

1. Scope

XXXX establish, implement and maintain this ISO9001:2015 QMS to consistently provide products that meet customer and applicable legal requirements, and to continuously improve customer's satisfaction and the performance of QMS. We strive to understand the dynamic external and internal context, and the changing need & expectation of relevant interesting parties, to identify and address the risks & opportunities, by utilizing process approach, PDCA and risk-based thinking, data analysis and quality management principles.

2. Normative reference

ISO 9000:2015, Quality management systems – Fundamentals and vocabulary

- **Characteristic** - A characteristic is a distinctive feature or property of something.
- **Context of the organization** – all of the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.
- **Correction** – any action that is taken to eliminate a nonconformity, but to address root causes.
- **Corrective action** – steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence of the existing nonconformities and potentially undesirable situations.
- **Interested party** – anyone who can affect, be affected by, or believe that they are affected by a decision or activity. It is a person, group, or organization that has an interest or a stake in a decision or activity.
- **Outsource** – when an outside organization to perform part of a function or process of organization.
- **Process approach** – manage and control the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.
- **Process-based quality management system** – using process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.
- **Quality** - the degree to which a set of inherent characteristics fulfills a set of requirements of an objective.
- **Risk** – the “effect of uncertainty on an expected result” and an effect is a positive or negative deviation from what is expected.
- **Risk-based thinking** refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives.

3. Terms and definitions

‘Purchased Product’ is replaced by ‘Externally Provided Processes, Products and Services’

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Michael Seilmaier



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Handbook of Research on Emerging Advancements and Technologies in Software Engineering Ghani, Imran,Kadir, Wan Mohd Nasir Wan,Ahmad, Mohammad Nazir,2014-04-30 Advanced approaches to software engineering and design are capable of solving complex computational problems and achieving standards of performance that were unheard of only decades ago Handbook of Research on Emerging Advancements and Technologies in Software Engineering presents a comprehensive investigation of the most recent discoveries in software engineering research and practice with studies in software design development implementation testing analysis and evolution Software designers architects and technologists as well as students and educators will find this book to be a vital and in depth examination of the latest notable developments within the software engineering community

Implementing ISO 9001:2000 Tom Taormina,Keith Brewer,2002 ISO 9001 2000 A start to finish implementation guide to the newly updated ISO standard from two of the world s leading quality practitioners The realist s guide to ISO 9001 2000 internal audits choosing registrars ensuring customer focus measuring results and much more Dell s Asset Recovery Business ARB A start to finish ISO 9001 case study from the insiders who made it happen Moving ISO 9001 from cost center to profit center To maintain their ISO 9001 certifications organizations worldwide must upgrade to the brand new ISO 9001 2000 standard In this book two of the world s leading quality practitioners present the most realistic business focused guide to ISO 9001 2000 implementation The book s focus isn t on mere conformance it shows companies how ISO 9001 2000 can support their key strategic initiatives and how to move ISO 9001 2000 from cost center to profit center Tom Taormina and Keith Brewer cover every aspect of ISO 9001 2000 including

the new process model the latest and most effective internal auditing techniques how to select a registrar how to reflect the new standards requirements for customer focus and management involvement and much more In a start to finish ISO 9001 case study the authors show how Dell's Asset Recovery Business ARB has gone beyond mere compliance leveraging ISO 9001 2000 standards to build a fully integrated business management system that uses continuous improvement models to drive operational excellence and profitability *QS-9000 Handbook* Jayanta Bandyopadhyay, 1996-04-01 Here is a survival strategy for suppliers to the automotive industry With QS 9000 serving as the new harmonized quality systems requirement of internal and external suppliers for Chrysler Ford General Motors as well as other automobile and truck manufacturers and assemblers the QS 9000 Handbook is your practical guide for achieving registration Any company that wishes to achieve registration must provide evidence of quality production to third party audits of the registrar The QS 9000 Handbook will do just that as well as show you how to document your quality systems train personnel in quality and improve the effectiveness of any independent quality assurance functions inside your operation Process Based Unification for Multi-model Software Process Improvement Z.D. Kelemen, 2013-01-30 Many different quality approaches are available in the software industry Some of the approaches such as ISO 9001 are not software specific i.e. they define general requirements for an organization and they can be used at any company Others such as Automotive SPICE have been derived from a software specific approach and can be used for improving specific in this case automotive processes Some are created to improve development processes e.g. CMMI for Development others focus on services e.g. CMMI for Services and again others are related to particular processes such as software testing e.g. TMMi or resource management e.g. People CMM A number of differences among quality approaches exist and there can be various situations in which the usage of multiple approaches is required e.g. to strengthen a particular process with multiple quality approaches or to reach certification of the compliance to a number of standards First of all it has to be decided which approaches have potential for the organization In many cases one approach does not contain enough information for process implementation Consequently the organization may need to use several approaches and the decision has to be made how the chosen approaches can be used simultaneously This area is called Multi model Software Process Improvement MSPI The simultaneous usage of multiple quality approaches is called the multi model problem In this dissertation we propose a solution for the multi model problem which we call the Process Based Unification PBU framework The PBU framework consists of the PBU concept a PBU process and the PBU result We call PBU concept the mapping of quality approaches to a unified process The PBU concept is operationalized by a PBU process The PBU result includes the resulting unified process and the mapping of quality approaches to the unified process Accordingly we addressed the following research question Does the PBU framework provide a solution **Australian Master Environment Guide** Carolyn Uyeda, 2010 Australian Master Environment Guide was previously published by CCH Australia The Australian Master Environment Guide is a practical handbook designed for environmental managers health and safety managers

business managers students and anyone who needs an overview of environmental best practice and law It contains information on key aspects of environmental management in industries such as techniques systems land development pollution chemicals energy waste water and biodiversity

SME Mining Engineering Handbook, Third Edition Peter Darling, Society for Mining, Metallurgy, and Exploration (U.S.), 2011 This third edition of the SME Mining Engineering Handbook reaffirms its international reputation as the handbook of choice for today's practicing mining engineer It distills the body of knowledge that characterizes mining engineering as a disciplinary field and has subsequently helped to inspire and inform generations of mining professionals Virtually all of the information is original content representing the latest information from more than 250 internationally recognized mining industry experts Within the handbook's 115 thought provoking chapters are current topics relevant to today's mining professional Analyzing how the mining and minerals industry will develop over the medium and long term why such changes are inevitable what this will mean in terms of challenges and how they could be managed Explaining the mechanics associated with the multifaceted world of mine and mineral economics from the decisions associated with how best to finance a single piece of high value equipment to the long term cash flow issues associated with mine planning at a mature operation Describing the recent and ongoing technical initiatives and engineering developments in relation to robotics automation acid rock drainage block caving optimization or process dewatering methods Examining in detail the methods and equipment available to achieve efficient predictable and safe rock breaking whether employing a tunnel boring machine for development work mineral extraction using a mobile miner or cast blasting at a surface coal operation Identifying the salient points that dictate which is the safest most efficient and most versatile extraction method to employ as well as describing in detail how each alternative is engineered Discussing the impacts that social and environmental issues have on mining from the pre exploration phase to end of mine issues and beyond and how to manage these two increasingly important factors to the benefit of both the mining companies and other stakeholders

Quality Progress, 1993 **Managing Quality in Architecture** Charles Nelson, 2007-06-07 This handbook addresses the question of how best to manage quality in architecture for the mutual benefit of design practices and their clients Based on research from the last two decades it explores the general principles tools and techniques that can be adapted to the unique culture of any design practice The book addresses all aspects of quality in creating the built environment with international contributions representing some of the best thinking that exists in design practice management It is aimed at the entire design team those who have a role in design inputs design processes and design execution including project managers contractors suppliers and clients An accompanying website also provides commentary and updates on the text Topics are linked to relevant sections of the current quality standard and the standard is interpreted as to its application to design practice Practices interested in establishing an ISO 9001 compliant quality system will find all the tools they need The interpretation of quality is comprehensive The focus is completely practical rather than theoretical

affording readers a concise picture of how the issues of excellence and quality performance flow across every aspect of design practice This focus provides the vital link that distinguishes truly successful practices from the rest Here simply is the answer to the forces of commoditization that challenge all designers in today s competitive environment The text is augmented and supported by chapters from twenty two authoritative contributors a foreword authored by Eugene Hopkins and illustrations by graphic artist Michael Lindell Key case studies are also provided focusing on Anderson Brul Architects San Jos CA Add Inc Cambridge MA Geyer Pty Ltd Melbourne VIC Australia Harley Ellis Devereaux Southfield MI RVK Architects San Antonio TX *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 and shows how to tailor those requirements to support not just quality but also productivity Learn ways to simplify ISO9000 s notorious paperwork by using procedures writing to support your goals not stifle them

Institutional Governance and Regulation of Water Services Michael J. Rouse,2013-09-14 Institutional Governance and Regulation of Water Services aims to provide the key elements of policy governance and regulation necessary for sustainable water and sanitation services On policy matters it covers important aspects including separation of policy and delivery integrated planning sustainable cost recovery provisions for the poor and transparency Regulation and Regulatory Bodies are presented in their various forms with discussion of why some form of independent scrutiny is essential for sustainability The focus is on what works and what does not based on consideration of basic principles and on case studies in both developing and developed countries The early chapters discuss the key elements with later chapters considering how these elements have come together in successful reforms of public sector operations A chapter is devoted to the successful use of the private sector based on lessons learnt from failures of private contracts and the need for the application of sound procurement principles The current trend is for a public sector model which benefits from business approaches the so called corporatised public utility Experience since the publication of the first edition in 2007 reinforces the importance of the key elements for sustainable water services This second edition brings the material up to date and with some increased emphasis on public participation in its many forms It refers to the opportunity for progress provided by the UN Declaration of Water and Sanitation as a Human Right but only if it is implemented in a practical and sustainable way Institutional Governance and Regulation of Water Services is aimed at providing an informative source for national and local governments responsible for water policy for water utility managers and for students who will be the policy makers of tomorrow It is a teaching aid for courses on water policy governance and regulation About the Author Michael Rouse is a Distinguished Research Associate at the University of Oxford and manages the Institutional Governance and Regulation module of the University s MSc Course on Water Science Policy and Management He was formerly Head of the Drinking Water Inspectorate in London and has extensive knowledge and experience of water governance and regulation including all aspects of audit and enforcement and the governance issues

related to both public sector management and privatisation He has wide knowledge of water technical and operational matters based on his applied research and development background at the Water Research Centre where he spent 9 years as Managing Director Michael has a good understanding of international water matters and advises governments on policy and regulation He is a Past President of the International Water Association He is a visiting professor at Tsinghua University in Beijing and at the Shanghai Academy of Social Science In 2000 he was awarded the CBE Commander of the British Empire for his professional services

Resources in Education, 1999 Handbook of Medical Device Regulatory Affairs in Asia Jack Wong, Raymond Tong, 2018-03-28 Medical device regulation in Asia has gained more importance than ever Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones A registered product requires a lot of technical documentation to prove its efficacy safety and quality A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government testing centers and hospitals and among doctors This handbook covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application It is the first to cover the medical device regulatory affairs in Asia Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs

Designing a World-Class Quality Management System for FDA Regulated Industries David N. Muchemu, 2008-04 This book accomplishes the following for you 1 It helps you design a Quality management system that meets and exceeds QSR requirements 2 It helps you understand requirements for the design of a Quality Management system for Medical Device Pharmaceutical Tissue and Biomedical industries 3 It provides the Quality system document structure 4 It helps you understand Quality system requirements for ISO 13485 and ISO 9001 5 It provides standard definitions for the Quality management system 6 It gives you examples of Quality system related warning letters written by the FDA during onsite audit

Passing Your ISO 9000/QS-9000 Audit Don Sanders, 1997-08-14 By mid 1996 over 10 000 companies in the United States had achieved ISO registration a staggering jump from the 100 registered at the end of 1991 Why the explosive growth For many ISO registration acts as proof that the company has an outstanding and continuously improving quality process As registration continues to grow at a rate of more than 400 companies a month it is clear that the ISO QS phenomenon shows no sign of slowing down To become ISO QS 9000 registered a company needs an effective plan Because the average process can take 12 to 18 months it is important to know exactly what steps need to be taken from start to finish And that is where this book comes in Passing Your ISO 9000 QS 9000 Audit is a clearly written step by step guide to passing the external audit and getting your company ISO QS 9000 registered Passing Your ISO 9000 QS 9000 Audit is ideal for ISO champions and management representatives those individuals within a company charged with implementing the ISO QS 9000 process as well as corporate executives interested in knowing more about the program Using this book as a guide any ISO champion should be able to effectively prepare his or her company for successful ISO

registration **Organizations, Policy, and the Natural Environment** Andrew J. Hoffman, Marc J. Ventresca, 2002 This book brings together emerging perspectives from organization theory and management environmental sociology international regime studies and the social studies of science and technology to provide a starting point for discipline based studies of environmental policy and corporate environmental behavior Reflecting the book's theoretical and empirical focus the audience is two fold organizational scholars working within the institutional tradition and environmental scholars interested in management and policy Together this mix forms a creative synthesis for both sets of readers analyzing how environmental policy and organizational practices are shaped spread and contested Food Australia ,2004 Clinical Hematology: Theory & Procedures, Enhanced Edition Mary Lou Turgeon, 2020-06-29 Clinical Hematology Theory Procedures Enhanced Sixth Edition is a competency based text with built in study tools to help you master the theory of clinical hematology and the procedures used to diagnose and treat disorders of the blood and bone marrow **Total Quality Management** ,1991 **Water Policy in Canada** Mohammed H. Dore, 2015-03-11 This book deals with the water policy and management in Canada It discusses various problems and risks in the fresh and drinking water supply in the second largest country in the world Mohammed Dore argues that water is underpriced and used wastefully in Canada In selected case studies he illustrates the major threats from human activity to Canadian freshwaters and drinking water resources including manufacturing mining oil sands production animal farming and agricultural use Selected case studies include reviews of even dramatic incidences e g the Walkerton tragedy of 2000 when 7 people were killed and 200 went onto permanent dialysis treatment because of water contamination with harmful pathogens The book warns that wastewater treatment standards are often not sufficient so that many drinking water resources are in peril of wastewater contamination As most of the water resources are provincial responsibility the book discusses the water management policies in the different provinces separately Through a detailed discussion and statistical analyses it can define water policy and management lessons that emerge from the investigated case studies It ends by contrasting water policy and practice in Canada with the practice in some European countries

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