standards and how they re used Practical illustrations checklists and questionnaires guide readers through the auditing process and updates are highlighted to call attention to recent changes This useful guide includes background information that sheds light on the reasoning behind each pronouncement as well as a comprehensive glossary that clarifies unfamiliar or nuanced terms Coverage also includes interpretations of all new Statements on Standards for Accounting and Review Services Compilation and Review statements with expert advice on remaining compliant as guidelines change Auditing standards guide the work of an entire industry but these standards are frequently revised and compliance is critical Wiley Practitioner s Guide to GAAS 2015 is a complete reference for the auditing professional logically organized to allow for quick navigation Understand the real world application of each standard Learn each standard s effective date and specific mandates Examine technical alerts definitions and interpretations Develop techniques for maintaining compliance Identifying interpreting and applying the many standards relevant to a particular engagement can be the most difficult part of the auditor s job This guide simplifies the process by combining the standards explanations tools and expert advice into a single easily navigated volume For the auditor who needs to be up to date Wiley Practitioner s Guide to GAAS 2015 provides the latest on GAAS compliance

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

The ISO 14000 EMS Audit Handbook Greg Johnson,2020-04-28 The ISO 14000 EMS Audit Handbook is an innovative and cost effective approach for the Environmental Management System EMS audit to ISO 14001 The Handbook presents comprehensive strategies for conducting all phases of the EMS audit including effective assessment processes for determining improved environmental performance *Wiley Practitioner's Guide to GAAS 2023* Joanne M. Flood,2023-03-28 The most comprehensive and up to date guide to critical auditing standards practices and procedures for 2023 The American Institute of Certified Public Accountants AICPA sets the Generally Accepted Auditing Standards or GAAS under which U S audits are conducted Auditors must comply with and understand every aspect of GAAS to comply with AICPA standards As a result it is crucial for CPAs to be up to date on all applicable guidelines rules and regulations Wiley Practitioner s Guide to GAAS 2023 delivers a thorough description and analysis of not only auditing standards SASs but also SSAEs SSARs and the Interpretations necessary to fully understand all the latest professional standards The 2023 Guide offers the most recent revisions to the standards including those on Audit evidence Auditing accounting estimates Use of pricing evidence Inquiries of predecessor auditors Quality management Materiality SSAE direct examination engagements and Practitioner s review reports Practical direction on the steps necessary to help you comply with GAAS Comprehensive guidance on the entire auditing process from start to finish Explanations of all attestation and review compilation and preparation standards A glossary of relevant terminology for each subject It explains the standards clearly and accurately providing explicit information on how to conduct your engagements efficiently effectively and properly all in one resource In addition Wiley Practitioner s Guide to GAAS 2023 provides readers with A crucial resource for accountants and auditors who are looking for a comprehensive explanation of the information used daily Wiley Practitioner s Guide to GAAS 2023 is an invaluable resource written to save you time and simplify your compliance with professional standards **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

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