

ISO Clause	Question	Answer	Notes:
4.1	<p><u>General Requirements</u></p> <p>A quality management system has been established, documented, implemented, maintained, and continually improved?</p> <p>Does the quality management system include:</p> <p>a. identification of the processes needed for the quality management system?</p> <p>b. determination of the sequence and interaction of these processes?</p> <p>c. determined criteria and methods required ensuring the effective operation and control of these processes?</p> <p>d. the availability of information necessary to support the operation and monitoring of these processes?</p> <p>e. methods to measure monitor and analyze these processes?</p> <p>f. implemented action necessary to achieve planned results and continual improvement?</p> <p>Are processes that are outsourced that may affect product or service conformity identified and documented?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
4.2.1	<p><u>General Documentation Requirements</u></p> <p>Does the quality management system documentation include documented procedures and records required ensuring effective operation and control of its processes?</p> <p>Is the extent of the quality management system documentation appropriate to:</p> <p>a. Size and type of the organization?</p> <p>b. Complexity and interaction of the processes?</p> <p>c. Competence of personnel?</p> <p>Does the quality system documentation include:</p> <p>a. a documented quality policy and quality objectives?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

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	b. a quality manual? c. documented procedures required by ISO 9001:2000? d. documents required by the organization? e. quality records required by ISO 9001:2000?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
4.2.2	<u>Quality Manual</u> Has a quality manual been established which includes: a. Scope of quality system, including details and justifications for exclusions? b. Procedures or references to procedures? c. Sequence and interaction of QMS processes or reference to them?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
4.2.3	<u>Control of Documents</u> Are documents required for the quality management system controlled ? Is there a documented procedure for: a. the approval of documents for adequacy prior to issue? b. the review, updating as necessary and re-approval of documents? c. the identification of the current revision status of documents? d. ensuring that relevant versions of applicable documents are available at points of use? e. for ensuring that documents remain legible, readily identifiable and retrievable? f. for ensuring that documents of external origin are identified and their distribution is controlled? g. preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	

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4.2.4	<p><u>Control of Quality Records</u></p> <p>Are quality records for resources and system planning available?</p> <p>Do these records provide evidence of conformance to requirements and of effective operation of the quality management system?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.1	<p><u>Management Commitment</u></p> <p>How has top management demonstrated commitment to the development and improvement of the quality management system?</p> <p>a. communicating to the organization the importance of meeting customer as well as regulatory & legal requirements?</p> <p>b. establishing the quality policy?</p> <p>c. ensuring that quality objectives are established?</p> <p>d. conducting management reviews?</p> <p>e. Ensuring the availability of resources?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.2	<p><u>Customer Focus</u></p> <p>Does top management ensure that customer requirements are determined and fulfilled with the aim of achieving customer satisfaction?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.3	<p><u>Quality Policy</u></p> <p>Has as top management ensured that the quality policy:</p> <p>a. is appropriate to the purpose of the organization?</p> <p>b. includes a commitment to meeting requirements and to continual improvement?</p> <p>c. provides a framework for establishing and reviewing quality objectives?</p> <p>d. is communicated and understood at within the organization?</p> <p>e. is reviewed for continuing suitability?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

ISO Clause	Question	Answer	Notes:
5.4 5.4.1	<p><u>Planning</u></p> <p><u>Quality Objectives</u></p> <p>What are the quality objectives that have been established at relevant functions and levels within the organization?</p> <p>Are the quality objectives measurable and consistent with the quality policy?</p> <p>Do quality objectives include those needed to meet requirements for product/service?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.4.2	<p><u>Quality Management System Planning</u></p> <p>How has Top Management ensured that:</p> <p>a. processes of the quality management system are carried out in order to meet the requirements?</p> <p>b. is the output of quality planning documented how?</p> <p>c. are changes conducted in a controlled manner and is the integrity of the QMS maintained during changes?</p> <p>d. how and what method is used when planning changes that may affect the quality management system?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.5 5.5.1	<p><u>Responsibility, authority and Communication</u></p> <p><u>Responsibility and authority</u></p> <p>How are the functions and their interrelations within the organization, including responsibilities and authorities, defined and communicated?</p> <p>How is responsibility and authority defined?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.5.3	<p><u>Internal Communications</u></p> <p>What communication channels have been established within the organization relating to quality management system effectiveness?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

ISO Clause	Question	Answer	Notes:
5.6	<p><u>General - Management Review</u></p> <p>Does top management review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness?</p> <p>What is the interval?</p> <p>Does the review evaluate the need for changes to the quality management system, including quality policy and quality objectives?</p> <p>How are opportunities for improvement and changes needed within the quality system evaluated and documented?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.6.2	<p><u>Review Input</u></p> <p>Do inputs to management review include current performance and improvement opportunities related to the following:</p> <p>a. results of audits?</p> <p>b. customer feedback?</p> <p>c. process performance and product conformance?</p> <p>d. status of preventive and corrective actions?</p> <p>e. follow-up actions from earlier management reviews?</p> <p>f. planned changes that could affect the quality management system?</p> <p>g. recommendations for improvement?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
5.6.3	<p><u>Review Output</u></p> <p>Do outputs to management review include current performance and improvement opportunities related to the following:</p> <p>a. improvement of the effectiveness of the QMS and its processes?</p> <p>b. improvement of product or service related to customer requirements?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

ISO Clause	Question	Answer	Notes:
	c. resource needs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6 6.1	<u>Resource Management</u> <u>Provision of resources</u> How have resources needed to implement and improve quality management system processes been provided? Are there adequate resources available to implement and maintain the QMS and to continually improve its effectiveness? Are resources available to ensure that customer satisfaction is enhanced? Are there defined responsibilities and authorities of all personnel who can affect quality?	 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
6.2.2	<u>Competence, Awareness and Training</u> Are personnel assigned responsibilities in the quality management systems qualified and deemed competent based on skills, experience, and education & training requirements? How has the organization: a. determined the necessary? b. competency for personnel? c. provided training to satisfy competency needs? d. evaluated the effectiveness of actions taken? e. ensured that its personnel are aware of their part in the QMS? f. maintained appropriate records of education, training, skills, and experience?	 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
6.3	<u>Infrastructure</u> Is the infrastructure of the organization such that: a. buildings, workspace, and associated utilities are determined, provided, and maintained? b. process equipment, hardware, and software	 <input type="checkbox"/> Yes <input type="checkbox"/> No	

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	are determined, provided, and maintained? c. supporting services such as transportation or communication are determined, provided, and maintained?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
6.4	<u>Work Environment</u> Does the organization identify and manage the human and physical factors of the work environment needed to achieve conformity of product/service?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7.1	<u>Planning of Product (Service) Realization</u> Is planning of the realization processes consistent with the other requirements of the organization's quality management system? Are realization processes documented in a form suitable for the organization's method of service deliver and/or operation? In planning product realization, has the organization determined: a. that quality objectives and requirements for the product, service? b. the need to establish processes and documents, and provide resources specific to the product/service? c. that verification, validation, monitoring, inspection and test activities, and the criteria for product/service acceptability? d. the records that are necessary to provide evidence of conformity of the processes and resulting product/service fulfill customer requirements?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.2 7.2.1	<u>Customer Related Process</u> <u>Determination of Requirements Related to the Product/Service</u> Has the organization determined customer requirements including: a. Product/service delivery requirements specified by the customer?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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	<p>b. Product/service delivery requirements not specified by the customer but necessary for intended or specified use?</p> <p>c. obligations related to product, including regulatory and legal requirements?</p> <p>d. Additional requirements determined by the organization?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.2.2	<p><u>Review of Requirements Related to the Product (Service)</u></p> <p>Does the organization review the identified requirements together with additional requirements determined by the organization prior to acceptance?</p> <p>Is this review conducted prior to the commitment to supply a product to the customer?</p> <p>Does the review ensure that:</p> <p>a. product/service delivery requirements are defined?</p> <p>b. where the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance?</p> <p>c. contract or order requirements differing from those previously expressed are resolved?</p> <p>d. the organization has the ability to meet defined requirements?</p> <p>Are the results of the review, actions, and subsequent follow up actions recorded (see ISO Element 4.2.4)?</p> <p>Where product/service requirements are changed, does the organization ensure that relevant documentation is amended?</p> <p>How are verbal orders handled, addressed, and documented?</p> <p>Does the organization ensure that relevant personnel are made aware of the changed requirement?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

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	How are customer requirements reviewed before services are provided? How are the results of the review of agreements and any follow-up actions recorded?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.2.3	<u>Customer Communication</u> How does the organization identify and implement arrangements for communication with Customers relating to: <ol style="list-style-type: none"> product information? enquiries, contracts, or order handling, including amendments? customer feedback, including customer complaints? 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.3.1/7.3.2	<u>Design and Development Planning and Design and Development Inputs</u> What is the design and development planning methodology described in the design procedure? How are the design and development stages planned and organized? Who is responsible to review, verify and validate each design and development stage? How are the interfaces between different groups involved in design identified and managed? Are design and development inputs relating to product requirements defined and documented ? Do these inputs include: <ol style="list-style-type: none"> functional and performance requirements? Applicable statutory and regulatory requirements? Where applicable, information derived from previous similar designs? Other requirements essential for design and development? 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	

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7.3.3	<p><u>Design and Development Outputs</u></p> <p>Are the outputs of the design and/or development process documented in a manner that enables verification against the design and/or development inputs?</p> <p>Does design and/or development output:</p> <p>a. meet the design and/or development input requirements?</p> <p>b. provide appropriate information for production and service operations?</p> <p>c. contain or reference product acceptance criteria?</p> <p>d. define the characteristics of the product that are essential to its safe and proper use?</p> <p>Are design and/or development output documents approved prior to release?</p> <p>Documentation of design outputs is maintained and easily accessible?</p> <p>A review of design outputs, change notices, customer complaints, and internal audit reports indicate consistent adherence to organizational standards for design output plans, etc.)?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.3.4	<p><u>Design and Development Review</u></p> <p>Are systematic reviews of design and/or development conducted at suitable stages?</p> <p>Do these reviews:</p> <p>a. evaluate the ability to fulfill requirements?</p> <p>b. identify problems and propose follow-up actions?</p> <p>Do participants in such reviews include representatives of functions concerned with the design and/or development stage(s) being reviewed?</p> <p>Are the results of the reviews and subsequent follow-up actions recorded?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

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	At what stages of the design are plans or other design documented? Where are records of design reviews maintained?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.3.5	<u>Design and/or Development Verification</u> Is design and/or development verification performed to ensure the output meets the design and/or development inputs? Are the results of the verification and subsequent follow-up actions recorded ?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.3.6	<u>Design and/or Development Validation</u> Is design and/or development validation performed to confirm that resulting product is capable of meeting the requirements for the intended use? Wherever applicable, is validation completed prior to the delivery or implementation of the product? If full validation is impractical prior to delivery or implementation, is partial validation performed to the extent applicable? Are the results of the validation and subsequent follow-up actions recorded ?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.3.7	<u>Control of Design and Development Changes</u> Are design and/or development changes identified, documented , and controlled? Does this process include evaluation of the effect of the changes on constituent parts and delivered products? Are changes verified and validated, as appropriate, and approved before implementation? Are the results of the review of changes and subsequent follow up actions documented?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.4.1	<u>Purchasing Process</u> Does the organization control its purchasing processes to ensure purchased product conforms to requirements? Is the type and extent of control dependent upon	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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	<p>the effect of subsequent realization processes and their output?</p> <p>Does the organization evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements?</p> <p>Are criteria for selection and periodic evaluation defined?</p> <p>Are the results of evaluations and subsequent follow up actions recorded?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.4.2	<p><u>Purchasing Information</u></p> <p>Do purchasing documents contain information describing the product to be purchased?</p> <p>Do these documents include where appropriate:</p> <p>a. requirements for approval or qualification of product, procedures, processes, equipment, and personnel?</p> <p>b. quality management system requirements?</p> <p>Is the adequacy of specified requirements contained in the purchasing documents and reviewed prior to their release?</p> <p>When purchasing good/services, does the purchaser provide subcontractors/suppliers with precise details of the order to ensure item/services are purchased correctly in the first place?</p> <p>NOTE: Sample purchase requisitions to determine the above.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.4.3	<p><u>Verification of Purchased Product</u></p> <p>Have activities necessary for the verification of purchased product been identified and implemented?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.5.1	<p><u>Control of Production and Service Provision</u></p> <p>Does the organization control service operations through:</p> <p>a. the availability of information that specifies the characteristics of the product?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

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	b. where necessary, the availability of work instructions? c. the use and maintenance of suitable equipment for production and service operations? d. the availability and use of measuring and monitoring devices? e. the implementation of monitoring activities? f. the implementation of defined processes for release, delivery, and applicable post-delivery activities?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.5.2	<u>Validation of Processes for Production and Service Provision</u> Does the organization validate any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring? Are any processes included where deficiencies may become apparent only after the product is in use or the service has been delivered? Does validation demonstrate the ability of the processes to achieve planned results? Do defined arrangements for validation include as applicable: a. qualification of processes? b. qualification of equipment and personnel? c. use of defined methodologies and procedures? d. requirements for records ? e. re-validation?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
7.5.3	<u>Identification and traceability</u> Is product identified by suitable means throughout production and service operations where appropriate? Is the status of the product with respect to	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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	<p>measurement and monitoring requirements clearly identified?</p> <p>Where traceability is a requirement, is the unique identification of product controlled and recorded?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.5.4	<p><u>Customer Property</u></p> <p>How does the organization exercise care with customer property while it is under the organization's control or being used by the organization?</p> <p>How is customer property provide for use or incorporation in product:</p> <p>a. Identified?</p> <p>b. Verified?</p> <p>c. Protected?</p> <p>d. Maintained?</p> <p>If any customer property is lost, damaged, or otherwise found to be unsuitable for use is it recorded and reported to the customer?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.5.5	<p><u>Preservation of Product</u></p> <p>Is product preserved to ensure that conformity with customer requirements is maintained during internal processing and delivery to the intended destination?</p> <p>Does this include identification, handling, packaging, storage, and protection?</p> <p>Do these controls also apply to the constituent parts of a product?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
7.6	<p><u>Control of Measuring and Monitoring Devices</u></p> <p>How does the organization identify the measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements?</p> <p>Are measuring and monitoring devices used and controlled to ensure that measurement capability is consistent with the measurement requirements?</p> <p>Where applicable, are measuring and monitoring</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

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	<p>devices:</p> <p>a. calibrated and adjusted periodically or prior to use, against devices traceable to International or national standards?</p> <p>b. Where no such standards exist, is the basis used for calibration recorded?</p> <p>c. safeguarded from adjustments that would invalidate the calibration?</p> <p>d. protected from damage and deterioration during handling, maintenance, and storage?</p> <p>e. have the results of their calibration been recorded?</p> <p>f. have the validity of previous results reassessed if they are subsequently found out of calibration and corrective action taken?</p> <p>NOTE: Investigate methods in which measurement and monitoring devices are controlled to ensure fitness for use (i.e. identification of calibration status, traceability of device to calibration record, method in which frequency of calibration is determined).</p> <p>Is software used for measuring and monitoring of specified requirements validated prior to use?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
8.2.1	<p><u>Customer Satisfaction</u></p> <p>Are measurement and monitoring activities needed to assure conformity and achieve improvement been identified and included in the product quality plan?</p> <p>Does this process include the determination of the need for, and use of, applicable methodologies including statistical techniques?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
8.2.2	<p><u>Internal Audit</u></p> <p>Are periodic internal quality audits conducted to determine whether the quality management system has been effectively implemented and maintained?</p> <p>Are internal quality audits planned, including consideration of the status and importance of the activities and areas to be audited as well as the</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

ISO Clause	Question	Answer	Notes:
	<p>results of previous audits?</p> <p>Is the audit scope, frequency, and methodologies defined?</p> <p>Are audits conducted by personnel other than those who performed the activity being audited?</p> <p>Are there documented procedures that include the responsibilities and requirements for conducting audits, ensuring their independence, recording results, and reporting to management?</p> <p>Have personnel conducting internal audits been trained?</p> <p>Are records of internal auditor training maintained and available?</p> <p>Does management take timely corrective action on deficiencies found during the audit?</p> <p>Do follow-up actions include the verification of the implementation of corrective action and the reporting of verification results?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>8.2.3</p>	<p><u>Measuring and Monitoring of Processes</u></p> <p>Are product realization processes measured and monitored by suitable methods to ensure customer requirements are met?</p> <p>Do these methods confirm the continuing ability of each process to satisfy its intended purpose?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>8.2.4</p>	<p><u>Measuring and Monitoring of Product (Service)</u></p> <p>Are product characteristics measured and monitored to verify that requirements for the product are met?</p> <p>Is this carried out at appropriate stages of the product realization process?</p> <p>Is evidence of conformity with the acceptance criteria documented?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>8.3</p>	<p><u>Control of Nonconformity</u></p> <p>Is product, which does not conform to requirements, clearly identified and controlled to prevent unintended use or delivery?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

ISO Clause	Question	Answer	Notes:
	<p>Are these activities defined in a documented procedure?</p> <p>Is nonconforming product corrected and subjected to re-verification after correction to demonstrate conformity?</p> <p>When nonconforming product is detected after delivery or use has started, is appropriate action taken regarding the consequences of the nonconformity?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>8.4</p>	<p>Analysis of Data</p> <p>How is appropriate data collected and analyzed to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made?</p> <p>Does this include data generated by measuring and monitoring activities and other relevant sources?</p> <p>How is this data analyzed to provide information on:</p> <p>a. customer satisfaction and/or dissatisfaction?</p> <p>b. conformance to customer requirements?</p> <p>c. characteristics of processes, product, and their trends?</p> <p>d. suppliers?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>8.5.1</p>	<p>Continual Improvement</p> <p>Are processes necessary for the continual Improvement of the quality management system planned and managed?</p> <p>How is continual improvement of the quality management system facilitated through the use of:</p> <p>a. quality policy?</p> <p>b. quality objectives?</p> <p>c. audit results?</p> <p>d. analysis of data?</p> <p>e. corrective and preventive action ?</p> <p>f. management review?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

ISO Clause	Question	Answer	Notes:
8.5.2	<p><u>Corrective Action</u></p> <p>How is corrective action taken to eliminate the cause of nonconformities in order to prevent recurrence?</p> <p>How is corrective action appropriate to the impact of the Problems encountered?</p> <p>Is there a documented procedure for corrective action which defines requirements for:</p> <p>a. identifying nonconformities (including customer complaints)?</p> <p>b. determining the causes of nonconformity?</p> <p>c. evaluating the need for actions to ensure that nonconformities do not recur?</p> <p>d. determining and implementing the corrective action needed?</p> <p>e. recording results of action taken?</p> <p>f. reviewing corrective action taken?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
8.5.3	<p><u>Preventive Action</u></p> <p>Does the organization identify preventive action to eliminate the causes of potential nonconformities to prevent occurrence?</p> <p>Are preventive actions taken appropriate to the impact of the potential problems?</p> <p>Is there a documented procedure for preventive action which defines requirements for:</p> <p>a. identifying potential nonconformities and their causes?</p> <p>b. determining and ensuring the implementation of preventive action needed?</p> <p>c. recording results of action taken?</p> <p>d. reviewing preventive action taken?</p> <p>Do the procedures ensure relevant information on actions taken is submitted for management review?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	