

Internal Quality Management System Audit Checklist (ISO 13485:2003/ISO 9001:2000)

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	<b>4 Quality management system</b>		
	<b>4.1 General requirements</b>		
4.1a	The organization shall establish, document, implement and maintain a quality management system and <b>maintain (continually improve)</b> its effectiveness in accordance with the requirements of this International Standard.	Has Organization established, documented, implemented and maintained a QMS and <b>maintained (continually improved)</b> its effectiveness in accordance with ISO 9001/13485? (Questions in section 4.1 are verified throughout the audit)	
4.1a	The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2).	Where has Organization identified the processes needed for the QMS and their application throughout the organization? (See 4.2.2)	
4.1a	The organization shall b) determine the sequence and interaction of these processes.	Where has Organization determined the sequence and interaction of QMS processes? (See 4.2.2)	
4.1a	The organization shall c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective.	What are the criteria and methods Organization uses to ensure that the operation and control of QMS processes are effective?	
4.1a	The organization shall d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes.	Has Organization provided resources and information needed to support the operation and monitoring of QMS processes? (See section 6)	
4.1a	The organization shall e) monitor, measure and analyse these processes, and	How does Organization monitor, measure and analyze QMS processes? (See section 8)	
4.1a	The organization shall f) implement actions necessary to achieve planned results and <b>maintain the effectiveness (continual improvement)</b> of these processes.	How has Organization implemented actions necessary to achieve planned results and <b>maintain the effectiveness (continual improvement)</b> of processes needed for the QMS?	
4.1a	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	Are processes needed for the QMS managed by the organization in accordance with the requirements of ISO 9001:2000?	
4.1a	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	When Organization outsources any process that affects product conformity with requirements, how is control ensured over such processes? (See 7.4)	
4.1a	Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).	Where is the control of outsourced processes that affect product conformity with requirements identified within the QMS? (See 7.4)	
	NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.		

# Internal Quality Management System Audit Checklist

**Tom Taormina**



## **Internal Quality Management System Audit Checklist:**

**ISO 9001:2015 Internal Audits Made Easy, Fourth Edition** Ann W. Phillips, 2015-11-10 Implementing the requirements of ISO 9001 can be a daunting task for many organizations. In an attempt to develop a system that will pass the registration audit, we are tempted to establish processes with the primary purpose of conforming to the requirements of ISO 9001. In doing so, however, it is easy to lose sight of the primary intent of the standard to continually improve the effectiveness of the quality management system (QMS) implemented at our organization. This book is intended to help managers, quality professionals, internal audit coordinators, and internal auditors implement a practical internal audit process that meets the requirements of ISO 9001:2015 while adding significant measurable value to the organization. The tools, techniques, and step-by-step guidelines provided in this book can also be used by those organizations that have a well-established internal audit process but are looking for easy ways to make that process more effective. The tools in the appendices of this book have also been provided on the enclosed CD to facilitate your customizing them to fit the specific needs of your organization.

Implement ISO 9001:2008 Quality Management System DIVYA SINGHAL, K. R. SINGHAL, 2012-04-02 ISO 9000 series standards have changed the whole concept of quality management methods. ISO 9001:2008 QMS standard has been implemented, and ISO 9000 series standards have been adopted as national standards or endorsed for use in 178 countries and economies. ISO 9001:2008 Quality Management System (QMS) is based on eight quality management principles, and there are various internal and external benefits of implementing this standard, whether or not an organization goes for certification. This book provides the readers with an accessible and up-to-date introduction to the essentials of a quality management system, discusses what is in the ISO 9001:2008 QMS, and shows how organizations can implement this system. With the authors' extensive experience in QMS audit training and advisory services, the book incorporates basic information on understanding and implementing ISO 9001:2008 QMS and highlights its importance towards making quality the fundamental business principle. The text contains plenty of practical tips and guidance on how to implement ISO 9001:2008 QMS in the real world. It discusses sample QMS procedures, emphasizes the importance of maintaining a value-added internal audit system, and highlights the necessity of developing the QMS documentation procedures. Apart from the regular BBA, MBA, and diploma courses in Total Quality Management, this book is also suitable for Management Development Programmes in Quality Management and ISO 9001 offered to professionals by many of the B schools.

**Quality Management System Handbook for Product Development Companies** Vivek Nanda, 2005-01-27 Quality Management System Handbook for Product Development Companies describes a systematic approach for quality management and continuous improvement via a formal management system. The approach centers on a high-level process for defining a QMS from essential prerequisites to improvement mechanisms. The book outlines the five major QMS.

**Six Sigma and Quality Management** Paulo Pereira, 2024-03-20 Six Sigma and Quality Management serves as an indispensable resource for professionals/practitioners.

and enthusiasts seeking a clear roadmap for implementing and optimizing Six Sigma and quality management system methodologies. From the fundamental principles of Six Sigma including the DMAIC approach to the broader spectrum of quality management, readers will gain practical insights into enhancing processes, reducing variation, and fostering a culture of continuous improvement. The text covers essential topics such as Total Quality Management (TQM), Lean principles, and improvement methodologies, offering actionable tools and techniques to streamline operations and enhance overall efficiency. With a focus on audits, corrective action, preventive action (CAPA) processes, and the intricacies of controlling externally provided processes, products, and services, this book provides a holistic view of quality management practices. In a specialized section, the book explores the unique challenges and stringent requirements for quality and competence in medical laboratories within the healthcare sector. Additionally, it delves into the integration of digital technologies into quality management, known as Quality 4.0, showcasing the transformative potential of data analytics and artificial intelligence. Real-world examples and practical insights throughout the book make it a valuable resource for both those new to these methodologies and seasoned professionals seeking to refine their approach. This book is a practical and insightful companion for organizations navigating the intricacies of Six Sigma and quality management to achieve excellence in their operations and deliver enhanced value to their stakeholders.

*Automotive Process Audits* D. H. Stamatis, 2021-04-29. With a detailed discussion on the preparation and tools needed for an automotive process audit, this book addresses the fundamental issues and concerns by focusing on two objectives: explaining the methods and tools used in the process for the organization and providing a reference or manual for dealing with documenting quality issues. This book addresses the fundamental issues and concerns for a successful automotive process audit and details specifically how to prepare for it. It presents a complete assessment of what an organization must do to earn certification in ISO standards, industry standards, and customer-specific requirements. It also focuses on the efficiency of resources within an organization so that an audit can be successful and describes the methodologies to optimize the process by knowing what to do, what to say, and how to prove it. A road map is offered for the process audit and the layered audit, and defines a clear distinction between the preparation details for each. This book is intended for those that conduct audits, those who are interested in auditing, and those who are being audited. It 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.

*ISO 9000 Quality Management System Design* Jay J. Schlickman, 1998. **How to Audit the Process-Based Qms** Dennis R. Arter, Charles A. Cianfrani, Jack West, 2003-02-01. This book is intended to help individuals involved in managing and conducting audits to ISO 9001:2000. It focuses on auditing as a management process as well as a key driver of continual improvement within an organization. An excellent resource for internal auditors, it is perfect for novice auditors or those who need a refresher on the fundamentals of auditing. This book can be used as a guide to establishing a new audit program or updating one that has been operational for some time. The authors

participated in integrating the process approach into ISO 9001 2000 and thoroughly understand its implications for auditing a QMS The three main areas of focus in this book include the basics of process based auditing the requirements for establishing and managing an internal quality auditing process and conducting audits One of its best features is the section on auditing worksheets forms checklists and questions Included are useful and adaptable examples from every aspect of auditing such as developing an audit schedule planning an audit writing findings documenting positive and best practices writing an audit report and requesting corrective action the book contains a comprehensive list of questions that auditors can use when conducting quality audits and features this information on the accompanying CD ROM **Integrating Business**

**Management Processes** Titus De Silva, 2020-08-18 Integrating Business Management Processes Volume 2 Support and Assurance Processes 978 0 367 48548 1 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 This volume provides a comprehensive coverage of the key support and assurance processes Topics include document control communication marketing information systems and technology human resource management training and development customer relations management financial management and measurement and analysis to name a few This book with its series of examples and procedures shows how organisations can benefit from satisfying customer requirement and the requirements of ISO standards to gain entry into lucrative markets 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 **Third IEEE International Software**

**Engineering Standards Symposium and Forum (ISESS 97)** ,1997 The proceedings from the June 1997 conference focusing on the effectiveness of software engineering standards and their future particularly in respect to critical systems The 35 selected tutorials technical papers panel discussions and workshops deal with aspects of software safety and compliance identifying software users software product measurement software and systems engineering fundamental principles and formal methods The keynote address features cautionary advice to standards writers engaged with the limited claims that can be made for software dependability Lacks an index Annotation copyrighted by Book News Inc Portland OR

**Electronic Systems Quality Management Handbook** Marsha Ludwig-Becker, 1997 Annotation Quality management for electronic systems has grown far beyond the basic inspection techniques of the past New performance based quality management approaches are now used at every electronics company from huge corporations to small start ups This book goes beyond generic quality approaches to present an electronics specific program for quality management **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 Implementing Total Quality Management Lesley Munro-Faure, Malcolm Munro-Faure, 1992 This book aims to provide a clear down to earth approach for implementing TQM and spearheading the drive for continuous quality improvement Illustrated by case histories it provides a methodology for making TQM work **Quality Management Systems for the Food Industry: A Guide to ISO 9001/2 A.** Bolton, 1997-07-31 The ISO 9001 2 series of standards for Quality Management Systems is of increasing importance to the food and drink industry it functions as an outward and visible sign to customers that the industry has a defined quality management system that has been independently appraised and is regularly audited ISO 9001 2 certification can enable a company to reduce the audit burden from a multitude of customers and can also help the manufacturer or distributor involved in auditing its own suppliers Above all it may improve the effectiveness of its own operation and profits Quality Management Systems for the Food Industry describes what the standards are what they mean and how to achieve them and identifies both the potential benefits and limitations It discusses choice of assessment house whether to use consultants or not and particularly points out the detail that assessors will be looking for Guidance is given on the basic format for a suitable quality management system **Proceedings**, 1997 **Quality Management for Software** Kevin Daily, 1992 This book explains how quality management practices can be applied to software development and related work and indicates what it means for software developers and their customers **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 Quality Management Benchmark Assessment James P. Russell, 1991 Virtual Leadership and the ISO9000 Imperative Tom Taormina, 1996 Expert Tom Taormina helps you slice through the wording of the ISO9000 standard to the key requirements

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