

ANNEXURE F – ISO 9001 2015 AUDIT CHECKLIST - TE24-KDS-8DH-07284

Clause	Details	Yes	No	Comments/Evidence/Audit Trails
4	Context of the organization			
4.1	Understanding the organization and its context			
	Has the organization determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization monitor and review information about these external and internal issues?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE 1 Issues can include positive and negative factors or conditions for consideration.</i>			
	<i>NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.</i>			
	<i>NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.</i>			
4.2	Understanding the needs and expectations of interested parties			
	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, has the organization determined:			
	a) the interested parties that are relevant to the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the requirements of these interested parties that are relevant to the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization monitor and review information about			
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	these interested parties and their relevant requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
4.3	Determining the scope of the quality management system			
	Has the organization determined the boundaries and applicability of the quality management system to establish its scope?	<input type="checkbox"/>	<input type="checkbox"/>	
	When determining this scope, has the organization shall considered:			
	a) the external and internal issues referred to in 4.1?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the requirements of relevant interested parties referred to in 4.2?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the products and services of the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	Has the organization applied all the requirements of ISO 9001 if they are applicable within the determined scope of its quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is the scope of the organization's quality management system available and maintained as documented information?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the scope state the types of products and services covered, and provide justification for any requirement of ISO 9001 that the organization determines is not applicable to the scope of its quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Do any requirements determined by the organization as not being applicable not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction?	<input type="checkbox"/>	<input type="checkbox"/>	
4.4	Quality management system and its processes			
4.4.1	Has the organization established, implemented, maintained and	<input type="checkbox"/>	<input type="checkbox"/>	

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	continually improved a quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001?			
	Has the organization determined the processes needed for the quality management system and their application throughout the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	Has the organization:			
	a) determined the inputs required and the outputs expected from these processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) determined the sequence and interaction of these processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) determined the resources needed for these processes and ensure their availability?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) assigned the responsibilities and authorities for these processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1?	<input type="checkbox"/>	<input type="checkbox"/>	
	g) evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results?	<input type="checkbox"/>	<input type="checkbox"/>	
	h) improved the processes and the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.2	To the extent necessary, does the organization:			
	a) maintain documented information to support the	<input type="checkbox"/>	<input type="checkbox"/>	

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	operation of its processes?			
	b) retain documented information to have confidence that the processes are being carried out as planned?	<input type="checkbox"/>	<input type="checkbox"/>	
5	Leadership			
5.1	Leadership and commitment			
5.1.1	General			
	Have top management demonstrated leadership and commitment with respect to the quality management system by:			
	a) taking accountability for the effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) ensuring the integration of the quality management system requirements into the organization's business processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) promoting the use of the process approach and risk-based thinking?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) ensuring that the resources needed for the quality management system are available?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) communicating the importance of effective quality management and of conforming to the quality management system requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	g) ensuring that the quality management system achieves its intended results?	<input type="checkbox"/>	<input type="checkbox"/>	
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	h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	i) promoting improvement?	<input type="checkbox"/>	<input type="checkbox"/>	
	j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Reference to “business” in ISO 9001 can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not for profit.</i>			
5.1.2	Customer focus			
	Has top management demonstrated leadership and commitment with respect to customer focus by ensuring that:			
	a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the focus on enhancing customer satisfaction is maintained?	<input type="checkbox"/>	<input type="checkbox"/>	
5.2	Policy			
5.2.1	Developing the quality policy			
	Has top management established, implemented and maintained a quality policy that:			

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	a) is appropriate to the purpose and context of the organization and supports its strategic direction?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) provides a framework for setting quality objectives?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) includes a commitment to satisfy applicable requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) includes a commitment to continual improvement of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
5.2.2	Communicating the quality policy			
	Is the quality policy:			
	a) available and maintained as documented information?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) communicated, understood and applied within the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) available to relevant interested parties, as appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
5.3	Organizational roles, responsibilities and authorities			
	Do top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	Have top management assigned the responsibility and authority for:			
	a) ensuring that the quality management system conforms to the requirements of ISO 9001?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) ensuring that the processes are delivering their intended outputs?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) reporting on the performance of the quality management	<input type="checkbox"/>	<input type="checkbox"/>	
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	system and on opportunities for improvement (see 10.1), in particular to top management?			
	d) ensuring the promotion of customer focus throughout the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	<input type="checkbox"/>	<input type="checkbox"/>	
6	Planning			
6.1	Actions to address risks and opportunities			
6.1.1	When planning for the quality management system, has the organization considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:			
	a) give assurance that the quality management system can achieve its intended result(s)?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) enhance desirable effects?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) prevent, or reduce, undesired effects?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) achieve improvement?	<input type="checkbox"/>	<input type="checkbox"/>	
6.1.2	Has the organization planned:			
	a) actions to address these risks and opportunities?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) how to:			
	1) integrate and implement the actions into its quality management system processes (see 4.4)?	<input type="checkbox"/>	<input type="checkbox"/>	

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	2) evaluate the effectiveness of these actions?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are actions taken to address risks and opportunities proportionate to the potential impact on the conformity of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.</i>			
	<i>NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.</i>			
6.2	Quality objectives and planning to achieve them			
6.2.1	Has the organization established quality objectives at relevant functions, levels and processes needed for the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are the quality objectives:			
	a) consistent with the quality policy?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) measurable?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) take into account applicable requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) relevant to conformity of products and services and to enhancement of customer satisfaction?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) monitored?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) communicated?	<input type="checkbox"/>	<input type="checkbox"/>	

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	g) updated as appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization maintain documented information on the quality objectives?	<input type="checkbox"/>	<input type="checkbox"/>	
6.2.2	When planning how to achieve its quality objectives, has the organization determined:			
	a) what will be done?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) what resources will be required?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) who will be responsible?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) when it will be completed?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) how the results will be evaluated?	<input type="checkbox"/>	<input type="checkbox"/>	
6.3	Planning of changes			
	When the organization determines the need for change to the quality management system (see 4.4) are changes carried out in a planned and systematic manner?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization consider:			
	a) the purpose of the change and any of its potential consequences?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the integrity of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the availability of resources?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the allocation or reallocation of responsibilities and	<input type="checkbox"/>	<input type="checkbox"/>	

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	authorities?			
7	Support			
7.1	Resources			
7.1.1	General			
	Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Has the organization considered:			
	a) the capabilities of, and constraints on, existing internal resources?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) what needs to be obtained from external providers?	<input type="checkbox"/>	<input type="checkbox"/>	
7.1.2	People			
	Has the organization determined and provided the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes?	<input type="checkbox"/>	<input type="checkbox"/>	
7.1.3	Infrastructure			
	Has the organization determined, provided and maintained the infrastructure necessary for the operation of its processes to achieve conformity of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Infrastructure can include:</i>			
	<i>a) buildings and associated utilities;</i>			
	<i>b) equipment, including hardware and software;</i>			
	<i>c) transportation resources;</i>			

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	<i>d) information and communication technology.</i>			
7.1.4	Environment for the operation of processes			
	<p>Has the organization determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services?</p> <p><i>NOTE A suitable environment can be a combination of human and physical factors, such as:</i></p> <p><i>a) social (e.g. non-discriminatory, calm, non-confrontational);</i> <i>b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);</i> <i>c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).</i></p> <p><i>These factors can differ substantially depending on the products and services provided.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	
7.1.5	Monitoring and measuring resources			
7.1.5.1	General			
	When monitoring or measuring is used to verify the conformity of products and services to specified, has the organization determined and provided the resources needed to ensure valid and reliable results?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization ensure that the resources provided:			
	a) are suitable for the specific type of monitoring and measurement activities being undertaken?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) are maintained to ensure their continued fitness for their purpose.	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources?	<input type="checkbox"/>	<input type="checkbox"/>	
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7.1.5.2	Measurement traceability			
	When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, is measuring equipment:			
	a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards?	<input type="checkbox"/>	<input type="checkbox"/>	
	when no such standards exist, is the basis used for calibration or verification retained as documented information?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) identified in order to determine its status?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary?	<input type="checkbox"/>	<input type="checkbox"/>	
7.1.6	Organizational knowledge			
	Does the organization determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is this knowledge maintained and made available to the extent necessary?	<input type="checkbox"/>	<input type="checkbox"/>	
	When addressing changing needs and trends, does the organization consider its current knowledge and determine how to acquire or access the necessary additional knowledge and	<input type="checkbox"/>	<input type="checkbox"/>	

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	required updates?			
	<i>NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.</i>			
	<i>NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).</i>			
7.2	Competence			
	Has the organization:			
	a) determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) ensured that these persons are competent on the basis of appropriate education, training, or experience?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) taken actions, where applicable, to acquire the necessary competence and evaluated the effectiveness of the actions taken?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) retained appropriate documented information as evidence of competence?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Applicable 'actions' can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.</i>			

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7.3	Awareness			
	Has the organization ensured that persons doing work under its control are aware of:			
	a) the quality policy?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) relevant quality objectives?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the implications of not conforming with the quality management system requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
7.4	Communication			
	Has the organization determined the internal and external communications relevant to the quality management system including:			
	a) on what it will communicate?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) when to communicate?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) with whom to communicate?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) how to communicate?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) who communicates?	<input type="checkbox"/>	<input type="checkbox"/>	
7.5	Documented Information			
7.5.1	General			
	Does the organization's quality management system include:	<input type="checkbox"/>	<input type="checkbox"/>	

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	a) documented information required by ISO 9001?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) documented information determined by the organization as being necessary for the effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
7.5.2	Creating and updating			
	When creating and updating documented information , does the organization ensure appropriate:			
	a) identification and description (e.g. a title, date, author, or reference number)?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic)?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) review and approval for suitability and adequacy?	<input type="checkbox"/>	<input type="checkbox"/>	
7.5.3	Control of documented information			
7.5.3.1	Is the documented information required by the quality management system and by ISO 9001 controlled to ensure:			
	a) it is available and suitable for use, where and when it is needed?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)?	<input type="checkbox"/>	<input type="checkbox"/>	
7.5.3.2	For the control of documented information , has the organization shall addressed the following activities, as applicable:			
	a) distribution, access, retrieval and use?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) storage and preservation, including preservation of legibility?	<input type="checkbox"/>	<input type="checkbox"/>	

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	c) control of changes (e.g. version control)?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) retention and disposition?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is documented information of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, identified as appropriate and controlled?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is documented information retained as evidence of conformity protected from unintended alterations.	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE 'Access' can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.</i>			
8	Operation			
8.1	Operational planning and control			
	Does the organization plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services and to implement the actions determined in 6, by:			
	a) determining requirements for the product and services;	<input type="checkbox"/>	<input type="checkbox"/>	
	b) establishing criteria for :			
	1) the processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) the acceptance of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) determining the resources needed to achieve conformity to product and service requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) implementing control of the processes in accordance	<input type="checkbox"/>	<input type="checkbox"/>	

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	with the criteria?			
	e) determining, maintaining and retaining documented information to the extent necessary:			
	1) to have confidence that the processes have been carried out as planned?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) to demonstrate conformity of products and services to their requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	Is the output of this planning suitable for the organization's operations?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization ensure that outsourced processes are controlled in accordance with 8.4?	<input type="checkbox"/>	<input type="checkbox"/>	
8.2	Requirements for products and services			
8.2.1	Customer communication			
	Does customer communication include:			
	a) providing information relating to products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) handling enquiries, contracts or order handling, including changes?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) obtaining customer feedback relating to products and services, including customer complaints?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the handling or controlling customer property?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) establishing specific requirements for contingency	<input type="checkbox"/>	<input type="checkbox"/>	

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	actions, when relevant?			
8.2.2	Determination of requirements related to products and services			
	When determining the requirements for the products and services to be offered to customers, does the organization ensure that:			
	a) the requirements for products and services are defined, including:			
	1) any applicable statutory and regulatory requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) those considered necessary by the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the organization can meet the claims for the products and services it offers?	<input type="checkbox"/>	<input type="checkbox"/>	
8.2.3	Review of requirements related to products and services			
8.2.3.1	Does the organization ensure that it has the ability to meet the requirements for products and services to be offered to customers?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization conduct a review before committing to supply products and services, including:			
	a) requirements specified by the customer, including the requirements for delivery and post-delivery activities?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) requirements not stated by the customer, but necessary for the specified or intended use, when known?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) requirements specified by the organization?			
	d) statutory and regulatory requirements applicable to the products and services?	<input type="checkbox"/>	<input type="checkbox"/>	

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	e) contract or order requirements differing from those previously expressed?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization ensure that contract or order requirements differing from those previously defined are resolved?	<input type="checkbox"/>	<input type="checkbox"/>	
	When the customer does not provide a documented statement of their requirements, are the customer requirements confirmed by the organization before acceptance?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.</i>			
8.2.3.2	Does the organization retain documented information , as applicable:	<input type="checkbox"/>	<input type="checkbox"/>	
	a) on the results of the review?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) on any new requirements for the products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
8.2.4	Changes to requirements for products and services			
	Does the organization ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	<input type="checkbox"/>	<input type="checkbox"/>	
8.3	Design and development of products and services			
8.3.1	General			
	Has the organization established, implemented and maintained a design and development process that is appropriate to ensure the subsequent provision of products and services.	<input type="checkbox"/>	<input type="checkbox"/>	
8.3.2	Design and development planning			
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Clause	Details	Yes	No	Comments/Evidence/Audit Trails
	In determining the stages and controls for design and development, does the organization consider:			
	a) the nature, duration and complexity of the design and development activities?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the required process stages, including applicable design and development reviews?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the required design and development verification and validation activities?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the responsibilities and authorities involved in the design and development process?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) the internal and external resource needs for the design and development of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) the need to control interfaces between persons involved in the design and development process?	<input type="checkbox"/>	<input type="checkbox"/>	
	g) the need for involvement of customers and users in the design and development process?	<input type="checkbox"/>	<input type="checkbox"/>	
	h) the requirements for subsequent provision of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	i) the level of control expected for the design and development process by customers and other relevant interested parties?	<input type="checkbox"/>	<input type="checkbox"/>	
	j) the documented information needed to demonstrate that design and development requirements have been met?	<input type="checkbox"/>	<input type="checkbox"/>	
8.3.3	Design and development inputs			
	Does the organization determine the requirements essential for the specific types of products and services to be designed and			
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	developed?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization consider:			
	a) functional and performance requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) information derived from previous similar design and development activities?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) statutory and regulatory requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) standards or codes of practice that the organization has committed to implement?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) the potential consequences of failure due to the nature of the products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are inputs adequate for design and development purposes, complete and unambiguous?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are conflicting design and development inputs resolved?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain documented information on design and development inputs.?	<input type="checkbox"/>	<input type="checkbox"/>	
8.3.4	Design and development controls			
	Does the organization apply controls to the design and development process to ensure that:			
	a) the results to be achieved are defined?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) verification activities are conducted to ensure that the design and development outputs meet the input	<input type="checkbox"/>	<input type="checkbox"/>	

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Clause	Details	Yes	No	Comments/Evidence/Audit Trails
	requirements?			
	d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) documented information of these activities is retained?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.</i>			
8.3.5	Design and development outputs			
	Does the organization ensure that design and development outputs:			
	a) meet the input requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) are adequate for the subsequent processes for the provision of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain documented information on design and development process?	<input type="checkbox"/>	<input type="checkbox"/>	
8.3.6	Design and development changes			

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Clause	Details	Yes	No	Comments/Evidence/Audit Trails
	Does the organization identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain documented information on:			
	a) design and development changes?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the results of reviews?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the authorization of the changes	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the actions taken to prevent adverse impacts.?	<input type="checkbox"/>	<input type="checkbox"/>	
8.4	Control of externally provided products and services			
8.4.1	General			
	Does the organization ensure that externally provided processes, products and services conform to requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization determine the controls to be applied to externally provided, processes, products and services when:			
	a) products and services from external providers are intended for incorporation into the organization's own products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) products and services are provided directly to the customer(s) by external providers on behalf of the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	Has the organization determined and applied criteria for the	<input type="checkbox"/>	<input type="checkbox"/>	
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Clause	Details	Yes	No	Comments/Evidence/Audit Trails
	evaluation, selection, monitoring of performance and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements?			
	Does the organization retain documented information of these activities and any necessary actions arising from the evaluations?	<input type="checkbox"/>	<input type="checkbox"/>	
8.4.2	Type and extent of control of external provision			
	Does the organization ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization:			
	a) ensure that externally provided processes remain within the control of its quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) take into consideration:			
	1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) the effectiveness of the controls applied by the external provider	<input type="checkbox"/>	<input type="checkbox"/>	
	d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements?	<input type="checkbox"/>	<input type="checkbox"/>	

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8.4.3	Information for external providers			
	Does the organization ensure the adequacy of requirements prior to their communication to the external provider?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization communicate to external providers its requirements for:			
	a) the processes, products and services to be provided?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the approval of:	<input type="checkbox"/>	<input type="checkbox"/>	
	1) products and services?			
	2) methods, processes and equipment?	<input type="checkbox"/>	<input type="checkbox"/>	
	3) the release of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) competence, including any required qualification of persons?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the external providers' interactions with the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) control and monitoring of the external provider's performance to be applied by the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises?	<input type="checkbox"/>	<input type="checkbox"/>	
8.5	Production and service provision			
8.5.1	Control of production and service provision			
	Has the organization implemented production and service provision under controlled conditions?	<input type="checkbox"/>	<input type="checkbox"/>	

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	Do those controlled conditions include, as applicable:			
	a) the availability of documented information that defines:			
	1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) the results to be achieved?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the availability and use of suitable monitoring and measuring resources?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the use of suitable infrastructure and environment for the operation of processes?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) the appointment of competent persons, including any required qualification?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?	<input type="checkbox"/>	<input type="checkbox"/>	
	g) the implementations of actions to prevent human error?	<input type="checkbox"/>	<input type="checkbox"/>	
	h) the implementation of release, delivery and post-delivery activities?	<input type="checkbox"/>	<input type="checkbox"/>	
8.5.2	Identification and traceability			
	Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and	<input type="checkbox"/>	<input type="checkbox"/>	

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	services?			
	Does the organization identify the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision?	<input type="checkbox"/>	<input type="checkbox"/>	
	When traceability is a requirement, does the organization control the unique identification of the outputs and retain any documented information necessary to enable traceability?	<input type="checkbox"/>	<input type="checkbox"/>	
8.5.3	Property belonging to customers or external providers			
	Does the organization exercise care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization identify, verify, protect and safeguard the customer's or external provider's property provided for use or incorporation into the products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, does the organization report this to the customer or external provider and retain documented information on what has occurred.	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data</i>			
8.5.4	Preservation			
	Does the organization preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.</i>			

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8.5.5	Post-delivery activities			
	Does the organization meet requirements for post-delivery activities associated with the products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	In determining the extent of post-delivery activities that are required, does the organisation consider:			
	a) statutory and regulatory requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the potential undesired consequences associated with its products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) the nature, use and intended lifetime of the products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) customer requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) customer feedback?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.</i>			
8.5.6	Control of changes			
	Does the organization review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain documented information describing the results of the review of changes, the person(s) authorizing the change and any necessary actions arising from the review?	<input type="checkbox"/>	<input type="checkbox"/>	
8.6	Release of products and services			

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	Does the organization implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the release of products and services to the customer not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain documented information on the release of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does this documented information include:			
	a) evidence of conformity with the acceptance criteria?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) traceability to the person(s) authorizing the release?	<input type="checkbox"/>	<input type="checkbox"/>	
8.7	Control of nonconforming process outputs, products and services			
8.7.1	Does the organization ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization take appropriate corrective action based on the nature of the nonconformity and its effect on the conformity of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does this also apply to nonconforming products and services detected after delivery of the products, during or after the provision of services?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization deal with nonconforming outputs in one or more of the following ways:			
	a) correction?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) segregation, containment, return or suspension of	<input type="checkbox"/>	<input type="checkbox"/>	

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	provision of products and services?			
	c) informing the customer?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) obtaining authorization for acceptance under concession?			
	When nonconforming outputs are corrected, is conformity to the requirements verified?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain documented information of actions taken on nonconforming process outputs, products and services, including on any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformity?	<input type="checkbox"/>	<input type="checkbox"/>	
8.7.2	Does the organization retain documented information that:	<input type="checkbox"/>	<input type="checkbox"/>	
	a) describes the nonconformity?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) describes the action taken?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) describes any concessions obtained?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) identifies the authority deciding the action in respect of the nonconformity.	<input type="checkbox"/>	<input type="checkbox"/>	
9	Performance evaluation			
9.1	Monitoring, measurement, analysis and evaluation			
9.1.1	General			
	Has the organization determined:			
	a) what needs to be monitored and measured?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the methods for monitoring, measurement, analysis and	<input type="checkbox"/>	<input type="checkbox"/>	
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	evaluation, as applicable, to ensure valid results?			
	c) when the monitoring and measuring shall be performed?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) when the results from monitoring and measurement shall be analysed and evaluated?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization evaluate the performance and the effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization retain appropriate documented information as evidence of the results?	<input type="checkbox"/>	<input type="checkbox"/>	
9.1.2	Customer satisfaction			
	Does the organization monitor customer perceptions of the degree to which their needs and expectations have been fulfilled?	<input type="checkbox"/>	<input type="checkbox"/>	
	Has the organization determined the methods for obtaining, monitoring and reviewing this information?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.</i>			
9.1.3	Analysis and evaluation			
	Does the organization analyse and evaluate appropriate data and information arising from monitoring, measurement?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are the results of analysis used to evaluate:			
	a) conformity of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the degree of customer satisfaction?	<input type="checkbox"/>	<input type="checkbox"/>	
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	c) The performance and effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) If planning has been implemented effectively?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) The effectiveness of actions taken to address risks and opportunities?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) the performance of external providers?	<input type="checkbox"/>	<input type="checkbox"/>	
	g) the need for improvements within the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE Methods to analyse data can include statistical techniques.</i>			
9.2	Internal audit			
9.2.1	Does the organization conduct internal audits at planned intervals to provide information on whether the quality management system:			
	a) conforms to:			
	1) the organization's own requirements for its quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) the requirements of ISO 9001?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) is effectively implemented and maintained?	<input type="checkbox"/>	<input type="checkbox"/>	
9.2.2	Does the organization:			
	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the processes concerned, customer feedback, changes	<input type="checkbox"/>	<input type="checkbox"/>	
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	affecting the organisation, and the results of previous audits?			
	b) define the audit criteria and scope for each audit?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) ensure that the results of the audits are reported to relevant management?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) take appropriate correction and corrective actions without undue delay?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) retain documented information as evidence of the implementation of the audit programme and the audit results?	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>NOTE See ISO 19011 for guidance.</i>			
9.3	Management review			
9.3.1	General			
	Does top management review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization?	<input type="checkbox"/>	<input type="checkbox"/>	
9.3.2	Management review inputs			
	Is the management review planned and carried out taking into consideration:			
	a) the status of actions from previous management reviews?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) changes in external and internal issues that are relevant	<input type="checkbox"/>	<input type="checkbox"/>	
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	to the quality management system?			
	c) information on the performance and effectiveness of the quality management system, including trends in:			
	1) customer satisfaction and feedback from relevant interested parties?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) the extent to which quality objectives have been met?	<input type="checkbox"/>	<input type="checkbox"/>	
	3) process performance and conformity of products and services?	<input type="checkbox"/>	<input type="checkbox"/>	
	4) nonconformities and corrective actions?	<input type="checkbox"/>	<input type="checkbox"/>	
	5) monitoring and measurement results?	<input type="checkbox"/>	<input type="checkbox"/>	
	6) audit results?	<input type="checkbox"/>	<input type="checkbox"/>	
	7) the performance of external providers?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) the adequacy of resources?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) the effectiveness of actions taken to address risks and opportunities (6.1)?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) opportunities for improvement?	<input type="checkbox"/>	<input type="checkbox"/>	
9.3.3	Management review outputs			
	Do the outputs of the management review include decisions and actions related to:			
	a) opportunities for improvement?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) any need for changes to the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	

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	c) Resource needs?			
	Does the organization retain documented information as evidence of the results of management reviews?	<input type="checkbox"/>	<input type="checkbox"/>	
10	Improvement			
10.1	General			
	Does the organization determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does this include:			
	a) improving products and services to meet requirements as well as to address future needs and expectations?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) correcting, preventing or reducing undesired effects?	<input type="checkbox"/>	<input type="checkbox"/>	
	c) improving the performance and effectiveness of the quality management system?			
	<i>NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
10.2	Non-conformity and corrective action			
10.2.1	When a nonconformity occurs, including those arising from complaints, does the organization:			
	a) react to the nonconformity and, as applicable:			
	1) take action to control and correct it?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) deal with the consequences?	<input type="checkbox"/>	<input type="checkbox"/>	

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	b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:			
	1) reviewing and analysing the nonconformity?	<input type="checkbox"/>	<input type="checkbox"/>	
	2) determining the causes of the nonconformity?	<input type="checkbox"/>	<input type="checkbox"/>	
	3) determining if similar nonconformities exist, or could potentially occur	<input type="checkbox"/>	<input type="checkbox"/>	
	c) implement any action needed?	<input type="checkbox"/>	<input type="checkbox"/>	
	d) review the effectiveness of any corrective action taken?	<input type="checkbox"/>	<input type="checkbox"/>	
	e) update risks and opportunities determined during planning, if necessary?	<input type="checkbox"/>	<input type="checkbox"/>	
	f) make changes to the quality management system, if necessary?	<input type="checkbox"/>	<input type="checkbox"/>	
	Are the corrective actions appropriate to the effects of the nonconformities encountered?	<input type="checkbox"/>	<input type="checkbox"/>	
10.2.2	Does the organization retain documented information as evidence of:			
	a) the nature of the nonconformities and any subsequent actions taken?	<input type="checkbox"/>	<input type="checkbox"/>	
	b) the results of any corrective action?	<input type="checkbox"/>	<input type="checkbox"/>	
10.3	Continual improvement			
	Does the organization continually improve the suitability, adequacy and effectiveness of the quality management system?	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the organization consider the results of analysis and evaluation, and the outputs from management review, to	<input type="checkbox"/>	<input type="checkbox"/>	

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	determine if there are needs or opportunities that shall be addressed as part of continual improvement?			

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