



## Document Control Procedure Template

### 1. Purpose:

The purpose of this document control procedure is to ensure the effective management of documented information within [Organization Name], in accordance with ISO 9001:2015 requirements. This procedure establishes the processes for creating, reviewing, approving, distributing, and revising documents to maintain accuracy, consistency, and compliance with quality management standards.

### 2. Scope:

This procedure applies to all documented information generated, utilized, or maintained by [Organization Name] as part of its Quality Management System (QMS).

### 3. Responsibilities:

- **Quality Manager:** The Quality Manager is responsible for overseeing the implementation of this document control procedure and ensuring compliance with ISO 9001 requirements. Responsibilities include:
  - Establishing document control processes and procedures.
  - Providing training and guidance on document control requirements.
  - Monitoring the effectiveness of document control activities and initiating improvements as necessary.
- **Document Owners:** Document Owners are responsible for creating, updating, and maintaining documents within their area of expertise. Responsibilities include:
  - Ensuring that documents are accurate, up-to-date, and aligned with relevant standards and procedures.
  - Reviewing and approving documents before distribution.
  - Notifying the Quality Manager of any changes or updates to documents.
- **Document Controllers:** Document Controllers are responsible for managing the day-to-day activities related to document control. Responsibilities include:
  - Maintaining a central repository of all documents and records.
  - Ensuring that document numbering, naming, and version control are maintained consistently.

# Sample Document Control Procedures

**Camilla Rothe**



## **Sample 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 *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 **EPA-600/4**, 1983 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

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**Security Controls Evaluation, Testing, and Assessment Handbook** Leighton Johnson,2019-11-21 Security Controls Evaluation Testing and Assessment Handbook Second Edition provides a current and well developed approach to evaluate and test IT security controls to prove they are functioning correctly This handbook discusses the world of threats and potential breach actions surrounding all industries and systems Sections cover how to take FISMA NIST Guidance and DOD actions while also providing a detailed hands on guide to performing assessment events for information security professionals in US federal agencies This handbook uses the DOD Knowledge Service and the NIST Families assessment guides as the basis for needs assessment requirements and evaluation efforts Provides direction on how to use SP800 53A SP800 115 DOD Knowledge Service and the NIST Families assessment guides to implement thorough evaluation efforts Shows readers how to implement proper evaluation testing assessment procedures and methodologies with step by step walkthroughs of all key concepts Presents assessment techniques for each type of control provides evidence of assessment and includes proper reporting techniques [The Process Approach Audit Checklist for Manufacturing](#) Karen Welch,2004-12-31 Finally a comprehensive process audit checklist has been developed to be used with ISO 9001 2000 This manual was developed to assist anyone involved with conducting or planning quality system audits including quality auditors quality managers quality system coordinators management representatives and quality engineers In addition potential auditees in any function or position should find the questions useful in preparing for an audit Although the checklist could be amended to work for a service company the manual was created with a focus on the manufacturing sector to cover common processes such as production management customer related design and development training purchasing etc The manual includes a brief overview of the process approach discussion of problem areas often found by third party auditors the process audit checklist and forms to be used in conjunction with the process audit checklist to increase audit effectiveness

**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 [Essentials of Blood Transfusion Science](#) Dr. Erhabor,Dr. Adias,2013-03-19 Blood transfusion is a field where there have been and continues to be significant advances in science technology and most particularly governance This book aims to provide you

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