Title: Internal Audit Checklist

Clause #	Audit questions	Audit evidence	Type of evidence[1]
4.	**Context of the Organization**		
4.1	Understanding the organisation and its context		
4.1	External and internal issues relevant to purpose and strategic direction determined? How do these affect the ability to achieve the intended result of QMS?		
4.1	How do you monitor and review information about these internal and external issues? Frequency, method, by whom?		
	NOTE 1 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. NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organisation.		
4.2	Understanding the needs and expectations of interested parties		
4.2	Interested parties and their needs and expectations determined; and their potential impact?		
4.2	How do you monitor and review the information about interested parties and their relevant requirements?		
4.3	Determining the scope of the quality management system		
4.3	The scope of QMS is established.		
	The external and internal issues; requirements of relevant interested parties and; the products and services considered when determining the scope.		
4.3	Any requirements of the International Standard determined as not applicable. Show me how conformity of products and services are not affected by this!		
4.3	Where is the scope available? Where is it maintained as documented information? Does it state which products and services are covered by the QMS? Does it justify standard requirements that are not applicable within QMS?		

[1] Mark it as compliance or non-compliance e.g. major (Maj), min (Min), an opportunity for improvement (OFI)

Clause #	Audit questions	Audit evidence	Type of evidence[1]
4.4	**Quality management system and its processes**		
4.4	**Defining the process** Is the process defined and documented? For example, process map, flow chart, value stream map etc. Is the process owner identified? How are responsibilities and authorities assigned? How are risks and opportunities considered and plans are made to implement actions to address them? Is there evidence that process inputs are accurately defined and understood by all staff involved? Is there evidence that process activities are accurately defined and understood by all staff involved? Is there evidence that process outputs are accurately defined and understood by all staff involved? Have procedures, instructions, and forms been established as needed to control the process? Are procedures, instructions and forms used in controlling the process readily available? Do procedures, instructions and forms accurately reflect the practices? Is relevant customer feedback available? For example, feedback from subsequent process Do process operatives understand documents? process resources Are operatives adequately trained to carry out roles, responsibilities, and authorities? Is equipment for e.g. manufacturing, measuring & monitoring; transport/logistics; hardware/software; PPE; etc. fit for purpose? Is equipment identified to allow operatives to determine its readiness for safe use prior to and during the operation? Are process owners accountable for the performance and compliance of their processes? Are staff satisfied with their work area? Is the work area clean and safe? Is there adequate equipment/tools/IT support? Are staff motivated and encouraged to make suggestions for process improvement? Are all staff aware of who their customers are and whether they are satisfied?		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	Are staff aware of the process metrics? Are they aware of the current data analysis related to these metrics and the plans in place to achieve them? Process implementation Is the observed process consistent with documented plans and procedures? Are redundant and non-value adding activities minimized. Is waste material effectively removed and segregated from the process? Are unused materials returned to the correct location in conditions suitable to allow re-use? Are process outputs passed on to subsequent process(es) only when all planned process activities are completed? Do the interfaces between the processes operate smoothly? Does product information flow freely between the support processes? Is there evidence for the reduction in process variation? **Process monitoring questions** Is the process monitored, measured, analysed and improved? Are monitoring activities carried out according to approved plans and procedures? Is process monitoring compared against standards to determine the status of the process? Is process status communicated to appropriate members of the process team? Are records of process monitoring maintained according to approved procedures? Have key performance indicators (KPIs) been established to allow the effectiveness of the process to be evaluated? Are KPIs consistent with quality and business objectives? Are KPIs consistent with customer requirements? Are KPIs reviewed and communicated to the process team, as appropriate, by process leaders? Is the process measured for effectiveness and efficiency? When a process is not performing, is there evidence of data analysis to determine the root cause? When a process is not performing, is there evidence that the cause(s) are dealt with in accordance with procedure? Are records of process monitoring reviewed regularly to determine opportunities for corrective and preventive action? **Process improvement questions** Is the performance of the process reviewed at an appropriate frequency by top		

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	management? Are process improvement objectives aligned with organizational objectives, e.g. the business plan? Is there evidence of an effective PDCA cycle? Can the process owner demonstrate how PDCA applies to their process? Can the process owner to show examples of improvements driven by their PDCA cycle? Can staff demonstrate areas of previous continual improvement? Are records of process upsets and actions taken reviewed to determine the need for corrective action? Where corrective actions have been implemented, have the action(s) taken been demonstrated as effective? Where opportunities for improvement have been implemented, have the action(s) taken been demonstrated as effective? Are all process operatives encouraged to be involved in identifying improvements?		
4.4	What documented information exists to support the operation of processes? How this is documented, information retained.		
5	**Leadership**		
5.1	**Leadership and commitment**		
5.1.1	**Leadership and commitment for the quality management system**		
5.1.1	Quality policy and objectives established; they are compatible with the strategic direction and the organizational context? How awareness of the process approach promoted?		
	NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purpose of the organisation’s existence; whether the organisation is public, private, for profit or not for profit.		
5.1.2	**Customer focus**		
5.1.2	How is the ability to enhance customer satisfaction determined and addressed? How is the focus on consistently providing products and services that meet customer and applicable statutory and regulatory requirements maintained? How is customer satisfaction maintained?		
5.2	**Quality policy**		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
5.2.1	How does top management establish, review and maintain a quality policy? How is it determined to be appropriate to the purpose and context of the organisation? Does it provide a framework for setting and reviewing quality objectives? Does it contain a commitment to satisfy applicable requirements? Does it include a commitment to continual improvement of the QMS?		
5.2.2	Where is the quality policy available as documented information? How is it communicated? How have you made it available to relevant interested parties?		
5.3	**Organizational roles, responsibility and authorities**		
5.3	How does top management ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation?		
5.3	How does top management assign the responsibility and authority for ensuring that the QMS conforms to the International standard? Ensuring processes are delivering their intended outputs. How is the performance of the QMS, opportunities for improvement and the need for change or innovation reported to top management? How is customer focus promoted within the organisation? How is the integrity of the QMS maintained when changes to the QMS are planned and implemented?		
6	**Planning for the quality management system**		
6.1	**Actions to address risks and opportunities**		
6.1.1	How are the internal and external issues and interested parties considered when planning for the QMS? How are risks and opportunities determined and addressed so that the QMS can a) achieve its intended results b) prevent or reduce undesired effects c) achieve continual improvement?		
6.1.2	How are actions planned to address risks and opportunities? How are actions integrated and implemented into the QMS processes? How do you evaluate the effectiveness of the actions?		
6.1.2	How are actions taken to address risks and opportunities determined as being appropriate to the potential impact on the conformity of products and services?		
6.2.2.1	**Product design skills**		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
6.2.2.1	How do you determine that personnel with product design responsibility are competent to achieve design requirements? How do you determine skills required in applicable tools and techniques? How do you identify applicable tools and techniques?		
	NOTE Options to address risks and opportunities can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood and or consequences, sharing the risk, or retaining risk by informed decision.		
6.2	**Quality objectives and planning to achieve them**		
6.2.1	Where are the quality objectives and are these at all relevant functions, levels and processes? Are they consistent with the quality policy? Are they measurable? Do they consider applicable requirements? Are they relevant to the conformity of products and services and do they enhance customer satisfaction? Are they monitored? How? How often? How are they communicated? How are they updated? Where is the documented information on the quality objectives?		
6.2.2	How does the organisation determine what will be done, with what resources, when completed and how will results be evaluated for quality objectives?		
6.3	**Planning of changes**		
6.3	How are changes to the QMS planned systematically? Demonstrate the purpose and potential consequences of changes; Demonstrate the integrity of the QMS; Demonstrate how resources are made available? Demonstrate how responsibility and authority is allocated or reallocated.		
7	**Support**		
7.1	**Resources**		
7.1.1	**General**		
7.1.1	Demonstrate how resources are determined for the establishment, implementation, maintenance and continual improvement of the QMS. Show me how the capabilities and constraints on internal resources are considered. Show me how needs from external providers are considered.		
7.1.2	**People**		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
7.1.2	How do you provide persons necessary to consistently meet customer, applicable statutory and regulatory requirements for the QMS including the necessary processes?		
7.1.3	**Infrastructure**		
7.1.3	How do you determine, provide and maintain the infrastructure for the operation of processes to achieve products and service conformity?		
	NOTE 1: Any product realisation change affecting customer requirements requires notification to, and agreement from, the customer.		
7.1.4	**Environment for the operation of processes**		
7.1.4	How do you determine, provide and maintain the environment for the operation of processes to achieve products and service conformity?		
	NOTE: Environment for the operation of processes can include physical, social, psychological, environmental and other factors (such as temperature, humidity, ergonomics and cleanliness).		
7.1.5	**Monitoring and measuring resources**		
7.1.5	How are the resources determined for ensuring valid and reliable monitoring and measuring results, where used?		
7.1.5	How do you ensure that resources provided are suitable for the specific monitoring and measurement activities and are maintained to ensure continued fitness for purpose?		
7.1.5	Show me the documented information that is evidence of fitness for purpose of monitoring and measurement resources.		
7.1.5	Where applicable, show me how measurement instruments are verified or calibrated at specified intervals against national or international measurement standards; If there are no standards, show me the documented information, which is used as the basis for calibration or verification. Show me how measurement instruments are identified to determine their calibration status. Show me how they are safeguarded from adjustments. Show me how they are safeguarded from damage and deterioration.		
7.1.5	How do you determine the validity of previous measurements if you find an instrument to be defective during verification or calibration? What appropriate actions can you take?		
7.1.6	**Organizational knowledge**		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
7.1.6	How do you determine necessary knowledge for the operation of processes? How do you determine necessary knowledge to achieve conformity of products and services?		
7.1.6	How do you maintain this knowledge and how do you make it available to the extent necessary?		
7.1.6	How do you consider current knowledge and how do you acquire additional knowledge when addressing changing needs and trends?		
	NOTE 1 Organizational knowledge can include information such as intellectual property and lessons learned. NOTE 2 To obtain the knowledge required, the organisation can consider a) internal sources e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organisation; b) external sources e.g. standards, academia, and conferences, gathering knowledge with customers or providers.		
7.2	**Competence**		
7.2	Show me how do you determine the necessary competence of people doing work under your control that affects quality performance; How do you determine competence on the basis of appropriate education, training or experience? How do you take actions to acquire necessary competence where applicable and how do you evaluate the effectiveness of those actions? Show me documented information where appropriate of competence.		
	NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed person; or the hiring or contracting of competent persons.		
7.3	**Awareness**		
7.3	How are people aware of • quality policy? • quality objectives? • Their contribution to the effectiveness of the QMS? • The benefits of improved performance? • The implications of not conforming to the QMS requirements?		
7.4	**Communication**		
7.4	How do you determine internal and external communications relevant to the QMS? How do you determine		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	What? When? Who? With whom? How?		
7.5	**Documented information**		
7.5.1	**General**		
7.5.1	What documented information do you have as required by this standard and What documented information do you have as being necessary for the effectiveness of your QMS?		
	NOTE The extent of documented information can differ from one organisation to another due to a) the size of organisation and its type of activities, processes, products and services b) the complexity of processes and their interactions c) the competence of persons		
7.5.2	**Creating and updating**		
7.5.2	Show me that your documented information contains Identification; Description; In what media format? Show me how the documented information is reviewed and approved for suitability and adequacy.		
7.5.3	**Control of documented information**		
7.5.3.1	Show me how you control documented information. Show me how you make it available and suitable for use. How do you protect your documented information?		
7.5.3.2	When controlling documented information, how do you address Distribution; Access; Retrieval; Use; Storage and preservation; Legibility; Control of changes;		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	Retention and disposition.		
7.5.3.2	How do you identify as appropriate and control documented information of external origin which you have determined as necessary for the QMS		
	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.		
8	**Operation**		
8.1	**Operational planning and control**		
8.1	How are processes needed to meet requirements for provision of products and services planned, implemented and controlled? How are requirements for products and services determined? How is criteria for processes and acceptance for products and services determined? How are resources determined? How is process control implemented? Show me the documented information that shows confidence in that the processes have been carried out as planned and can demonstrate conformity of products and services.		
8.1	How have you determined that the output from the planning process is suitable for your operations?		
8.1	How do you control planned changes? How do you review the consequences of unintended changes? What action is taken to mitigate any adverse effects?		
8.1	How do you control outsourced processes?		
8.2	**Determination of requirements for products and services**		
8.2.1	**Customer communication**		
8.2.1	What are your processes for communicating with customers? How do you communicate information relating to Products; Services; Enquiries; Contracts; Order handling; Customer views, perceptions and complaints; Handling or treatment of customer property; Specific requirements for contingency actions?		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
8.2.2	**Determination of requirements related to products and services**		
8.2.2	What is your process to determine the requirements for products and services to be offered to potential customers? How do you establish, implement and maintain this process?		
8.2.2	How do you define product and service requirements including statutory and regulatory requirements? How do you ensure that you have the ability to meet the defined requirements and substantiate any claims for your products and services?		
8.2.3	**Review of requirements related to products and services**		
8.2.3	How do you review Customer requirements for delivery and post-delivery? Requirements necessary for customers' specified or intended use, where known; Additional statutory and regulatory requirements applicable to products and services; Any other contract or order requirements.		
	NOTE Requirements can also include those arising from relevant interested parties.		
8.2.3	Show me that the review is conducted prior to your commitment to supply products and services to your customers. How do you resolve contract or order requirements, which differ from those previously defined?		
8.2.3	How do you confirm customer requirements where the customer does not provide a documented statement?		
8.2.3	Show me where you retain documented information, which describes results of the review including any new or changed requirements.		
8.2.3	Show me the documented information containing changes to products and services. How do you ensure that relevant personnel are made aware of those changes?		
8.3	**Design and development of products and services**		
8.3.1	**General**		
8.3.1	How do you establish, implement and maintain a design and development process (where detailed requirements of your products and services are not already established or defined by the customer or other parties).		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	NOTE 1 The organisation can also apply the requirements given in 8.5 to the development of processes for production and services provision. NOTE 2 For services, design and development planning can address the whole service delivery process. The organisation can therefore choose to consider the requirements of clauses 8.3 and 8.5 together.		
8.3.2	**Design and development planning**		
8.3.2	When determining the stages and control for design and development, show me how you consider The nature, duration and complexity of the activities; Requirements that specify particular process stages including applicable reviews; Required verification and validation; Responsibilities and authorities; How interfaces are controlled between individuals and parties; The need for involvement of customer and user groups. Show me documented information that confirms design and development requirements have been met.		
8.3.3	**Design and development inputs**		
8.3.3	Can you show me how you determine: Requirements essential for the type of products and services being designed and developed, including as applicable: Functional & performance requirements; Statutory and regulatory requirements; Standards or codes of practice where there is a commitment to implement; Internal and external resources needed for the design and development of products and services; Potential consequences of failure; Level of control expected of the design and development process by customers and other relevant parties.		
8.3.3	How do you determine that inputs are adequate, complete and unambiguous for design and development? How do you resolve conflicts among inputs?		
8.3.4	**Design and development controls**		
8.3.4	How do controls that are applied to the design and development process ensure: Results achieved by design and development activities are clearly defined? Design and development reviews are conducted as planned. Outputs meet the input requirements by verification/validation is conducted to ensure that the resulting products and services are capable of meeting the requirements for		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	the specified application or intended use (when known)?		
8.3.5	**Design and development outputs**		
8.3.5	How do you ensure that design and development outputs: Meet the input requirements for design and development? Are adequate for the subsequent processes for the provision of products and services? Include or reference monitoring and measuring requirements, and acceptance criteria, as applicable? Ensure products to be produced, or services to be provided, are fit for intended purpose and their safe and proper use?		
8.3.5	Show me the documented information, which results from the design and development process.		
8.3.6	**Design and development changes**		
8.3.6	How do you review, control and identify changes made to the design inputs and outputs during design and development of products and services ensuring no impact on conformity to requirements?		
8.3.6	Show me the documented information for design and development changes.		
8.4	**Control of externally provided products and services**		
8.4.1	**General**		
8.4.1	How do you ensure externally provided processes, products and services conform to specified requirements?		
8.4.1	Show me how you apply specified requirements for the control of externally provided products and services when: Products and services are provided by external providers for incorporation into your own products and services; You provide products and services directly to customers by external providers on your behalf; A process or part-process is provided by an external provider as a result of a decision to outsource a process or function.		
8.4.1	Show me how you establish and apply criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers. How do you assess their ability to provide processes or products and services in accordance with specified requirements?		
8.4.1	What documented information do you have of the results of evaluations, monitoring		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	of performance and re-evaluations of external providers?		
8.4.2	**Type and extent of control of external provision**		
8.4.2	How do you determine the controls applied to the external provision of processes, products and services and take into consideration: a) The potential impact of the externally provided processes, products and services on the ability to consistently meet customer and applicable statutory and regulatory requirements? b) The perceived effectiveness of the controls applied by the external provider?		
8.4.2	What verification or other activities do you have to ensure externally provided processes, products and services do not adversely affect your ability to consistently deliver conforming products and services to your customers?		
8.4.2	When processes or functions have been outsourced to external providers, how do you consider a) and b) in 8.4.1 and how do you define the controls intended to be applied to the external provider and to the resulting process output?		
8.4.3	**Information for external providers**		
8.4.3	Show me how you communicate to external providers, applicable requirements for: Products and services to be provided or the processes to be performed on behalf of the organisation; Approval or release of products and services, methods, processes or equipment; Competence of personnel, including necessary qualification; Their interactions with the organisation's quality management system; The control and monitoring of the external provider's performance to be applied by the organisation; Verification activities that the organisation, or its customer, intends to perform at the external provider's premises.		
8.4.3	Before you communicate with external providers, how do you ensure the adequacy of specified requirements?		
8.5	**Production and service provision**		
8.5.1	**Control of production and service provision**		
8.5.1	What controlled conditions do you have for production and service provision, including delivery and post-delivery activities?		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
8.5.1	Can you show me controlled conditions for: a) the availability of documented information defining the characteristics of the products and services; b) the availability of documented information defining the activities to be performed and the results to be achieved; c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met. d) the use, and control of suitable infrastructure and process environment; e) the availability and use of suitable monitoring and measuring resources; f) the competence and, where applicable, required qualification of persons; g) the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement; h) The implementation of products and services release, delivery and post-delivery activities.		
8.5.2	**Identification and traceability**		
8.5.2	What means do you use to identify process outputs to ensure conformity of products and services?		
8.5.2	How do you identify the status of process outputs?		
8.5.2	How do you control the unique identification of process outputs, where applicable? What documented information do you retain?		
	NOTE Process outputs are the results of any activities which are ready for delivery to the organisation's customer or to an internal customer (e.g. receiver of the inputs to the next process); they can include products, services, intermediate parts, components, etc.		
8.5.3	**Property belonging to customers or external providers**		
8.5.3	What care do you provide for customer or external provider's property while under your control? How do you identify, verify, protect and safeguard that property which is provided for use or incorporation into your products or services?		
8.5.3	What means do you use to report to the customer or external provider if their property is incorrectly used, lost, damaged or found to be unsuitable for use?		
	NOTE Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data.		
8.5.4	**Preservation**		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
8.5.4	How do you ensure preservation of process outputs during production and service provision to maintain conformity to product requirements?		
	NOTE Preservation can include identification, handling, packaging, storage, transmission or transportation, and protection.		
8.5.5	**Post-delivery activities**		
8.5.5	How do you meet requirements for post-delivery activities associated with products and services?		
8.5.5	How do you determine: Risk; Nature, use and intended lifetime; Customer feedback; Statutory and Regulatory requirements, when determining the extent of post-delivery activities required with products and services.		
	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.		
8.5.6	**Control of changes**		
8.5.6	How do you review and control unplanned changes to ensure continuing conformity with specified requirements?		
8.5.6	What documented information can you show me which describes the results of reviews of changes, the personnel authorizing change and any necessary actions?		
8.6	**Release of products and services**		
8.6	Show me how planned arrangement have been implemented at appropriate stages to verify product and service requirements have been met. Show me what evidence you retain.		
8.6	Show me how the release of products and services is held until planned arrangements for verification of conformity have been satisfactorily completed, unless approved by a relevant authority, or the customer if applicable. Show me documented information that shows traceability to the person authorizing release of products and services.		
8.7	**Control of non-conforming process outputs, products and services**		
8.7	How do you identify and control process outputs, products and services that do not conform to requirements and prevent their unintended use or delivery?		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
8.7	What appropriate corrective actions are taken based on the nature of the nonconformity and its impact on the conformity of products and services? How do you apply this to nonconformity detected after delivery?		
8.7	How you deal with nonconforming process outputs, products and services in terms of Correction; segregation, containment, return or suspension of provision of products and services? Informing the customer? Obtaining authorization for use as-is? Release, continuation or re-provision of the products and service? Acceptance under concession?		
8.7	How do you verify conformance where process outputs, products and services are corrected following non-conformance?		
8.7	What documented information do you keep following actions taken to address nonconformities, including any concessions obtained and on the person or authority that made the decision regarding dealing with the non-conformance.		
9	**Performance evaluation**		
9.1	**Monitoring, measurement, analysis and evaluation**		
9.1.1	**General**		
9.1.1	Show me how you determine: What needs to be monitored and measured? Methods for monitoring, measurement, analysis and evaluation to ensure valid results? When to perform monitoring and measuring? When results shall be analysed and evaluated?		
9.1.1	What documented information can you show me that monitoring and measurement activities have been implemented in accordance with determined requirements?		
9.1.1	Show me how you evaluate the quality performance and the effectiveness of the QMS.		
9.1.2	**Customer satisfaction**		
9.1.2	How do you monitor customer perception of the degree to which requirements have been met?		
9.1.2	How do you obtain information relating to customer views and opinions of your products and services?		
9.1.2	What methods for obtaining and using this information do you have?		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	NOTE: Information related to customer views can include customer satisfaction or opinion surveys, customer data on delivered products or services quality, market-share analysis, compliments, warranty claims and dealer reports.		
9.1.3	**Analysis and evaluation**		
9.1.3	Show me how you analyse and evaluate data and information arising from monitoring, measurement and other sources.		
9.1.3	Show me how the output of analysis and evaluation is used to: Demonstrate conformity of products and services to requirements? Assess and enhance customer satisfaction? Ensure conformity and effectiveness of the QMS? Demonstrate that planning has been successfully implemented? Assess process performance? Assess performance of external providers? Determine the need or opportunities for improvements within the QMS?		
9.1.3	Show me where the results of analysis and evaluation are used to provide inputs to management review.		
9.2	**Internal audit**		
9.2.1	Are internal audits being conducted at planned intervals? Do they determine whether the QMS conforms to the requirements of ISO 9001 and to the other requirements established by Organisation? (Review records to demonstrate conformance) Do they determine whether the QMS is effectively implemented and maintained? (Review records)		
9.2.2	Can you show me audit program(s) that takes into consideration the quality objectives, importance of the processes, customer feedback, changes impacting the organisation and the results of previous audits? Where are the audit criteria and scope for each audit? Can you demonstrate that selection of auditors and the conduct of audits are objective and impartial and that auditors do not audit their own work? How are audit results reported to relevant management? Can you demonstrate that necessary correction and corrective actions are taken without undue delay? Can you show me documented information of the audit program and the audit results?		
	NOTE See ISO 19011 for guidance.		

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9.3	**Management review**		
9.3.1	What is the frequency that top management reviews the organisation's QMS? How the QMS deemed suitable, adequate and effective?		
9.3.1	What kinds of information are reviewed in management reviews? These must include actions status of previous reviews; changes to internal and external issues relevant to the QMS; issues that affect strategy; KPIs for nonconformities and corrective actions; monitoring and measurement of results; audit results; customer satisfaction; issues concerning external providers; issues concerning other relevant parties; adequacy of resources and effectiveness of QMS; process performance; conformity of products and services; actions taken to address risks and opportunities and their effectiveness; new potential opportunities for continual improvement.		
9.3.2	Show me that management reviews include decisions and actions relating to: Continual improvement opportunities; The need for changes to the QMS including resource needs.		
9.3.2	Show me what documented information you have as evidence of management reviews.		
10	**Improvement**		
10.1	**General**		
10.1	How do you determine and select opportunities for improvement? What necessary actions have you implemented so that you have met customer requirements and enhanced customer satisfaction?		
10.1	Show me how you have: Improved processes to prevent nonconformities; Improved products and services to meet known and predicted requirements; Improved QMS results.		

Clause #	Audit questions	Audit evidence	Type of evidence[1]
	NOTE Improvement can be effected reactively (e.g. corrective action), incrementally (e.g. continual improvement), by step change (e.g. breakthrough), creatively (e.g. innovation) or by re-organisation (e.g. transformation).		
10.2	**Nonconformity and corrective action**		
10.2.1	When nonconformities occur, show me how; You react; Take action to control and correct it; Deal with the consequences; Evaluate the need for action to eliminate the cause so that it does not recur or occur elsewhere by: Reviewing the nonconformity; Determining the cause of the nonconformity; Determining if similar nonconformities exist or could potentially occur; Actions needed are implemented; Review the effectiveness of corrective actions taken, if any; Make necessary changes to the QMS.		
10.2.1	Show me how correction actions were appropriate to the effects of the nonconformities encountered.		
	NOTE 1 In some instances, it can be impossible to eliminate the cause of a nonconformity. NOTE 2 Corrective action can reduce the likelihood of recurrence to an acceptable level.		
10.2.2	What documented information can you show me as evidence of: The nature of the nonconformities and subsequent actions taken; The results of any corrective action.		
10.3	Demonstrate that you continually improve the suitability, adequacy and effectiveness of the QMS.		
10.3	Demonstrate that outputs of analysis and evaluation and the outputs from management review are considered to confirm if there are areas of underperformance or opportunities that shall be addressed as part of continual improvement.		
10.3	What applicable tools and methodologies for investigation of the causes of underperformance and to support continual improvement are selected?		