

## **4.5 Document control**

### **4.5.1 Document approval and issue**

The supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of this International Standard. These documents shall be reviewed and approved for adequacy by authorized personnel prior to issue. The control shall ensure that

- a. the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
- b. obsolete documents are promptly removed from all points of issue or use.

### **4.5.2 Document changes/modifications**

Changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. The designated organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

A master list or equivalent document control procedure shall be established to identify the current revision of documents in order to preclude the use of non-applicable documents.

Documents shall be re-issued after a practical number of changes have been made.

# Iso Control Of Documents Procedure

**PT Brinkman**



## **Iso Control Of Documents 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 Statistical Process Control

Leonard A. Doty, 1996 This in depth introduction to SPC examines the technical aspects of the practices and procedures that are used to apply the quality management system in manufacturing As in the successful first edition the author provides a description and history of SPC along with an analysis of how it is applied to control quality costs productivity product improvement and work efficiency New to this edition are an explanation of seven basic tools new charts and an exploration of current trends

*Integrating Business Management Processes* Titus De Silva, 2020-08-18 Integrating Business Management Processes Volume 3 Harmonising Quality Food Safety and Environmental Processes 978 0 367 48547 4 Shelving Guide

Business Management The backbone of any organisation is its management system It must reflect the needs of the organisation and the requirements of its customers Compliance with legal requirements and ethical environmental practices contributes towards the sustainability of the management system Whatever the state of maturity of the management this book one of three provides useful guidance to design implement maintain and improve its effectiveness and is intended to provide readers with practical how to methods for integrating quality safety and environmental management processes This volume sets out procedures and flowcharts to show how the integration of these processes can be achieved Separated into management procedures core procedures support procedures and assurance procedures and complemented by practical examples this book is an invaluable resource for complete systems development and integration This book along with its two companion volumes is a practical guide for real managers designed to help them manage their business more effectively and gain competitive advantage Titus De Silva is a consultant in management skills development pharmacy practice quality management and food safety and an advisor to the newly established National Medicines Regulatory Authority NMRA in Sri Lanka

**Managing Web Projects** Edward B. Farkas, 2009-10-27 Getting Web projects done right and delivered on time is all about efficiency Putting the information you need and tools you can rely on at your ready disposal Managing Web Projects is a complete guide for project managers in the Internetworking industry Whether you are a Web developer or an Internet Service Provider whether your project is a qu

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specifically addresses how to prepare for an automotive process audit for readers who are involved in quality manufacturing and operations management and those who work with suppliers      *Guidelines for Writing Effective Operating and Maintenance Procedures* American Institute of Chemical Engineers. Center for Chemical Process Safety,1996-05-15 The EPA investigation of a 1994 chemical plant tragedy concluded that the explosion resulted from a lack of written safe operating procedures While good written procedures can t guarantee zero accidents they can reduce the number of accidents caused by human error This new book shows how to remedy this problem through selecting and implementing actions that promote safe efficient operations and maintenance improve quality continuity profitability and cost control build upon and record process experience and promote the concept that operating and maintenance procedures are vital plant components It includes practical samples of procedure formats checklists and many references      **Tool and Manufacturing Engineers Handbook: Plastic Part Manufacturing** Philip Mitchell,1996-12-09 This volume focuses on the practical application of processes for manufacturing plastic products It includes information on design for manufacturability DFM material selection process selection dies molds and tooling extrusion injection molding blow molding thermoforming lamination rotational molding casting foam processing compression and transfer molding fiber reinforced processing assembly and fabrication quality plant engineering and maintenance management      *Export Quality Management* International Trade Centre UNCTAD/WTO.,2001 The Uruguay Round of multilateral trade negotiations significantly reduced tariff barriers to trade However exporters continue to face non tariff barriers in the form of standards technical regulations sanitary and phytosanitary measures and conformity assessment procedures To meet the requirements these impose and demonstrate compliance with them is a difficult and costly process for exporters in developing countries and transition economies Many of these countries have not yet been able to take full advantage of the WTO Agreements largely because of a lack of resources Given this the International Trade Center has produced this guide providing SME managers in developing countries and transition economies with answers in simple language to their most frequently asked questions on standards and conformity assessment The questions address issues such as technical regulations and standards product certification testing metrology quality management ISO 9000 other management systems accreditation and the Agreements on TBT and SPS      Total Quality Safety Management and Auditing Michael B. Weinstein,1997-08-11 Total Quality Management TQM is a business philosophy that yields customer satisfaction and continuous process improvement This new reference and workbook embraces the TQM revolution and explains to readers how TQM principles are applied to safety and health programs The text also focuses on the ISO 9000 Quality Program Voluntary Protection Program and Process Safety Management For each of these topics the key principles are identified and described and the quality principles are adapted to safety      **ISO 9000 Implementation and Assessment: A Guide to Developing and Evaluating Quality Management Systems** ,1996

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