ISO 9001:2015
Quality Management System
Assessment Checklist
RP-2

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The *Quality System Checklist* is intended to help you gain a better understanding of the requirements of ISO 9001:2015. ISO 9001:2015 requires the adoption of the process approach which extends to internal quality audits. *This checklist follows the structure of the standard, thus it is not process based. For this reason it is not intended to be used as the only tool for internal quality audits*.

You can gain a better understanding of ISO 9001:2015 Standard as it applies to your company by reviewing these questions. You may wish to discuss them with your auditors to enhance everyone's understanding of the ISO 9001:2015 requirements and the assessment process.

You should be aware that although the following questions include most of the requirements of the ISO 9001:2015 standard, they do not necessarily cover all aspects of the Standard. So, the use of this checklist will give you only a sample of your organization's conformance to the ISO 9001:2015 standard.

Assessment Summary Sheet

The *Assessment Summary Sheet* may be used for visualizing the big picture: what areas were checked and where discrepancies were found. You'll see from the sample *Assessment Summary Sheet* that assessment of the Purchasing Process uncovered discrepancies for clauses 4.1, 5.3, 7.1.5, 8.1, 8.2, 8.3.1 and 8.5.3. This may be a sign of problems in that process, which warrant planning and close monitoring of corrective actions. The *Processes Assessed* column reveals that for clause 7.1.2 for *Resource Requirements or 8.2 for Determination of requirements for products and services*, discrepancies were uncovered in all applicable areas. This may give evidence of a system breakdown.

On the sample *Assessment Summary Sheet*, the circled numbers correspond to the following:

① The *ISO 9001:2015 Assessment Standard* correspond to the ISO9001:2015 International Standard which your company has selected for assessment.

② The column Process *Assessed* lists the areas (i.e. process) where compliance to given clauses will be evaluated.

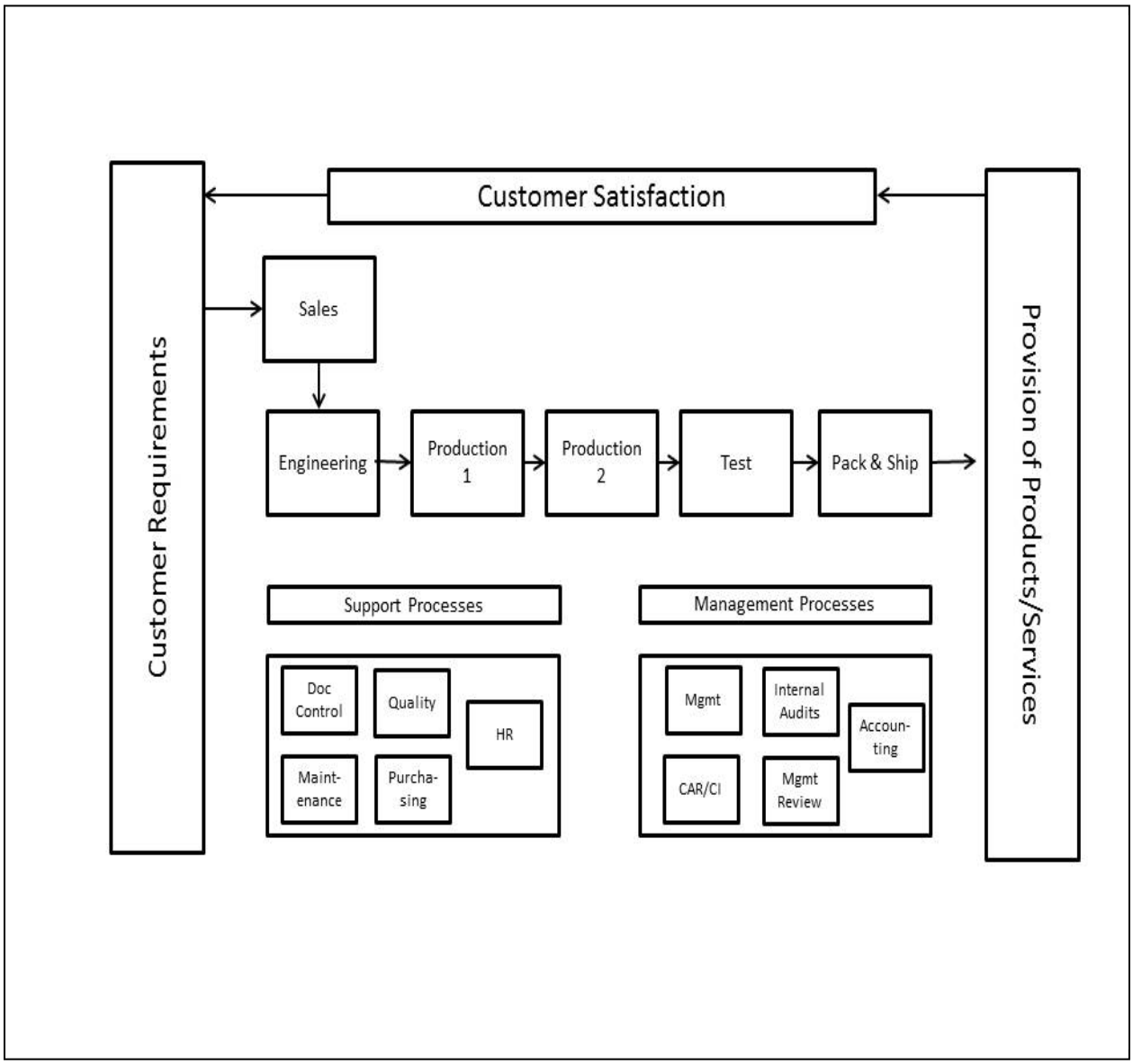
③ These columns contain the list of clauses for the applicable ISO Standard to which compliance is being sought. NOTE: All clauses of the ISO 9001 Standard must be addressed. *See section 0.1. "Forward", for further information.*

④ Use this grid to indicate where discrepancies are found by entering a "D" into the corresponding boxes. Where no discrepancies are uncovered, enter an "X" in the appropriate boxes.

0.2 Process Approach

ISO9001:2015 promotes the adoption of a process approach. As a first step, all processes of the organization need to be identified and their interrelation defined. A process is a set of activities that transform inputs into outputs. The outputs of one process may be the input of another process, or the finished product. Although a process map is not required, it is an effective method for demonstrating process interrelation. Any other method will equally meet the requirements of the standard as long as the process interaction is somehow shown.

An example of a typical process map is noted on the next page. Please note that a process map is not a process flow diagram, but merely highlights the main processes of the organization that are needed to be effectively monitored to ensure “consistent and predictable results”. Also, the processes noted are not the names of the functions within the organization, but value added activities within the organization that may involve sub-processes that will have to be further defined.


Customer Satisfaction
Customer Requirements
Sales
Engineering
Production 1
Production 2
Test
Pack & Ship
Provision of Products/Services
Support Processes
Doc Control
Quality
HR
Maint-enance
Purcha-sing
Management Processes
Mgmt
Internal Audits
Accoun-ting
CAR/CI
Mgmt Review

Assessment Summary Sheet – SAMPLE

	ISO 9001:2015 ①	Processes of the Organization ②																	Discrepancy Reference Number
	Quality Management Systems: Requirements	Management	Sales	Engineering	Cust. Sat.	Purchasing	Production 1	Production 2	Test	Pack & Ship	HR	Maintenance	Doc. Control	Quality	CAR/CI	Internal Audits	Mgt. Review	Accounting	
Clause Number	Clause Description ③																		
4.1	Understanding the organization and its context	X															X		
4.2	Needs and Expectations of the Interested Parties	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
4.3	Determining the scope of the quality management system	X																	
4.4	Quality Management System and its processes	X																	
5.1	Leadership and commitment	X															X		
5.2	Quality Policy	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
5.3	Organizational roles, responsibilities and authorities	X	X	X	X	D	X	X	X	X	X	X	X	X	X	X	X	X	
6.1	Actions to address risks and opportunities	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
6.2	Quality objectives and planning to achieve them	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
6.3	Planning of changes	D								X									
7.1	Resources	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
7.1.1	General			X															
7..1.2	People	D	D	D	D	D	D	D	D	D	D	D							
7.1.3	Infrastructure	X	X				X	X	X	X		X						X	
7.1.4	Environment for the operation of processes	X	X	X			X	X	X	X		X						X	
7.1.5	Monitoring and Measuring			X		D	X	X	X			X							
7.1.6	Organizational Knowledge	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
7.2	Competence	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
7.3	Awareness	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
7.4	Communication	X					X	X									X		

	ISO 9001:2015 ①	Processes of the Organization ②																	Discrepancy Reference Number
	Quality Management Systems: Requirements	Management	Sales	Engineering	Cust. Sat.	Purchasing	Production 1	Production 2	Test	Pack & Ship	HR	Maintenance	Doc. Control	Quality	CAR/CI	Internal Audits	Mgt. Review	Accounting	
Clause Number	Clause Description ③																		
7.5	Documented Information	X	X	X	X	X	X	X	X	D	X	X	X	X	X	X	X	X	
7.5.1	General	X																	
7.5.2	Creating and updating	X												X					
7.5.3	Control of documented Information	X												X					
8.1	Operational planning and control	X	X	X	X	D	X	X	X	X									
8.2	Determination of requirements	D	D	D	D	D	D	D	D	D									
8.2.1	Customer communication	X	X	X															
8.2.2	Determination of requirements related to products and services		x	X															
8.2.3	Review of requirements related to products and services		X																
8.2.4	Changes to requirements		X																
8.3	Design and Development	X		X					X				X	X	X				
8.3.1	General	X	X	X	X	D	X	X	X	X									
8.3.2	Design and development planning	X		X															
8.3.3	Design and development inputs	X		X															
8.3.4	Design and development controls.	D		X						X			④						
8.3.5	Design and development Outputs			X					X										
8.3.6	Design and development changes			X					X										
8.4.2	Type and extent of control of external provision					X													
8.4.3	Information for external providers					X													
8.5.1	Control of production and Service		X			X													

	ISO 9001:2015 ①	Processes of the Organization ②																	Discrepancy Reference Number
	Quality Management Systems: Requirements	Management	Sales	Engineering	Cust. Sat.	Purchasing	Production 1	Production 2	Test	Pack & Ship	HR	Maintenance	Doc. Control	Quality	CAR/CI	Internal Audits	Mgt. Review	Accounting	
Clause Number	Clause Description ③																		
8.5.2	Identification and traceability			X			X	X	X	X									
8.5.3	Property belonging to customers or external providers					D													
8.5.4	Preservation			X			X	X	X	X									
8.5.5	Post-delivery activities		X				X	X		X									
8.5.6	Control of changes	X	X	X															
8.6	Release of products and services						X	X		X									
8.7	Control of nonconforming products						X	X	X	D				X	X				
9.1.1	Monitoring, measurement, analysis	X	X	X	X	X	X	X	X	D	X	X	X	X	X	X	X		
9.1.2	Customer Satisfaction	X	X		X														
9.1.3	Analysis and evaluation	X	X	X	X	X	X	X	X	D	X	X	X	X	X	X	X		
9..2	Internal Audits	X													X				
9.3	Management Review	X														X			
10.1	Improvement – General	X	X	X	X	X	X	X	X	D	X	X	X	X	X	X	X		
10.2	Nonconformity/Corrective Action						X	X	X	D				X	X				
10.3	Continual improvement	X	X	X	X	X	X	X	X	D	X	X	X	X	X	X	X		

*** Use an "X" to indicate that the clause was assessed in the area described.**
Use a "D" to indicate that a discrepancy was found.

Assessment Summary Sheet

	ISO 9001:2015 ①	Processes of the Organization ②																	Discrepancy Reference Number
	Quality Management Systems: Requirements																		
Clause Number	Clause Description ③																		
4.1	Understanding the organization and its context																		
4.2	Needs and Expectations of the Interested Parties																		
4.3	Determining the scope of the quality management system																		
4.4	Quality Management System and its processes																		
5.1	Leadership and commitment																		
5.2	Quality Policy																		
5.3	Organizational roles, responsibilities and authorities																		
6.1	Actions to address risks and opportunities																		
6.2	Quality objectives and planning to achieve them																		
6.3	Planning of changes																		
7.1	Resources																		
7.1.1	General																		
7..1.2	People																		
7.1.3	Infrastructure																		
7.1.4	Environment for the operation of processes																		
7.1.5	Monitoring and Measuring																		
7.1.6	Organizational Knowledge																		
7.2	Competence																		
7.3	Awareness																		
7.4	Communication																		

	ISO 9001:2015 ①	Processes of the Organization ②																	Discrepancy Reference Number
	Quality Management Systems: Requirements																		
Clause Number	Clause Description ③																		
7.5	Documented Information																		
7.5.1	General																		
7.5.2	Creating and updating																		
7.5.3	Control of documented Information																		
8.1	Operational planning and control																		
8.2	Determination of requirements																		
8.2.1	Customer communication																		
8.2.2	Determination of requirements related to products and services																		
8.2.3	Review of requirements related to products and services																		
8.2.4	Changes to requirements																		
8.3	Design and Development																		
8.3.1	General																		
8.3.2	Design and development planning																		
8.3.3	Design and development inputs																		
8.3.4	Design and development controls.																		
8.3.5	Design and development Outputs																		
8.3.6	Design and development changes																		
8.4.2	Type and extent of control of external provision																		
8.4.3	Information for external providers																		
8.5.1	Control of production and Service																		

	ISO 9001:2015 ①	Processes of the Organization ②																	Discrepancy Reference Number
	Quality Management Systems: Requirements																		
Clause Number	Clause Description ③																		
8.5.2	Identification and traceability																		
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8.5.4	Preservation																		
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8.5.6	Control of changes																		
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9.1.1	Monitoring, measurement, analysis																		
9.1.2	Customer Satisfaction																		
9.1.3	Analysis and evaluation																		
9..2	Internal Audits																		
9.3	Management Review																		
10.1	Improvement – General																		
10.2	Nonconformity/Corrective Action																		
10.3	Continual improvement																		

*** Use an "X" to indicate that the clause was assessed in the area described. Use a "D" to indicate that a discrepancy was found**.

On the following pages, ▲ indicates new/significantly changed requirements.

Quality Management System Checklist			
ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
4	*Context of the organization*		
4.1	*Understanding the organization and its context*		
4.1 ▲	Has the organization identified all external and internal issues relevant to its purpose and direction?		
4.1 ▲	What is the process for monitoring and review of the external and internal issues?		
4.2	*Understanding the needs and expectations of interested parties*		
4.2 ▲	Has the organization identified all relevant interested party requirements that are relevant to the quality management system? How is the information monitored?		
4.3	*Determining the scope of the Quality Management System*		
4.3 ▲	Is the scope of the quality management system, including products and services provided and justification for any exclusion, defined?		
4.3 ▲	Is the scope of the quality management system maintained as documented information?		
4.3 ▲	Are the following considered when determining the scope? • External and Internal Issues • Requirements of relevant interested parties • The products and services provided.		
4.3 ▲	Is there assurance that all requirements of the standard that can be applied, have been applied by the organization and those determined non-applicable do not affect the organization's ability or responsibility to ensure conformity?		

ISO9001:2015 Clause #	Quality Management System Requirements	Documented Information Reference	Explanatory Notes and Comments
4.4	Quality Management System and its processes		
4.4	Have the processes of the organization been identified? • Inputs and Outputs • Sequence and interaction • Criteria, method and performance indicators • Resources needed • Defined responsibility and authority for all personnel. • Risks and Opportunities • Method for monitoring and change to ensure intended results • Opportunities for improvement of the processes		
4.4	Has the organization defined • Needed documented information to support the operation of its processes? • Documented information to be retained as evidence that the processes are being carried out as planned?		
5	Leadership		
5.1.1	Has top management demonstrated leadership by • Taking accountability of the process? • Establishing the Quality Policy and Objectives? • Communicating the Policy? • Ensuring QMS Requirements are integrated into the processes? • Making available adequate resources? • Communicating QMS effectiveness? • Ensuring achievement of results? • Engaging/directing/supporting process effectiveness? • Promoting continual improvement? • Supporting other management roles within the organization to do the same?		

ISO9001:2015 Clause #	Quality Management System Requirements	Documented Information Reference	Explanatory Notes and Comments
5.1.1	Can top management demonstrate evidence of commitment to the development, implementation and improvement of the effectiveness of the quality management system by: • Communicating to the organization the importance of meeting customer requirements? • Establishing the quality policy? • Ensuring that quality objectives are established? • Conducting management reviews? • Ensuring the availability of resources?		
5.1.2	*Customer Focus*		
5.1.2	Has top management demonstrated leadership by • Identifying customer requirements? • Identifying regulatory requirements? • Identifying statutory requirements? • Risks and Opportunities determined and addressed? • Focus to consistently provide products/services that meet customer requirements? • Enhancing customer satisfaction?		
5.2	*Quality Policy*		
5.2.1	Has top management established a quality policy that • Is appropriate to the organization? • Allows for review of process indicators and objectives? • Includes a commitment to satisfy applicable requirements? • Includes a commitment to continual improvement? • Is communicated and understood throughout the organization • Is reviewed for continuing suitability?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
5.2.1 ▲	Are the quality objectives measurable and consistent with the quality policy?		
5.2.2 ▲	Is the quality policy • Documented? • Communicated and understood? • Available to relevant interested parties?		
5.3	*Organizational roles, responsibilities and authorities*		
5.3 ▲	Has top management defined • Responsibility and authority for all personnel affecting quality? • Ensuring that the processes are effective and delivering their intended results? • Reporting on the performance of the QMS and opportunities? • Ensuring Customer Focus throughout the organization? • Maintaining the integrity of QMS when changes are implemented?		
6	*Planning for the Quality Management System*		
6.1.1 ▲	Has the organization considered risks and opportunities noted in 4.1 and 4.2 and have assurances that QMS • Can achieve its intended results? • Mitigate Risk by prevention or reduction of undesired effects? • Enhance desirable effects? • Achieve improvements?		
6.1.2 ▲	Does the organization plan • Actions needed to address risks and opportunities? • Integrate actions into its QMS processes? • Evaluate the effectiveness of actions?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
6.2.1 ▲	Has the organization established Quality objectives that are: • Consistent with the Quality Policy? • Are measurable? • Considered applicable requirements? • Relevant? • Monitored? • Communicated? • Updated?		
6.2.2 ▲	Has the organization planned how to achieve its quality objectives by • Identifying what has to be done? • Identifying the needed resources? • Identifying the responsibility for achievement? • Due date for achievement? • Evaluation of the results?		
6.3 ▲	For changes to the QMS, has the organization proceeded in a planned and systemic manner by • Identifying the changes and their consequence? • The integrity of the QMS? • Availability of resources? • Allocation or reallocation of responsibilities and authorities?		
7	*Support*		
7.1.1 ▲	Has the organization determined the needed resources while considering • Limitations of internal resources? • What has to be obtained from external providers?		
7.1.2	*People*		
7.1.2	Are adequate human resources in place to ensure compliance with the customer and applicable regulatory and statutory requirements?		

ISO9001:2015 Clause #	Quality Management System Requirements	Documented Information Reference	Explanatory Notes and Comments
7.1.3	*Infrastructure*		
7.1.3	Has the organization identified the infrastructure needed for effective operation of the QMS, , including • Maintenance of equipment? • Buildings and associated utilities? • Transportation? • Information and Communication Technology?		
7.1.4	*Environment for the operation of processes*		
7.1.4	How will it be demonstrated that the organization determines and manages the work environment needed to achieve conformity to product and service requirements?		
7.1.5	*Monitoring and measuring resources*		
7.1.5	Has the organization determined the monitoring and measurement to be undertaken, and the monitoring and measurement resources needed to provide evidence of conformity to determined requirements?		
7.1.5	Are suitable monitoring and measuring resources available to ensure valid and reliable results, including • Ensuring suitable resources? • Resources are maintained to ensure their continued fitness for their purpose? • Maintaining documented information as evidence of fitness of the monitoring and measuring resources? • Determining suitability of the specific type of monitoring and measurement activities?		
7.1.5	Have all monitoring and measuring activities determined?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
7.1.5	Are monitoring and measuring resources • Suitability maintained?		
7.1.5	What documented information is maintained as evidence of fitness for the monitoring and measurement resources?		
7.1.5	• Is measuring equipment calibrated or verified, or both, at specified intervals or prior to use against traceable international or national measurement standards? (If international or national measurement standards are not available, the basis for calibration or verification shall be defined) • Identified in order to determine its calibration status? • Safeguarded from adjustments that would invalidate the measurement result? • Protected from damage and deterioration during handling, maintenance and storage?		
7.1.5	How will it be demonstrated that: • The validity of previous measuring results are assessed by the organization when equipment is found not to conform to requirements? • Appropriate action is taken on the equipment and any affected product?		
7.1.6	*Organizational Knowledge*		
7.1.6 ▲	What evidence is available to ensure that the organization has determined the knowledge necessary for effective operation of its processes?		
7.1.6 ▲	Is the knowledge necessary for the operation of the various processes determined, maintained, and made available, if needed?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
7.2	*Competence*		
7.2	Has the necessary competence for personnel performing work affecting conformity to product requirements been determined? • Appropriate documented information for education, training, skills and experience are maintained?		
7.2	Where applicable, is the Training provided or other actions taken evaluated for effectiveness in meeting the necessary competence?		
7.2	Are Personnel aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?		
7.2	Are documented information maintained to demonstrate competency achievements thru education, training, skills and experience?		
7.3	*Awareness*		
7.3	Are methods in place to ensure understanding of the following by all affected personnel: • The quality policy? • Relevant Quality Objectives? • Contributions to the effectiveness of the quality management system? • Benefits of improved quality performance? • Implications of not conforming with the quality management system requirements?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
7.4	*Communication*		
7.4 ▲	Have the following been addressed for all internal and external communication channels? • Subject of Communication? • When to communicate? • With whom? • How? • Who?		
7.4 ▲	Is Leadership able to demonstrate how they ensure that appropriate communication processes are established within the organization, and that communication takes place regarding the effectiveness of the quality management system?		
7.5	*Documented Information*		
7.5.1 ▲	Does the organization's quality management system include • Documented information required by ISO9001:2015? • Documented information determined by the organization to be necessary for the effectiveness of the quality management system?		
7.5.2	Are all documented information • Properly identified (e.g. title, date, author or reference)? • In defined format – language, software version, graphics, media? • Reviewed and approved for adequacy?		
7.5.3.1	Are all documented information controlled to ensure • Its suitability and availability? • Adequately protected from use or improper use?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
7.5.3.2	Have the following issues addressed for control of Documented Information; • Distribution, control, access, retrieval and use? • Storage and preservation, including legibility? • Control of changes (version control)? • Retention and disposition? • Identification and control of documents of external origin?		
8	*Operation*		
8.1	Are adequate actions in place to ensure effective planning, implementation and control of the processes, including, the methods needed to ensure • Adequate identification of requirements for products and services? • Establishment of criteria for products and services? • Determination of needed resources? • Implementation of the processes in accordance with the noted criteria? • Retention of documented information to show process effectiveness, and to demonstrate conformity of products and services to requirements?		
8.1 ▲	• How are the consequences of unintended changes controlled, and how are actions take to mitigate their adverse effects?		

ISO9001:2015 Clause #	Quality Management System Requirements	Documented Information Reference	Explanatory Notes and Comments
8.2	Determination of requirements for products and services		
8.2.1	Is there a process in place for communicating with customers in relation to: • Information related to products and services? • Handling of enquiries, contracts, including changes? • Obtaining customer views and perceptions, including customer complaints? • Handling customer supplied property? • Requirements of actions for contingencies?		
8.2.2	Have the processes been implemented for • Identification of product requirements, including applicable statutory and regulatory requirements? • Ability to meet the defined requirements and substantiate the claims for the products or services?		
8.2.3	How are the following requirements determined? • Customer specified requirements including delivery and post-delivery. • Requirements not stated by the customer but necessary for specified or intended use when known. • Statutory and regulatory requirements applicable to the product. • Any additional requirements considered necessary by the organization.		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.2.3	Is there a process in place to • Review requirements specified by the customer? • Consider requirements not stated by the customer, but necessary? • Identify the applicable statutory and regulatory requirements for the products or services? • Handle order changes? • Review of customer orders prior to order acceptance? Also, are documented information maintained as a result of the review and handling of change orders.		
8.2.3	Are Requirements related to the product reviewed prior to the commitment to supply a product to the customer?		
8.2.3	Does the review activity ensure: • Product requirements are defined? • Contract or order requirements differing from those previously expressed are resolved? • The organization's ability to meet defined requirements?		
8.2.3	How will it be demonstrated that the organization confirms customer requirements when no documented statement of requirement is provided by the customer?		
8.2.4	How will the relevant documented information amended, and persons made aware of the changes, when the requirements are changed?		
8.3	*Design and development of products and services*		
8.3.2	Is evidence available that the organization plans and controls the design and development of products and services, considering the nature, duration and complexity of the design activities?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.3.2	Is the following determined during design and development planning? • The design and development stages • The review, verification and validation appropriate to each design and development stage. • The responsibilities and authorities for design and development.		
8.3.2	Are the interfaces between different groups involved in design and development managed to ensure effective communication and clear assignment of responsibility, including involvement of customer and/or user groups?		
8.3.2	Are documented information maintained to demonstrate that the design and development requirements have been met?		
8.3.3	*Design and development Inputs*		
8.3.3	Are inputs relating to product requirements determined and documented information maintained relating to: • Functional and performance requirements? • Applicable statutory and regulatory requirements? • Applicable information from previous similar designs? • Other requirements essential for design and development? • Level of control by customers and other relevant interested parties.		
8.3.3	What evidence is available to indicate that • Design and development inputs are reviewed for adequacy? • Requirements are complete, unambiguous and not in conflict with each other?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.3.4	*Design and development controls*		
8.3.4	Are controls in place to ensure • The results to be achieved are clearly defined? • Design and Development reviews are planned and conducted? • Verification activities are conducted to ensure all inputs are met? • Validation is conducted to ensure suitability for the intended use?		
8.3.4	Is verification performed to ensure that design and development outputs have satisfied the design and development input requirements?		
8.3.4	Is design and development validation conducted to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application?		
8.3.5	*Design and development outputs*		
8.3.5	Are controls in place to ensure • Input requirements have been met? • Outputs are adequate for the subsequent processes of the provision of products and services? • Identification of monitoring and measuring requirements, and the acceptance criteria? • Designed products are fit for intended purpose and their safe and proper use?		
8.3.5	Are documented information maintained for the design and development activities?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.3.6	*Design and development changes*		
8.3.6	Are design and development changes: • Controlled during, and after, the design and development process? • Identified? • Reviewed? • Verified and validated as appropriate? • Evaluated for effect on constituent parts and delivered products? • Approved before implementation? • Considered to have no adverse impact on conformity to requirements		
8.3.6	Are documented information on results of changes and any necessary actions maintained?		
8.4	*Control of externally provided products and services*		
8.4.1	What processes exist to ensure that externally provided processes, products and services conform to specified purchase requirements?		
8.4.1	Are the requirements in 8.4.2 applied to all suppliers who • Provide products for incorporation in the products • Provide products directly to the customers • Provide full or partial outsourced process to the organization.		
8.4.1	Are external providers evaluated and selected, monitored for performance and re-evaluated based upon their ability to supply product in accordance with the organization requirements?		
8.4.1	Are documented information of the results of supplier evaluations and any necessary actions arising from evaluations maintained?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.4.2	*Type and extent of control*		
8.4.2	Does the external provider monitoring process take into consideration: • The type and extent of controls to be applied? • The potential impact of the externally provided processes, products and services on the ability to meet applicable statutory and regulatory requirements? • The perceived effectiveness of the controls applied by the external provider?		
8.4.2	Have necessary verification processes been implemented to ensure the externally provided processes, products and services do not adversely affect the organization's ability to meet customer requirements?		
8.4.2	Are controls of outsourced processes and functions remain within the scope of the organization's quality management system?		
8.4.2	Are documented information maintained as a result of evaluation, monitoring and re-evaluation of external providers?		
8.4.2	Have inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements been established and implemented?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.4.3	*Information for external providers*		
8.4.3	Does the organization ensure communication to external providers concerning: • Products and services to be provided or provided on behalf of organization? • Approval of products and services, methods, processes or equipment? • Competence of personnel, including needed qualification? • Interactions with the organization's quality management system? • Control and monitoring of the external provider's performance? • Notification of verification activities to be conducted by the organization at the external provider's premises?		
8.4.3	Is the adequacy of specified purchase requirements ensured prior to their communication to the supplier?		
8.5	*Production and Service provision*		
8.5.1	*Control of production and service provision*		
8.5.1	Are production and service operations carried out under controlled conditions?		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
8.5.1	What evidence is available to demonstrate that controlled conditions include the following, as applicable? • The availability of information that describes the characteristics of the product. • The availability of the required documented information. • The use of suitable equipment. • The availability and use of monitoring and measurement resources. • The implementation of monitoring and measurement. • The implementation of release, delivery and post-delivery activities. • The competency requirements or qualification of personnel. • The implementation of products and services release, delivery and post-delivery activities.		
8.5.1	Can it be demonstrated that measurement and monitoring of the product is carried out at various stages of the product realization process in accordance with planned arrangements?		
8.5.1	Are production and service processes validated, and periodically revalidated, where the resulting output cannot be verified by subsequent monitoring or measurement?		
8.5.2	*Identification and traceability*		
8.5.2	Are process outputs identified, as appropriate, by suitable means throughout the product/service realization process?		
8.5.2	Is product status identified with respect to measuring and monitoring requirements throughout product realization?		
8.5.2	Is traceability a specified requirement? If so, is unique identification of the product outputs controlled and documented information maintained to ensure adequate traceability?		

ISO9001:2015 Clause #	Quality Management System Requirements	Documented Information Reference	Explanatory Notes and Comments
8.5.3	*Property belonging to customers or external providers*		
8.5.3	Is customer property provided for the use or incorporation into the product under the control or use of the organization? If so, does a process exist which ensures that care is provided for customer or external provider property?		
8.5.3	Is the organization reporting to the customer or external provider, when their property is incorrectly used, lost, damaged or otherwise found to be unsuitable for use?		
8.5.3	How will it be demonstrated that customer property is: Identified? Verified? Protected? Safeguarded?		
8.5.3	Is lost, damaged, or unsuitable product reported to the customer?		
8.5.4	*Preservation*		
8.5.4	How will it be demonstrated that product, and constituent parts of the product, are preserved during internal processing and delivery to the intended destination in order to maintain conformity to requirements?		
8.5.4	As applicable, are product preservation methods established, as appropriate, for: • Identification? • Handling? • Packaging? • Storage? • Protection?		
8.5.5	*Post-delivery activities*		
8.5.5 ▲	Is the organization meeting requirements for post-delivery activities?		

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8.5.5	With respect to post-delivery activities, are the following considered? • The risks associated • The nature, use and intended lifetime of the products and services • Customer feedback • Statutory and regulatory requirements		
8.5.6	*Control of changes*		
8.5.6	Are documented information maintained describing the results of the review of the changes, the personnel authorizing the change, and the necessary actions?		
8.6	*Release of products and services*		
8.6	Are planned arrangements in place to ensure achievement of the product and service requirements?		
8.6	Are documented information maintained as evidence of conformity with the acceptance criteria?		
8.6	Are controls in place to ensure that release of product and delivery of service to the customer do not proceed until all planned arrangements are satisfactorily completed? Do documented information identify the person authorizing the release?		
8.7	*Control of nonconforming outputs*		
8.7	Are products and services that do not conform to the requirements, identified and controlled to prevent their unintended use or delivery?		
8.7	Do the dispositions include any of the following? • Correction • Segregation, containment • Informing the customer • Obtaining authorization for use “as-is”, continuation or acceptance under concession.		
8.7	Are documented information maintained as evidence of conformity with the acceptance criteria?		

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8.7	Are corrected nonconforming products and services verified for compliance after rework?		
9	*Performance Evaluation*		
9.1.1 	Has the organization identified • What has to be monitored • The methods for monitoring, measurement, analysis, evaluation • When the monitoring to be performed • When the results to be analyzed.		
9.1.1 	Is documented information maintained to ensure that the monitoring and measurement activities are implemented in accordance with the above requirements?		
9.1.1 	Does this evaluation include review of the quality performance data to ensure effectiveness of the quality management system?		
9.1.2	*Customer Satisfaction*		
9.1.2	Is information relating to customer perception to whether the organization has fulfilled customer requirements monitored?		
9.1.2	Is information obtained related to customer views and opinions of the organization and its products and services?		
9.1.2	Is the method for obtaining and using the customer satisfaction information determined?		
9.1.3	*Analysis and evaluation*		
9.1.3	Does the organization analyze and evaluate the data arising from monitoring and measurement activities?		

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9.1.3	Is the organization using the sources of data to • Demonstrate conformity of products and services to requirements? • Assess and enhance customer satisfaction? • Ensure conformity of effectiveness of the quality management system? • Demonstrate that planning has been successfully implemented? • Assess the performance of processes? • Assess the performance of external providers? • Determine the need or opportunities for improvement within the quality management system?		
9.1.3 ▲	Are the results of the above analysis provided as input to management review?		
9.2	*Internal Audits*		
9.2.1 ▲	Does the internal quality audit activity determine whether the quality management system: • Conforms to planned arrangements? • Conforms to ISO 9001:2015? • Conforms to quality management system requirements established by the organization? • Is effectively implemented and maintained?		
9.2.2 ▲	Is evidence available to confirm that internal audits are conducted at planned intervals based upon: • The status and importance of the processes and areas to be audited? • The results of previous audits? • Customer feedback? • Changes impacting the organization?		
9.2.2	Have audit criteria, scope, frequency and methods been defined?		

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9.2.2	Is evidence available to confirm that internal auditors do not audit their own work, and are objective and impartial of the audit process?		
9.2.2	Does the management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes?		
9.2.2	Are documented information maintained as evidence of the implementation of the audit program and the audit results?		
9.3	*Management Review*		
9.3.1	Does top management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness?		
9.3.1	Does management review evaluate the need for changes to the quality management system, including the quality policy and quality objectives?		
9.3.1	Is documented information maintained as the result of management reviews?		
9.3.2	Do the inputs to management review include information on the following (including quality indicators (if any): • Results of audits • Customer Satisfaction • Nonconformities and Corrective Actions • Monitoring and measurement results • Issues concerning external providers and other relevant interested parties • Adequacy of resources • Process performance and conformity of products and services • Effectiveness of actions taken to address risks and opportunities. • Performance of external suppliers.		

ISO9001:2015 Clause #	*Quality Management System Requirements*	*Documented Information Reference*	*Explanatory Notes and Comments*
9.3.3	Do the outputs from management review include decisions and actions related to: • Improvement of the effectiveness of the quality management system and its processes? • Improvement of product related to customer requirements? • Resource needs?		
9.3.3	Are documented information maintained as evidence of management reviews?		
9.3.3 ▲	Does management review evaluate the need for changes to the quality management system, including the quality policy and quality objectives?		
10.1	*Improvement*		
10.1	Is the organization selecting opportunities for improvement and implementing necessary actions to meet customer requirements?		
10.1 ▲	Is the organization taking actions to prevent nonconformities, improve products and services, and improve the overall quality management system results?		
10.2	*Nonconformity and corrective action*		
10.2	In the presence of a nonconformity, does the organization • React to the nonconformity by taking actions to control and correct it, and dealing with its consequences? • Evaluate the need for action to eliminate the cause? • Implement any action needed? • Review the effective of any corrective action? • Make change to the quality management system?		
10.2 ▲	In the presence of a nonconformity, does the organization react to the nonconformity by taking actions to control and correct it, and dealing with its consequences?		

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10.2	Are actions taken appropriate to the effects, or potential effects of the nonconformity?		
10.2	Are corrective actions taken appropriate to the effects of the nonconformities encountered?		
10.2 ▲	Is action taken to eliminate the causes of nonconformities in order to prevent recurrence?		
10.2	Is documented information maintained to show the nature of the nonconformity and any subsequent actions taken, and the results of any corrective action taken?		
10.3	*Continual Improvement*		
10.3	Is the organization continually improving the suitability, adequacy and effectiveness of the quality management system?		
10.3	Are the outputs of analysis and evaluation, and the outputs from the management review process used to identify the areas of underperformances?		
10.3	Are specialized tools and methodologies used for investigation of the causes of underperformance?		
10.3 ▲	How is it demonstrated that the effectiveness of the quality management system is being continually improved?		

How to contact DQS Inc.

If you have additional questions or would like more information on how to proceed, please feel free to contact DQS Inc. at: 1-800-285-4476 from North America.

You can also access DQS Inc.'s website at www.***dqs****us.com* for more information.

Questions concerning any aspect of this document may be sent to

ISO9001_2015_Questions@dqsus.com