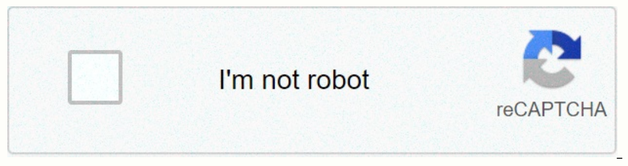

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ISO Copyright Office Ch. de Blandonnet 8 • CP 401 CH-1214 Wernier, Geneva, Switzerland Tal. +41 22 749 01 11 Fax +41 22 749 09 47 [Protected E-www.iso.org II Licensed to Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copying and monitoring networking is not allowed. © ISO 2015 – All rights reserved to ISO 9001:2015(E) The introduction to the page..... The Boa... And.... 12 34 normative references... 1 Terms and Conditions... One context of the organization... 14.1 Understanding the organization and its context... 14.2 Understanding the needs and expectations of stakeholders... 2 4.3 Determining the scope of the quality management system... 2 4.4 Quality management system and processes.... 25 leadership... 3 5.1 Leadership and commitment... 3 5.1.1 General... 3 5.1.2 Customer Zip Code... 3 5.2 4 5.2.1 Setting quality policy... 4 5.2.2 Transfer of Quality Policy... 4 5.3 Organizational roles, responsibilities and authorities... 46 Planning... 4 6.1 Actions to address risks and opportunities... 4 6.2 Quality goals and planning to achieve them... 5 6.3 Planning changes... 57 support... 6 7.1 Resources... 6 7.1.1 General... 6 7.1.2 People... 6 7.1.3 Infrastructure... 6 7.1.4 Environment for operating processes... 6 7.1.5 Monitoring and Measuring Resources... 7 7.1.6 Organizational knowledge... 7 7.2 8 7.3 Ads... 8 7.4 Communication... 8 7.5 Documented information... 8 7.5.1 General... 8 7.5.2 Create and Update... 9 7.5.3 Control of documented information... 98 Operation... 9 8.1 Operational Planning and Control... 9 8.2 Requirements for Products and Services... 10 8.2.1 Customer Communications... 10 8.2.2 Determining the requirements for products and services..... 10 8.2.3 Review of requirements for products and services... 10 8.2.4 Changes in requirements for products and services... 11 8.3 Design and development of products and services... 11 8.3.1 General... 11 8.3.2 Design design and development... 11 8.3.3 Design and Development Logins... 8.3.4 Design and development controls... 12 8.3.5 Design and Development Outputs... 12 8.3.6 Design and development changes... 12 © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netwerk is prohibited. iii ISO 9001:2015(E) 8.4 8.5 9 8.6 8.7 Control of processes, products and services provided from outside... 13 8.4.1 General... 13 8.4.2 Type and scope of control... 13 8.4.3 Third Party Information... 13 Supply of production and service... 14 8.5.1 Control of manufacturing and service delivery... 14 8.5.2 Detection and Detection... 14 8.5.3 Property belonging to customers or third parties... 15 8.5.4 Conservation... 15 8.5.5 Activities after delivery... 15 8.5.6 Control changes... 15 Release products and services... 15 Control of unplugged yields... 16 20 00:00: 9.1 Monitoring, measuring, analyzing and evaluating... 16 9.1.1 General... 16 9.1.2 Customer Satisfaction... 17 9.1.3 Analysis and Evaluation... 17 9.2 Internal review... 17 9.3 Management Review... 18 9.3.1 General... 18 9.3.2 Management Review Inputs... 18 9.3.3 Outputs Management Review... 18 10 improvement... 19 10.1 General... 19 10.2 Discrepancy and corrective action... 19 10.3 Continuous improvement... 19 Appendix A (informative) clarification of new structure, terminology and concepts... 21 Appendix B (Informative) Other international standards on quality management and quality management systems developed by ISO/TC 176.... 28 iv Licensed Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netwerk is prohibited. © ISO 2015 – All Rights Reserved ISO 9001:2015(E) Introduction to ISO (International Organization for Documenta) is a global federation of national standards bodies (ISO member bodies). The work of preparing international standards is usually carried out through ISO technical committees. Any member body interested in the matter for which a technical committee has the right to be represented in this committee. International, government and non-governmental organizations, in connection with ISO, are also taking part in the work. ISO cooperates closely with the International Electrotechnical Committee (IEC) on all issues of electrotechnical standardization. The procedures used to develop this document and those intended for further maintenance are described in iso/IEC instructions, part 1. In particular, the different certification criteria required for the different types of ISO documents must be specified. This document was drafted in accordance with the ISO/IEC editing rules, Part 2 (www.iso.org/directives). Attention is drawn to the possibility that some elements of this document may be the subject of patent rights. ISO will not be held liable for identifying such or all patent rights. Details of any patent rights identified during the development of the document will be in the introduction and/or list of patent declarations received (see www.iso.org/patents). Any trade name used in this document is information that is provided for the convenience of users and is not a certificate. For an explanation of the significance of specific ISO terms and phrases related to match evaluation, as well as information about ISO adherence to World Trade Organization (WTO) principles at the Technical Barriers to Commerce (TBT) see the following URL: www.iso.org/iso/foreword.html. The committee responsible for this document is ISO/TC 176 of the Technical Committee, Quality Management and Quality Assurance, SC Subcommittee 2, Quality Systems. This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically amended, by adopting a sequence of revised clauses and adapting the revised quality management principles of new concepts. It also disables and replaces corrigendum 9001:2008/Cor.1:2009 technical ISO. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. v ISO 9001:2015(e) Introduction 0.1 Adoption Rules of A management system is a strategic decision for an organization that can help improve its overall performance and provide a solid foundation for sustainable development initiatives. The potential advantages to the organization of implementing a quality management system based on this international standard are: a) the ability to consistently provide products and services that are poor on applicable customer requirements and regulation; b) faciliting opportunities to improve customer satisfaction; c) addressing the risks and opportunities related to its context and objectives; d) The ability to demonstrate compliance with the specified quality management system requirements. This international standard can be used by internal and external factors. This international standard does not intend to imply the need for: — uniformity in the structure of different quality management systems; — aligning the documentation to the section structure of this international standard; — The use of the specific termination of this international standard within the organization. The quality management system requirements specified in this international standard complete the requirements for products and services. This international standard uses the process approach, which combines the Do-Check-Act (PDCA) program cycle and risk-based thinking. The process approach allows the organization to plan its processes and interactions. The PDCA cycle enables the organization to ensure that its processes are properly sweated and managed, and that opportunities for improvement are determined and worked. Risk-based thinking enables the organization to determine the causes of disappearances to cause its processes and quality management system to deviate from the planned results, place contraceptive controls to minimize negative effects, and use more opportunities when they arise (see Section A.4). Consistently meeting requirements and meeting future needs and expectations presents a challenge for organizations in an increasingly dynamic and complex environment. To achieve this goal, the organization may see fit to adopt various forms of improvement in addition to continuous repair and improvement, such as breakthrough change, innovation, and restructuring. This international standard uses the following verbal forms: shall — specifies a requirement; — should indicate recommendation; — may specifies permission; — can indicates an option or capability. Information marked as a comment is for guidance in understanding or clarifying the associated requirement. vi Licensed Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copy Ventur prohibited. © ISO – All rights reserved iso 9001:2015(e) 0.2 Principles of quality management This international standard is based on the quality management principles described in iso 9000. The descriptions include a statement of each principle, a rationale for why the principle is important to the organization, some examples of advantages related to the principle, and examples of typical actions to improve the organization's performance when applying the principle. The principles of quality management are: — customer focus; — leadership; — people's involvement; — process access; — improvement; — evidence-based decision-making; — Relationship management. 0.3 Access Process 0.3.1 This international standard promotes adoption of process access when developing, implementing and improving the efficiency of a quality management system, to improve customer satisfaction by meeting customer requirements. Specific requirements considered essential for adoption of process access are included in 4.4. Understanding and managing related processes as a system contributes to the efficiency and efficiency of the organization in achieving its intended results. This approach allows the organization to control inter-relationships and interdependence between system processes so that the overall performance of the organization can be improved. The process approach involves systematically defining and managing processes, and their interactions, to achieve the results intended in accordance with the organization's quality policy and strategic direction. Process management and the system as a whole can be achieved through the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at seizing opportunities and preventing unwanted results. Implementing the process approach in a quality management system enables: a) understanding and consistency in compliance requirements; b) consideration of processes in terms of added value; c) achievement of efficient process performance; d) Improving processes based on data and information evaluation. Figure 1 provides a schematic representation of each process and shows the interaction of its elements. The monitoring and measurement testing points, which are necessary for control, are specific to each process and vary depending on the associated risks. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. vii ISO 9001:2015(e) Figure 1 — Schematic representation of the elements of a single process 0.3.2 program-do-check-act cycle can be applied to all processes and quality The whole system. Figure 2 illustrates how sentences 4 through 10 can be grouped in relation to the PDCA cycle. Note Numbers in brackets refer to the clauses in this international standard. Figure 2 - Representation of the structure of this international standard in the PDCA viii cycle licensed to the Department of Medical Sciences / warangkana oncoung ([Protected E-ore]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copying and Netwerx is prohibited. © ISO 2015 – All rights reserved to ISO 9001:2015(e) PDCA Cycle can be briefly described as follows: — Program: Determine system goals and processes, and the resources necessary to deliver results in accordance with customer requirements and enterprise policies, and identify and address risks and opportunities; — Will: Implement what was planned; — Check: monitor (if available) measure processes and products and services that are created against policies, objectives, requirements, and planned activities, and report the results; - ACTION: Take actions to improve performance, if necessary. 0.3.3 Risk-based risk-based thinking (see section A.4) is essential to achieving an effective quality management system. The idea of risk-based thinking was implied in previous releases of this international standard, including, for example, taking preventive action to avoid potential discrepancies, analyzing any discrepancies occurring, and taking action to prevent a recurrence corresponding to the effects of discrepancies. To meet the requirements of this international standard, an organization needs to plan and implement actions to address risks and opportunities. Handling both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results, and preventing negative impacts. Opportunities can result from a positive situation to achieve a deliberate outcome, for example, a set of circumstances that allow an organization to attract customers, develop new products and services, reduce waste, or improve productivity. Actions to address opportunities can also include taking into account the associated risks. Risk is the effect of uncertainty and any such uncertainty can have a positive or negative impact. A positive deviation resulting from risk can provide opportunity, but not all positive effects of risk cause opportunities. 0.4 Contact with other management system standards This international standard applies the framework developed by ISO to improve the alignment between its international standards and management systems (see Section A.1). This international standard allows the organization to use the process approach, combined with PDCA turnover and risk-based thinking, to align or integrate risk-based thinking A management system with requirements of other management system standards. This international standard refers to iso 9000 and ISO 9004 as follows: — ISO 9000 quality management systems — basics and vocabulary provide an essential background for proper understanding and implementation of this international standard; — ISO 9004 Management for continued enterprise success — Access to quality management provides guidance to organizations that choose to move beyond the requirements of this international standard. Appendix B provides details of other international standards on quality management and quality management systems developed by ISO/TC 176. This international standard does not include specific requirements for other management systems, such as those for environmental management, occupational health and safety management, or financial management. Sector-specific quality management system standards based on the requirements of this international standard have been developed for several sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance for implementing this international standard in the particular sector. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. ix ISO 9001:2015(e) Matrix showing the correlation between the statements of this international standard and the previous release (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access website at: www.iso.org/tc176/sc02/public. x Licensed Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor is prohibited. © ISO 2015 – All rights reserved international standard quality management systems ISO 9001:2015(e) — Requirements 1 Scope of this international standard specifies requirements for a quality management system when an organization: a) should demonstrate its ability to consistently provide products and services that meet statutory and regulatory requirements applicable, b) aims to improve customer satisfaction through the efficient implementation of the system, including processes to improve the system and ensure customer compliance and applicable statutory and regulatory requirements. All requirements of this international standard are generic and are intended to be applicable to any organization, regardless of its type or size, or to the products and services it provides. Note 1 In this international standard, the terms product or service apply only Products and services intended for or required by the customer. Note 2 Statutory and regulatory requirements can be expressed as legal requirements. 2 Normative references The following documents, in whole or in part, have a normative reference in this document and are necessary for its implementation. For outdated references, only the cited edition applies. For undated references, the latest release of the referenced document (including any corrections) has been started. ISO 9000:2015, Quality Management Systems — Vocabulary Basics 3 terms and definitions for the purposes of this document, the terms and settings given in ISO 9000:2015 apply. 4 The organization's relationship 4.1 Understanding the organization and its context will determine external and internal issues relevant to its objective and strategic direction, which affect its ability to achieve the intended results of its quality management system. The organization will monitor and review information about these external and internal issues. Note 1 Issues can include positive and negative factors or conditions for consideration. Note 2 Understanding the external context can be alleviated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. Note 3 Understanding the internal context can be facilitated by considering issues related to the values, culture, knowledge and performance of the organization. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 1 ISO 9001:2015(E) 4.2 Understanding the needs and expectations of stakeholders because of their impact or potential impact on the organization's ability to consistently provide products and services that meet applicable statutory and regulatory requirements, the Organization shall determine: a) stakeholders relevant to the quality management system; b) The requirements of these stakeholders relevant to the quality management system. The organization will monitor and review information about these stakeholders and their relevant requirements. 4.3 Determining the scope of the enterprise quality management system will determine the limits and applicability of the quality management system to establish its scope. When determining this scope, the organization will consider: a) the external and internal issues mentioned in 4.1; b) the requirements of relevant stakeholders mentioned in 4.2; c) The products and services of the organization. The organization will apply all requirements of this international standard if they Within the scope of its quality management system. The scope of the organization's quality management system will be available and saved as documented information. This scope attributes the types of products and services covered, and will provide justification for any requirements of this international standard that the organization establishes are not available to the scope of its quality management system. This international standard can only be argued if the requirements set as incompetent do not affect the organization's ability or responsibility to ensure the suitability of its products and services and improved customer satisfaction. 4.4 Quality management system and its processes 4.4.1 The organization will establish, implement, maintain and continuously improve a quality management system, including the necessary processes and their interactions, in accordance with the requirements of this international standard. The organization will determine the processes necessary for the quality management system and implement them throughout the organization, and will determine: a) the required inputs and the plaques expected from these processes; b) determine the sequence and interaction of these processes; c) determine and apply the criteria and methods (including monitoring, measurements and performance-related indicators) necessary to ensure the effective operation and control of these processes; d) determine the resources needed for these processes and ensure their availability; e) assign responsibilities and authorities for these processes; f) address risks and opportunities as determined in accordance with Requirements 6.1; g) evaluate these processes and implement all necessary changes to ensure that these processes achieve their intended results; Licensed Department of Medical Sciences / warangkana oncoung ([Protected E-op]) 2 ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copying and Netwock is prohibited. © ISO 2015 – All rights reserved iso 9001:2015(e) h) improve processes and quality management system. 4.4.2 To the extent necessary, the Organization will retain: a) documented information to support the performance of its processes; b) Save documented information to be sure that the processes are going as planned. 5 Leadership 5.1 Leadership and Commitment 5.1.1 The Supreme General Management will show leadership and commitment with respect to the quality management system by: a) taking responsibility for the effectiveness of the quality management system; b) ensure that quality policies and quality objectives are set for the quality management system and are compatible with the organization's strategic context and direction; c) Ensuring a combination of quality management requirements for the organization's business processes; d) promoting the use of process approach and risk-based thinking; e) ensure that the resources required for the quality management system are available; f) communicate the importance of efficient quality management and compliance with quality management system requirements; g) ensure that the quality management system achieves its intended results; h) Engaging, deliberate and supporting people contribute to the efficiency of the quality management system; i) improving promotion; c) Supporting other relevant management roles to demonstrate their leadership as it applies to their responsibilities. Note A reference to businesses of this international standard can be widely interpreted so that activities that are at the core of the organization's existence, whether public, private, for-profit, or not-for-profit. 5.1.2 Targeting the customer The supreme management will show leadership and commitment with respect to customer focus by ensuring that: a) applicable statutory and regulatory requirements are determined, structured and consistently fulfilled; b) the risks and opportunities that can affect the suitability of products and services and the ability to improve customer satisfaction are determined and addressed; c) The focus on improving customer satisfaction is maintained. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 3 ISO 9001:2015(E) 5.2 Policy 5.2.1 Establishing quality policies The Supreme Management will establish, implement and maintain quality policies: a) fit for purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality goals; c) includes an obligation to comply with applicable requirements; d) Includes a commitment to continuous improvement of the quality management system. 5.2.2 The transfer of quality policies to quality policies shall be: a) be available and maintained as documented information; b) be transferred, understood and implemented within the organization; c) Be available to relevant stakeholders, as necessary. 5.3 Organizational positions, responsibilities and senior management authorities will ensure that responsibility and authorities for the relevant positions are assigned, transferred and understood within the organization. Senior management will assign responsibility and authority for: a) ensure that the quality management system complies with the requirements of this international standard; b) ensure that the processes provide their intended braces; c) Reporting on quality management system performance and for improvement (see 10.1), especially for senior management; d) ensure promotion of customer focus across the organization; e) Ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 6 Planning 6.1 actions to address risks and opportunities 6.1.1 When designing the quality management system, the organization will consider the issues mentioned in 4.1 and the requirements mentioned in 4.2 and determine the risks and opportunities that need to be addressed: a) ensure that the quality management system can achieve its intended results); b) improve desired effects; c) prevent, or reduce, unwanted effects; d) Achieve improvement. 4 Authorized Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is not allowed. © ISO 2015 – All rights reserved to ISO 9001:2015(E) 6.1.2 The Organization will plan: a) actions to address these risks and opportunities; b) How: 1) integrate and implement the actions in the processes of its quality management system (see 4.4); 2) Assess the effectiveness of these actions. Actions taken to address risks and opportunities will be proportional to the potential impact on the suitability of products and services. Note 1 Risk management options can include avoiding risk, taking a risk to pursue an opportunity, eliminating the source of risk, changing the likelihood or consequences, sharing the risk or maintaining risk by making an informed decision. Note 2 opportunities can lead to adoption of new practices, launching new products, opening up new markets, responding to new customers, building partnerships, using new technology, and other desirable and worthwhile options to address the needs of your organization or its customers. 6.2 Quality and planning objectives for achieving them 6.2.1 The organization will establish quality goals in relevant functions, levels and processes needed for the quality management system. The quality objectives will be: a) will be consistent with quality policies; b) be measuring; c) take into account the requirements that apply; d) be relevant to adapting products and services and improving customer satisfaction; e) be monitored; f) be transferred; g) Will be updated as needed. The organization will retain documented information about quality goals. 6.2.2 When planning how to achieve its quality goals, the Organization will determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) How the results will be assessed. 6.3 Planning changes When the organization determines the need for changes to the quality management system, changes will be made to Mode (see 4.4). © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 5 ISO 9001:2015(E) The organization will consider: a) the purpose of the changes and their possible consequences; b) quality management system health; c) resource availability; d) Assign or reallocate responsibilities and authorities. 7 Support 7.1 Resources 7.1.1 Enterprise rules will determine and provide the resources necessary for the establishment, implementation, maintenance and continuous improvement of the quality management system. The organization will consider: a) the capabilities of existing internal resources, and constraints; b) What you should get from third parties. 7.1.2 People The organization will determine and provide the people necessary for efficient implementation of its quality management system and to operate and control its processes. 7.1.3 The organization's infrastructure will determine, provide and maintain the infrastructure necessary to provide and achieve adaptation of products and services. Note infrastructure can include: a) associated buildings and utilities; b) equipment, including hardware and software; c) Transportation resources; d) Information and communication technology. 7.1.4 An environment to constitute processes the organization will determine, provide and maintain the environment necessary for its importation and the customization of products and services. Note An appropriate environment can be a combination of human and physical factors, such as: a) social (e.g. not discriminatory, calm, not confrontational); b) psychological (e.g. stress reduction, abrasion prevention, emotional protection); c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). These factors may vary significantly depending on the products and services provided. 6 Licensed Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All rights reserved iso 9001:2015(e) 7.1.5 monitoring and measuring resources 7.1.5.1 Enterprise rules will determine and provide the resources necessary to ensure valid and reliable results when monitoring or measuring is used to verify the suitability of products and services to requirements. The organization will ensure that the resources provided: a) correspond to the specific type of monitoring and measurement activities in progress; b) are saved to ensure their continued competency to The organization will retain appropriate documented information as evidence of fitness for the purpose of monitoring and measuring resources. 7.1.5.2 Measurement tracking when measurement tracking is a requirement, or is considered by the organization to be an essential part of providing security in the validity of measuring results, measuring equipment shall be: a) uquited or verified, or both, at specified intervals, or prior to use, against measurement standards that can be tracked by international or national measurement standards; Where no such standards exist, the basis used for calibration or authentication will be saved as documented information; b) have been found to determine their condition; c) Protected against adjustments, damage or deterioration that will eliminate calibration status and subsequent measurement results. The organization will determine whether the validity of the previous measurement results was adversely affected when it was found that measuring equipment did not fit its intended purpose, and would take appropriate action if necessary. 7.1.6 The organization's organizational knowledge will determine the knowledge necessary to determine its processes and to achieve the adaptation of products and services. This knowledge will be retained and available to the extent necessary. When responding to changing needs and trends, the organization will consider its current knowledge and determine how to acquire or access any additional knowledge and required updates needed. Note 1 Organizational knowledge is organization-specific knowledge; It's usually accumulated by experience. This is information that is used and shared to achieve the organization's goals. Note 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge accumulated from experience; lessons learned from successful failures and projects; capturing and sharing undocumented knowledge and experience; results of improvements in processes, products and services); and the results of improvements in processes, products and services. b) External sources (e.g., standards; academia; conferences; gathering knowledge from customers or third parties). © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 7 ISO 9001:2015(E) 7.2 As an enterprise service will determine: a) the required ability of people to do work under its control that affects the performance and efficiency of the quality management system; b) ensure that these individuals are eligible on the basis of appropriate education, training or experience; c) Where available, actions must be taken to obtain the necessary capability, and assess the effectiveness of the actions taken; d) Maintain adequate Information as evidence of ability. Note Applicable actions can include, for example, the provision of training to, the mentoring of, or the reasseal of people currently employed; Or the hiring or contracting of talented people. 7.3 The Organization's ads will ensure that individuals renowned in the Organization are aware: a) of the Quality Policy; b) relevant quality objectives; c) contributing to the efficiency of the quality management system, including the benefits of improved performance; d) The consequences of mismatching the requirements of the quality management system. 7.4 The organization's communication will determine the internal and external communications relevant to the quality management system, including: a) what it will transfer; b) when to communicate; c) with whom to communicate; d) how to communicate; e) Who's calling. 7.5 Documented Information 7.5.1 The Rules of the Organization's Quality Management System shall include: a) documented information required by this international standard; b) Documented information determined by the organization to be necessary for the efficiency of the quality management system. Note The scope of documented information for a quality management system can differ from one organization to another because: — the size of the organization and the type of activities, processes, products, and services it has; 8 Authorized Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor is prohibited. © ISO 2015 – all rights reserved iso 9001:2015(e) — the complexity of their processes and interactions; — people's ability. 7.5.2 Creating and updating when creating and updating documented information, the Organization will ensure appropriate: a) identification and description (e.g. title, date, author or reference number); b) format (e.g., language, software version, graphics) and media (e.g. paper, electronic); c) Review and approval to adapt and adapt. 7.5.3 Control of documented information 7.5.3.1 Documented information required by the Quality Management System and by this international standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) It is adequately protected (for example, from loss of confidentiality, improper use, or loss of integrity). 7.5.3.2 to control documented information, the Organization will address the following activities, as necessary: a) distribution, access, retrieval and use; b) storage and conservation, including the safeguarding of the Ligisman; c) control changes (e.g. version control); d) Retention and character. Documented information from an external source determined by the organization to be necessary for planning The operation of the quality management system will be identified as correct, and will be controlled. Documented information saved as evidence of matching will be protected from unintended changes. Note Access can imply a decision about permissions to view only the documented information, or permission and permission to view and modify the documented information. 8 Operation 8.1 Operational Planning and Control The Organization will design, implement and control the processes (see 4.4) necessary to meet the requirements for providing products and services, and to implement the actions set forth in Section 6, by: a) determining the requirements for the products and services; b) Setting criteria for: 1) the processes; 2) receipt of products and services; c) determine the resources necessary to meet product and service requirements; Licensed Department of Medical Sciences / warangkana oncoung ([Protected E-©) © ISO 2015 – All rights reserved to ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copy and Monitor Prohibited. 9 ISO 9001:2015(e) d implements process control according to criteria; e) determine, save, and retain documented information if necessary: 1) to be sure that the processes were carried out as planned; 2) To demonstrate the suitability of products and services to their requirements. This design throughput will be suitable for enterprise operations. The organization will control the planned changes and examine the consequences of unintended changes, and take action to reduce side effects, if necessary. The organization will ensure that outsourced processes are controlled (see 8.4). 8.2 Requirements for products and services 8.2.1 Customer communication with customers will include: a) providing information relating to products and services; b) handling investigations, contracts or orders, including modifications; c) receiving customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) Determine specific requirements for contingency operations when applicable. 8.2.2 Determining the requirements for products and services when determining the requirements for the products and services offered to customers, the Organization will ensure that: a) the requirements for the products and services are defined, including: 1) all applicable statutory and regulatory requirements; 2) those deemed necessary by the organization; b) The organization can meet the claims for the products and services it offers. 8.2.3 Review requirements for products and services 8.2.3.1 The organization will ensure that it has the ability to meet the requirements for products and services that will be offered Customers. The organization will conduct a test before committing to providing products and services to the customer, to include: a) requirements specified by the customer, including the requirements for shipping and shipping activities; b) requirements not specified by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to products and services; e) Contract or order requirements other than those expressed in the past. 10 Authorized Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitoring prohibited networking. © ISO 2015 – All rights reserved to ISO 9001:2015(E) The organization will ensure that the contract or order requirements other than those previously defined will be resolved. Customer requirements will be approved by the organization prior to receipt, with the customer not providing a documented statement of their requirements. Note In some situations, such as online sales, an official review is impractical for each order. Instead, the review can cover relevant product information, such as catalogs. 8.2.3.2 The Organization will retain documented information, according to the documentation: a) about the results of the audit; b) For all new requirements for products and services. 8.2.4 Changes in product and service requirements The Organization will ensure that the relevant documented information is corrected, and that relevant persons are aware of the changed requirements, when the requirements for products and add-ons change. 8.3 Planning and development of products and services 8.3.1 The organization's rules will establish, implement and maintain a planning and development process suitable for ensuring the next delivery of products and services. 8.3.2 Planning planning and development in determining the stages and controls for planning and development, the organization will consider: a) the nature, duration and complexity of planning and development activities; b) the required stages of process, including applicable design and development audits; c) the required planning and development authentication and compliance activities; d) the responsibilities and authorities involved in the planning and development process; e) internal and external resource needs for designing and developing products and services; f) the need to control interfaces between people involved in the planning and development process; g) the need for the involvement of customers and users in the planning and development process; h) the requirements for the provision of products and services thereafter; i) The level of control expected for the planning and development process by customers and other relevant interested parties j) The documented information needed to prove that the design and development requirements were met. 8.3.3 The organization's design and development inputs will determine the essential requirements for specific types of products and services for planning and development. The organization will consider: a) functional requirements and performance; © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 11 ISO 9001:2015(e) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or practice codes that the organization has committed to implement; e) Possible consequences of failure due to the nature of products and services. Inputs will be suitable for design and development purposes, complete and unequivocal. Conflicting design and development inputs will be resolved. The organization will retain documented information on design and development inputs. 8.3.4 Enterprise design and development controls will apply controls to the planning and development process to ensure: a) the results to be achieved are defined; b) Reviews are conducted to assess the ability of design and development results to meet requirements; c) Authentication activities are performed to ensure that design and development ports meet input requirements; d) Authentication activities are performed to ensure that the products and services that are created meet the requirements for the specified application or for the intended use; e) All necessary actions are taken on issues prescribed during reviews, or authentication and compliance activities; f) Documented information of these activities is retained. Note Design and development reviews, authentication, and authentication have different purposes. They can be managed separately or in any combination, depending on the products and affiliations of the organization. 8.3.5 The organization's design and development outputs will ensure that the planning and development outputs: a) meet the input requirements; b) are suitable for the following processes for providing products and services; c) include or refer to monitoring and measurement requirements, according to the appropriate criteria and acceptance; d) Specify the characteristics of products and services that are essential to their intended purpose and their safe and necessary delivery. The organization will retain documented information on design and development outputs. 8.3.6 The organization's design and development changes will

identify, review and control changes made during or after, the design and development of products and services, to the extent necessary to ensure that there is no Impact on compliance with requirements. The organization will retain documented information on: a) design and development changes; b) the results of the reviews; 12 Licensed Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All rights reserved to ISO 9001:2015(e) c) approval of the changes; d) The actions taken to prevent adverse effects. 8.4 Control of the processes, products and services provided from outside 8.4.1 The organization's rules will ensure that processes, products and services provided from outside comply with the requirements. The organization will determine the controls to be applied to processes, products and services provided from outside when: a) third-party products and services are intended to be incorporated into the organization's own products and services; b) Products and services are provided directly to the customer by third parties on behalf of the organization; c) A process, or part of a process, is provided by a third party as a result of a decision by the organization. The organization will determine and apply criteria for third-party evaluation, selection, performance monitoring, and reassessment, depending on their ability to provide processes or products and services according to requirements. The organization will retain documented information about these activities and any required actions arising from the assessments. 8.4.2 The type and scope of control the Organization will ensure that processes, products and services provided from the outside do not adversely affect the organization's ability to consistently provide products and services that are compatible with its customers. The organization will ensure: a) that processes provided from the outside remain under the control of its quality management system; b) define both the controls it intends to apply to a third party and the controls it intends to apply to the output generated; c) Consider: 1) the potential impact of the processes, products and services provided from the outside on the organization's ability to consistently meet applicable constitutional and regulatory requirements; 2) the effectiveness of the controls applied by the third party; d) Determine the authentication, or other activities, necessary to ensure that the processes, products and services provided from outside meet the requirements. 8.4.3 Third Party Information The Organization will ensure the suitability of the requirements prior to their communications to the third party. The Organization will transfer to third parties its requirements for: a) the processes, products and services to be provided; © ISO 2015 – All rights reserved are authorized to the Department of Medicine / Warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copying and Netweke is prohibited. 13 ISO 9001:2015(E) B Certification: 1 Products and Services; 2) methods, processes and equipment; 3) release of products and services; c) competency, including any required training of persons; d) third party interactions with the organization; e) control and monitor the performance of third-party providers to be applied by the organization; f) Authentication or verification activities that the organization, or its client, intends to perform on the third party territories. 8.5 Production allocation and service 8.5.1 Control of production delivery and service enterprise will implement production and service delivery under controlled conditions. The controlled terms will include, according to Hibber: a) the availability of the documented information defining: 1) the characteristics of the products to be produced, the services to be provided or the activities to be performed; 2) the results to be achieved; b) the availability and use of appropriate monitoring and measurement resources; c) implementing monitoring and measurement activities at appropriate stages to ensure that the criteria for controlling processes or outputs, and acceptance criteria for products and services, have been met; d) Use of appropriate infrastructure and environment to operate processes; e) the appointment of qualified persons, including any required training; f) the validation, and periodic revaluation, of the ability to obtain planned results of the processes for production and service delivery, in which the output generated by consecutive monitoring or measurement cannot be verified; g) implementation of actions to prevent human error; h) Implementation of release, delivery, and shipping activities. 8.5.2 Identifying and locating the organization will use appropriate means to detect outputs when necessary to ensure the suitability of products and services. The organization will identify the status of outputs with respect to monitoring and measurement requirements throughout production and service delivery. The organization will maintain the unique identification of the plates when tracking capability is a requirement, and will retain the documented information needed to enable surveillance. 14 Authorized Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All rights reserved to ISO 9001:2015(E) 8.5.3 Property belonging to customers or third parties The organization will operate handling of property belonging to customers or third parties when it is under Control or used by your organization. The organization will identify, verify, protect and protect the property of customers or third-party suppliers provided for use or incorporation in products and services. When a customer's property or third party is lost, damaged, or otherwise found to be unusable, the organization will report it to the customer or third party and retain documented information about what occurred. Note The property of a third party or customer may include materials, components, tools and equipment, discounts, intellectual property, and personal data. 8.5.4 The conservation of the organization will maintain outputs during the delivery of production and service, to the extent necessary to ensure compliance with requirements. Note Conservation can include identification, treatment, pollution control, packaging, storage, transmission or transportation, and protection. 8.5.5 Activities after delivery The Organization will meet the requirements for post-delivery activities related to products and services. In determining the scope of the activities after delivery required, the organization will consider: a) statutory and regulatory requirements; b) the potential undesirable consequences associated with its products and services; c) the nature, use and intention of the life of its products and services; d) Customer requirements; e) Customer feedback. Note After delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplemental services such as recycling or final disposal. 8.5.6 Control of changes the organization will review and control changes for production or service delivery, to the extent necessary to ensure continued compliance with requirements. The organization will retain documented information describing the results of the change review, the people approving the change, and all necessary actions resulting from the review. 8.6 Release of products and services The Organization will implement planned arrangements, in the appropriate stages, according to the value of the product and service requirements. The release of products and services to the customer will not continue until the planned arrangements are completed, unless otherwise approved by a relevant authority and, as appropriate, by the customer. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 15 ISO 9001:2015(E) The organization will retain documented information about the release of products and services. The documented information will include: a) evidence to match the acceptance criteria; b) Tracking the people Release. 8.7 Control of incompatible yields 8.7.1 The organization will ensure that ports that do not comply with their requirements are detected and controlled to prevent unintended use or delivery. The organization will take appropriate action in accordance with the nature of the discrepancy and its impact on the suitability of products and services. This will also apply to products and services that cannot be implemented that are detected after products are provided, during, or after the provision of services. The organization will handle outputs that cannot be asses in one or more of the following ways: a) repair; b) separation, containment, reimbursement or suspension of the supply of products and services; c) notify the customer; d) Obtaining a receipt receipt with a reseal. The adjustment to requirements matches when correcting incompatible outputs. 8.7.2 The Organization will retain documented information describing the discrepancy; b) describes the actions taken; c) describes concessions obtained; d) Identifies the authority that decides the action in relation to the discrepancy. 9 Performance Assessment 9.1 Monitoring, Measuring, Analyzing and Evaluating 9.1.1 Enterprise Rules will determine: a) What should be tracked and measured; b) the monitoring, measurement, analysis and evaluation methods necessary to ensure valid results; c) when monitoring and index will be performed; d) When the results of monitoring and measurement are analyzed and evaluated. The organization will assess the performance and efficiency of the quality management system. The organization will retain appropriate documented information as evidence of the results. 16 Licensed Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All rights reserved iso 9001:2015(e) 9.1.2 Customer satisfaction The organization will monitor customer perceptions of the extent to which their needs and expectations have been met. The organization will determine the methods for obtaining this information, monitoring and testing. Note Examples of customer perception monitoring can include customer surveys, customer feedback on products and services delivered, customer meetings, market share analysis, compliments, warranty claims, and merchant reports. 9.1.3 Analysis and evaluation the Organization will analyze and evaluate appropriate data and information arising from supervision and measurement. The results of the analysis will be used to evaluate: a) adaptation of products and services; b) the degree of customer satisfaction; c) the performance and efficiency of the quality management system; d) if the design was implemented effectively; e) of actions taken to address risks and opportunities; f) third-party performance; g) The need for improvements in the quality management system. Note Methods for analyzing data can include statistical techniques. 9.2 Internal audit 9.2.1 The organization will conduct internal audits at planned intervals to provide information if the quality management system: a) complies with: 1) the requirements of the organization itself for its quality management system; 2) the requirements of this international standard; b) Implemented and maintained effectively. 9.2.2 The Organization will design, establish, implement, implement and maintain audit programs including frequency, methods, responsibilities, planning and reporting requirements, which will take into account the importance of the processes concerned, changes affecting the organization and the results of previous audits; b) define the audit criteria and scope for each audit; c) Select accountants and perform audits to ensure the objectivity and impartiality of the audit process; d) ensure that the results of the reviews are reported to the relevant management; e) take the appropriate amendment and corrective actions without unnecessary delay; © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 17 ISO 9001:2015(e) and retain documented information as evidence of implementation of the audit program and audit results. Note See ISO 19011 for guidance. 9.3 Management will examine the organization's quality management system, at planned intervals, to ensure its continued suitability, suitability, effectiveness and alignment with the organization's strategic direction. 9.3.2 Management review inputs The administrative review will be designed and executed with the consideration: a) the status of the actions from previous management audits; b) changes in external and internal issues relevant to the quality management system; c) information about the performance and efficiency of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant stakeholders; 2) the degree to which quality goals are met; 3) process performance and adaptation of products and services; 4) discrepancies and corrective actions; 5) Monitoring and measuring results; 6) Audit results; 7) third-party performance; d) resource value; e) effectiveness of actions taken to address risks and opportunities (see 6.1); f) Opportunities for improvement. 9.3.3 Management review yields The management review outputs will include related decisions and actions: a) opportunities for improvement; B) I don't know what to do. the need for changes to the quality management system; c) Resource needs. The organization will retain documented information as evidence of the results of management reviews. 18 Authorized Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All rights reserved ISO 9001:2015(e) Improvement 10.1 Enterprise Rules will determine and select opportunities to improve and implement all necessary actions to meet customer requirements and improve customer satisfaction. These will include: a) improving products and services to meet requirements, as well as to meet future needs and expectations; b) correcting, preventing or reducing unwanted effects; c) Improving the performance and efficiency of the quality management system. Note Examples of improvement can include repair, corrective action, continuous improvement, breakthrough change, innovation, and restructuring. 10.2 Discrepancy and corrective action 10.2.1 When a discrepancy occurs, including any action arising from complaints, the Organization: a) will respond to the discrepancy, and in accordance with the value character: 1) act to control and correct; 2) deal with the consequences; b) assess the need for action to eliminate the causes of discrepancy, so that it does not occur elsewhere or occur elsewhere, by: 1) reviewing and analyzing discrepancy; 2) determining the reasons for the discrepancy; 3) determine whether similar discrepancies exist, or may occur; c) implement any action required; d) examine the effectiveness of any corrective action taken; e) update risks and opportunities set during planning, if necessary; f) Make changes to the quality management system, if necessary. Corrective actions will be appropriate for the effects of discrepancies encountered. 10.2.2 The Organization shall retain documented information as evidence: a) the nature of discrepancies and the following actions taken; b) The results of any corrective action. 10.3 Continuous enterprise improvement will continuously improve the suitability, suitability and efficiency of the quality management system. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 19 ISO 9001:2015(E) The organization will consider the results of the analysis and evaluation, and the outputs from management review, to determine whether there are needs or opportunities to be addressed as part of an ongoing improvement. 20 Authorized Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: Only single user license, copying and networking are prohibited. © ISO 2015 – All rights reserved iso 9001:2015(e) Appendix A (informative) clarification of new structure, Terminology and concepts A.1 Structure and terminology structure of sections (i.e. section sequence) and part of the terminology of this international standard, compared to the previous release (ISO 9001:2008), have been changed to improve alignment with other management system standards. This international standard does not require its structure and terminology to be applied to the documented information of the organization's quality management system. The structure of the sentences is designed to provide a consistent presentation of requirements, not a model for documenting an organization's policies, goals, and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both processes operated by the organization and information maintained for other purposes. There is no requirement that the conditions used by an organization be replaced by the conditions used in this international standard to specify quality management system requirements. Organizations can choose to use terms appropriate for their actions (for example through records, documentation, or protocols instead of documented information; or a provider, partner, or vendor, not a third party). Table A.1 shows the major differences in termination between this edition of this international standard and the previous one. Table A.1 — Major Differences in Minology Between ISO 9001:2008 and ISO 9001:2015 ISO 9001:2008 ISO 900 1:2015 Unused Products and Services Exclusions (see Section A.5 to Clarify Applicability) Unused Management Representative (Similar Responsibilities and Services Assigned but No Requirement for Single Management Representative) Documentation, Quality Guide, Documented documents are documented, pro-documented. Environment workspace records for the operation of third-party processes provider monitoring and measuring monitoring equipment and measuring resources purchased from a product that is provided to external products and services A.2 products and services ISO 9001:2008 Use product term to include all output categories. This international standard is used in products and services. Products and services include all output categories (hardware, services, software, and processed materials). © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 21 ISO 9001:2015(E) Specific inclusion of services is designed to highlight the differences between products and services in the implementation of certain requirements. The characteristic of the services is that at least some of the output is realized in the interface with the client. This means, for example, that it is not possible to necessarily approve adjustment to requirements before the service is provided. In most cases, products and services are used together. Most of the plats that organizations provide to customers, or are provided to them by third parties, include both products and services. For example, a tangible or intangible product could be part of the service associated with it or the service could be some tangible or intangible product. A.3 Understanding the needs and expectations of Subclause 4.2 stakeholders specifies requirements for the organization to determine stakeholders relevant to the quality management system and the requirements of those stakeholders. However, 4.2 does not imply an expansion of quality management system requirements beyond the scope of this international standard. As stated in scope, this international standard is applicable when an organization needs to demonstrate its ability to consistently provide products and services that meet applicable statutory and regulatory requirements, and aims to improve customer satisfaction. There is no requirement in this international standard for an organization to consider stakeholders when it has decided that these parties are irrelevant to its quality management system. The organization must decide whether a specific requirement of a relevant interest is relevant to its quality management system. A.4 risk-based thinking The idea of risk-based thinking was implied in previous releases of this international standard, for example through requirements for planning, review and improvement. This international standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as the basis for planning (see 6.1). This represents the implementation of risk-based thinking for the planning and implementation of quality management system processes (see 4.4) and will help determine the scope of documented information. One of the main goals of a quality management system is to act as a preventive tool. As a result, this international standard does not include a separate clause or subuse of preventive action. The idea of preventive action is expressed through risk-based thinking in formulating quality management system requirements. The risk-based thinking implemented in this international standard has enabled some reduction in pre-precedent requirements and their replacement with performance-based requirements. There is more flexibility than iso 9001:2008 requirements for processes, Information and claiming organizational responsibility. Although 6.1 indicates that the organization will plan risk-handling operations, there is no requirement for formal risk management methods or a documented risk management process. Organizations can decide whether to develop a broader risk management methodology required by this international standard, such as by implementing other guidelines or standards. Not all quality management system processes represent the same level of risk in terms of the organization's ability to meet its goals, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for implementing its risk-based thinking and the actions it takes to address the risk, including whether to keep documented information as evidence of determining its risks. 22 Licensed Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All rights reserved iso 9001:2015(e) A.5 Applicability this international standard does not address exclusions with respect to the applicability of its requirements to the organization's quality management system. However, an organization can examine the applicability of the requirements because of the size or complexity of the organization, the management model it adopts, the variety of organization activities, and the nature of the risks and opportunities it encounters. Applicability requirements are handled in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can decide that a requirement is not only available if its decision does not cause a failure to achieve the suitability of products and services. A.6 Information is recorded as part of the alignment with other management system standards, a common section of documented information has been adopted without significant modification or addition (see 7.5). If necessary, text elsewhere in this international standard has been adapted to its requirements. As a result, documented information is used for all document requirements. When ISO 9001:2008 used specific technology such as document or documented procedures, a quality guide, or a quality plan, this release of this international standard defines requirements for keeping information documented. When ISO 9001:2008 used the term records to specify documents needed to provide evidence to match requirements, this is now reflected as a requirement to keep information documented. The organization is responsible Determines the documented information to keep, the amount of time for which it should be saved, and the media to be used to preserve it. Requiring documented information to be kept does not exclude the organization from also having to keep the same documented information for a specific purpose, such as to keep previous versions of it. Where this international standard applies to information and not documented information (for example, in 4.1: the organization will monitor and review the information about these external and internal issues), there is no requirement to record that information. In such situations, the organization can decide whether it is necessary or appropriate to keep information documented. A.7 Enterprise Knowledge On 7.1.6, this international standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure the operation of its processes and to achieve adaptation of products and services. Requirements regarding organizational knowledge were presented for the purpose of: a) protecting the organization from loss of knowledge, for example — through employee turnover; — failure to capture and share information; b) Encouraging the organization to acquire knowledge, for example — learning from experience; — mentoring; - Benchmark. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 23 ISO 9001:2015(e) A.8 control processes, products and services provided from the outside all forms of processes, products and services provided from outside are handled in 8.4, for example, whether through: a) a satisfying purchase; b) arrangement with a partner company; c) Outsourcing processes to a third party. Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed on the interface between the provider and the organization. The controls required for external allocation may vary widely depending on the nature of processes, products, and services. The organization can apply risk-based thinking to determine the type and scope of controls appropriate for certain third parties and the processes, products, and services provided from outside. 24 Licensed Department of Medical Sciences / warangkana oncoung ([Protected E-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single User License Only, Copying and Netweke is prohibited. © ISO 2015 – All Rights Reserved ISO 9001:2015(e) Appendix B (Informative) Other International Standards on Quality Management and Quality Management Systems Developed by ISO/TC 176 Devices described in this wing were developed by ISO/TC 176 to provide supporting information for organizations that apply this international standard, and to provide guidance to organizations that choose to move beyond their requirements. Guidance or requirements contained in the documents listed in this Appendix do not add or change the requirements of this international standard. Table B shows the relationship between these standards and the relevant statements of this international standard. This addendum does not include reference to sector-specific quality management system standards developed by ISO/TC 176. This international standard is one of three core standards developed by ISO/TC 176. — ISO 9000 quality management systems — basics and vocabulary provide a vital backdrop for proper understanding and implementation of this international standard. The principles of quality management are described in detail in iso 9000 standard and were taken into account during the development of this international standard. These principles are not requirements themselves, but they form the basis of the requirements specified by this international standard. ISO 9000 also defines the terms, definitions, and concepts used in this international standard. — ISO 9001 (this international standard) specifies requirements primarily to trust products and services provided by an organization, thereby improving customer satisfaction. A proper application can also be expected to bring other organizational benefits, such as improved internal communication, better understanding, and control of organizational processes. — ISO 9004 Management for continued enterprise success — Access to quality management provides guidance to organizations that choose to move beyond the requirements of this international standard to address a wider range of issues that can lead to improved overall enterprise performance. ISO 9004 includes guidance on self-esteem methodology so an organization can assess the maturity level of its quality management system. The international standards listed below can provide assistance to organizations as they establish or seek to improve their quality management systems, processes, or activities. — ISO 10001 Quality Management — Customer Satisfaction — Guidelines for codes of conduct for organizations provide guidance to the organization in determining customer satisfaction and meet customer needs and expectations. Its use can improve customer confidence in your organization and improve customers' understanding of what to expect from an organization, reducing the likelihood of misunderstandings and complaints. — ISO 10002 Quality Customer Satisfaction - Guidelines for handling complaints in organizations provide guidance on the process of handling complaints by recognizing and addressing the needs and expectations of complainants and resolving any complaint received. ISO 10002 provides an open, efficient and easy-to-use complaints process, including people's training. It also provides training for small businesses. — ISO 10003 Quality Management — Customer Satisfaction — External Enterprise Dispute Resolution Guidelines provides effective and effective external dispute resolution guidance for © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected email]) ISO Invitation Store: OP-111383 / Download: 2015-12-25 Single User License Only Copying and networking are prohibited. 25 product complaints related to product 25 ISO 9001:2015(e). Dispute resolution gives an avenue of correction when organizations do not amend an internal complaint. Most complaints can be resolved successfully within the organization, without conflict proceedings. — ISO 10004 Quality Management — Customer Satisfaction — Monitoring and Measurement Guidelines provide guidelines for actions to improve customer satisfaction and set opportunities to improve customer-valued products, processes, and features. Such actions can strengthen customer loyalty and help keep customers safe. — ISO 10005 Quality Management Systems — Guidelines for quality programs provide guidance on establishing and using quality programs as a means of addressing requirements related to the process, product, project, or contract, practices, and practices that support product implementation. The benefits of establishing a quality plan are increased confidence that the requirements will be met, that processes are under control and the motivation that it can give to those involved. — ISO 10006 Quality Management Systems — Guidelines for quality management in projects apply to large to small projects, from a simple and complex project, from a single project to being part of a portfolio of projects. ISO 10006 will be used by project management personnel and must ensure that their organization implements the procedures included in ISO quality management system standards. — ISO 10007 Quality Management Systems — Configuration management guidelines are to help organizations apply configuration management for the technical and administrative direction across the product lifecycle. Configuration management can be used to meet the product identification and tracking capability requirements specified in this international standard. — ISO 10008 Quality Management — Customer Satisfaction — Guidelines for Consumer-Business E-Commerce Transactions Provide Guidance on How Organizations Can An efficient and efficient business-to-consumer e-commerce transaction system (B2C ECT), thereby providing a basis for consumers to have increased confidence in B2C ECTs, improve the ability of organizations to satisfy consumers and help reduce complaints and disputes. — ISO 10012 Measurement Management Systems — Requirements for measurement processes and measuring equipment provide guidance for managing measuring processes and nuisance approval of equipment measurement used to support and demonstrate compliance with theological requirements. ISO 10012 provides quality management criteria for a measurement management system to ensure that the metrological requirements are met. — ISO/TR 10013 guidelines for documenting a quality management system provide guidelines for developing and maintaining the documentation required for a quality management system. ISO/TR 10013 can be used for document management systems other than ISO quality management system standards, such as environmental management systems and safety management systems. — ISO 10014 Quality Management — Guidelines for realizing financial and economic benefits addressed to senior management. It provides guidelines for realizing economic and economic benefits by implementing quality management principles. It facilitates the implementation of principles of management and selection of methods and tools that enable the sustainable success of an organization. — ISO 10015 Quality Management — Training Guidelines provide guidance for helping organizations address training-related issues. ISO 10015 can be applied whenever guidance is required to interpret education and training references in ISO quality management system standards. Each reference to training includes all types of education and training. — ISO/TR 10017 Guidance on Statistical Techniques for ISO 9001:2000 explains statistical techniques that track the variance that can be viewed in the behavior and results of processes, even under conditions of apparent stability. Statistical techniques enable better use of available data to help make decisions, helping to continuously improve the quality of products and processes to achieve customer satisfaction. 26 Licensed Department of Medical Sciences / warangkana oncoung ([Doel Protected]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and netweke is prohibited. © ISO 2015 – All Rights Reserved ISO 9001:2015(E) — ISO 10018 Quality Management — Guidelines on People Engagement and Capability provides guidelines that affect people's engagement and capability. Quality management system depends on the involvement of talented individuals and how they are presented and integrated into It is important to determine, develop and evaluate the knowledge, skills, behavior and work environment required. — ISO 10019 guidelines for selecting quality management system consultants and using their services provide guidance for selecting quality management system consultants and using their services. It provides guidance on the process for evaluating the competency of a quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met. — ISO 19011 guidelines for audit management systems provide guidance on audit program management, management system audit planning, as well as auditor and audit staff competency and evaluation. ISO 19011 is designed to apply to accountants, organizations that implement management systems, and organizations that need to audit management systems. Table B.1 — Relationship between other International Standards on quality management and quality management systems and the clauses of this International Standard Other International Standard ISO 9000 ISO 9004 ISO 10001 ISO 10002 Clause in this International Standard 4 All All ISO 10003 ISO 10004 ISO 10005 ISO 10006 ISO 10007 All 5 All All 5.3 All 6 7 All All All All 6.1, 6.2 All All All 8 All All 9 All All 8.2.2, 8.5.1 9.1.2 8.2.1, All All 8.5.2 9.1.2 9.1.2 9.1.2, 9.1.3 9.1 All 10 All All 10.2.1 10.2 All ISO 10008 All All All All All All All ISO 10014 All All All All All All All ISO 10018 All All All All All All All ISO 10012 ISO/TR 10013 ISO 10015 ISO/TR 10017 ISO 10019 ISO 19011 7.1.5 7.5 7.2 6.1 7.1.5 8.4 9.1 9.2 NOTE All indicates that all the subclauses in the specific clause of this International Standard are related to the Another international standard. © ISO 2015 – All rights reserved authorized to department of medical sciences / warangkana oncoung ([protected e-e-op]) ISO Store Order: OP-111383 / Download: 2015-12-25 Single user license only, copying and monitor prohibited. 27 ISO 9001:2015(e) Bibliography [1] ISO 9004, Management for Continued Enterprise Success — Access to Quality Management [3] ISO 10002, Quality Management — Customer Satisfaction — Guidelines for Handling Complaints in Organizations [2] [4] [5] [6] [7] ISO 10001, Quality Management — Customer Satisfaction — Guidelines for Conduct Codes for ISO 10003 Organizations, Quality Management — Customer Satisfaction — External Dispute Resolution Guidelines for ISO 10004 Organizations, Quality Management — Customer Satisfaction — ISO 10005 Monitoring and Measurement Guidelines, Quality Management Systems — GUIDELINES FOR ISO 10006 Quality Plans, Quality Management Systems — Guidelines for Quality Management projects ISO 10007, Quality Management Systems — Configuration Management Guidelines [10] ISO 10012, Measurement Management Systems — Requirements for Measurement Processes and Measuring Equipment [9] [11] [12] [13] ISO 10008, Quality Management — Customer Satisfaction — Guidelines for ISO/TR Consumer Business E-Commerce Transactions 10013, Guidelines for Documenting ISO 10014 Quality Management System, Quality Management — Guidelines for Realizing ISO Financial and Economic Benefits Quality Management - Training Guidelines [14] ISO/TR 10017, Statistical Training techniques for ISO 9001:2000 [16] ISO 10019, Guidelines for Selecting Quality Management System Advisors and Using Their Services [18] ISO 19011 Guidelines for Audit Management Systems [20] ISO 37500, Outsourcing Training [22] IEC 60300-1, Reliability Management — Part 1: Management and Implementation Training [15] [17] [19] ISO 10018 Quality Management - Guidelines for People Engagement and ISO 14001 Capability, Environmental Management Systems — Requirements with ISO 31000 , Risk Management — Principles and Guidelines [21] ISO/IEC 90003, Software Engineering — GUIDELINES FOR ISO 9001:2008 FOR COMPUTER SOFTWARE [23] IEC 61160, Design Review [25] Selecting and Using a Family of ISO 9000, ISO1) Standards [24] [26] [26] Quality Management Principles, ISO1) ISO 9001 for Small Business — What to Do, ISO1) 1) is available from the website: . 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