ISO 9001: 2015 Quality GAP Analysis

The revised ISO 9001 standard was published on 22nd September 2015. This revision was the first significant revision to this standard since ISO 9001:2000 was published 15 years ago.

How to use this document

This document provides an overview of the changes between ISO 9001:2008 and ISO 9001:2015 standard. It has been designed to help you identify the new and revised requirements found in the ISO 9001:2015 standard.

This document is a guide to give you an indication of your readiness for your audit against ISO 9001:2015. It is suggested that you use this document as an indication of how close to compliance you are and to give you confidence when applying for the standard upgrade. Our consultants will have this document as a guidence of compliance. Please be aware that completion of this document does not guarantee that you will be recommended for certification to ISO 9001:2015. You will also need to obtain a copy of the ISO 9001:2015 standard as the clauses are not covered in their entirety by this document.

Further detailed information and guidance covering new concepts and new and revised requirements within ISO 9001:2015 can be obtained by clicking on the link below:
http://www.eurova.co.uk

If you have any questions or concerns regarding the ISO 9001:2015 transition please contact your local Eurova Office:

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4. Context of the organisation

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
4.1 Understanding the organisation and its context	New requirement	You must identify, monitor and review internal and external issues that are relevant to your organisations purpose and strategic direction and that have the ability to impact the QMS intended results. Such factors include legal, technological, competitors, economic environment, internal values, culture knowledge and performance. You will need to be able to evidence this process to your auditors.	We have determined the external & internal issued that are relevant to our organisations purpose and strategic direction and that have the ability to impact the QMS intended results?	☐
			We can demonstrate that we monitor and review information about internal and external issues on a regular basis?	☐
4.2 Understanding the needs and expectations of interested parties	New requirement	You must determine the **relevant** interested parties and their requirements. Interested parties may include customers, shareholders and regulators. This must not be a one off exercise. This information must be monitored and reviewed regularly to maintain currency as relevant interested parties may change over time.	We can evidence that we have been through a process initially to identify the interested parties and have identified their requirements that are relevant to our QMS?	☐
			We can demonstrate that we will monitor and review information about interested parties on a regular basis?	☐
4.3 Determining the scope of the quality management system	1. Scope 1.2 Application 4.2.2 Quality manual	When determining the scope of your QMS you must take into consideration the internal and external issues and the relevant requirements of interested parties. The scope must be documented and must state the products and services covered by the QMS. Standard exclusions - If you determine that a requirement is not applicable and the requirement impacts your ability or responsibility to ensure the conformity of products / services then you cannot claim conformity to ISO 9001:2015.	The scope of our QMS has been determined taking into consideration the internal and external issues and the relevant requirements of interested parties?	☐
			The scope is retained as documented information?	☐
			Any exclusions are recorded and the rationale for the exclusion is stated and justified?	☐

4.4 Quality management system and its processes	4. Quality management system 4.1 General requirements	You are required to establish a process based quality management system. The process approach is now mandatory. You will need to determine required process inputs and expected outputs, assign responsibilities and authorities for processes and identify risks and opportunities for processes and plan to address these. Documented information is required to show that the planned process operation is in line with the actual operation. Existing operational procedures, work instructions remain valid documented information as evidence that the requirement for documented information to support operation of processes are being met.	Our QMS has been established including the processes needed and their sequence and interaction?	☐
			We have criteria for managing processes together with responsibilities, methods, measurements and related performance indicators needed for the effective operation and control?	☐

5. Leadership

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
5.1 Leadership and commitment	5 Management responsibility 5.1 Management commitment 5.2 Customer focus	This clause will require top management to demonstrate their leadership and commitment to the quality management system by taking responsibility for the effective running of your QMS. They can do this by ensuring that the quality policy, quality objectives and commitment is consistent with the organisation's overall business plan. Top management shall also ensure that the requirements of the quality management system are aligned with your organisation's business practices and they should promote awareness of the system throughout the organisation Top management are required to take the lead in demonstrating customer commitment within the organisation by ensuring that all applicable statutory, regulatory and customer requirements are identified and achieved while, at the same time, ensuring that the organisation continues to provide the products and services expected by their customer. Evidence must be available to demonstrate that top management has a "hands on" approach to the management of the QMS and that clause 5.1.1 items a-j have been completed. Where the word "ensuring" is used, top management may still assign task to others for completion and confirm that the task has been completed. Where the words "promoting", "taking", "engaging" or "supporting" appear, these activities cannot be assigned and must be undertaken by top management themselves. You must make top management aware of the new requirements, and ensure that top management will be available to be audited as a matter of routine.	Top management has taken accountability for the effectiveness of the QMS?	☐
			Top management has ensured that the policy and objectives for the QMS have been established and communicated?	☐
			Top management has ensured that the requirements for the QMS have been integrated into the business processes?	☐
			Top management has promoted the awareness of the process approach and risk based thinking?	☐
			Top management has communicated the importance of effective quality management throughout the organisation?	☐
			Customer requirements and applicable statutory and regulatory requirements have been determined, understood and communicated throughout the organisation?	☐
			The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed?	☐

5.2 Policy	5.3 Quality policy	Top management must establish a quality policy. The policy must be appropriate to the context of the organisation as well as its purpose and context. The policy must provide a framework for setting objectives and include a commitment to satisfy and applicable requirements. Your organisations objectives must be consistent with the policy. It is the responsibility of top management to implement and maintain the quality policy. The quality policy must be communicated, understood and applied throughout the organisation. How this is done is up to you. The new requirement for the quality policy to be available to relevant interested parties, as appropriate, means that you will need to consider how this is done for example on a website, social media or literature. The quality policy must be retained as documented information.	Top management have established a quality policy that meet the requirements of clause 5.2.1 items a-d?	☐
			The quality policy is retained a documented information?	☐
			The quality policy has been communicated and understood within the organisation?	☐
			The quality policy is available to relevant interested parties as appropriate?	☐
5.3 Organisational roles, responsibilities and authorities	5.5.1 Responsibility and authority 5.5.2 Management representative	Top management must ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within your organisation. The role of Management representative has disappeared. Duties assigned to the Management Representative in ISO 9001:2008, including ensuring QMS processes are established and maintained, the reporting of QMS performance and promotion of customer requirements across the organisation can now be assigned to any role or split across several roles. You may wish to retain the role of the management representative if this is working well for your organisation. Note: there is a new requirement for top management to ensure that someone is tasked with preserving the integrity of the quality management system while planning and undergoing change. You may have to revisit the existing responsibilities and authorities with regards to the QMS, especially the responsibilities of top management. The review may identify gaps (knowledge and skills), which will need to be addressed to demonstrate compliance.	Top management has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation?	☐
			The duties currently assigned to the management representative are still assigned and undertaken within the organisation?	☐
			Top management has ensured that the responsibilities and authorities for preserving the integrity of the QMS while planning and undergoing change?	☐

6. Planning

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
6.1 Actions to address risks and opportunities	New requirements	This is a new and key requirement and is linked to clauses 4.1 and 4.2. Once you have thought about internal and external issues and the requirements of interested parties you must then determine the risks and opportunities that have the potential to impact the operation and performance of your QMS, both positively and negatively. You must then determine the actions needed to address the risks and realise the opportunities. Please note the statement in the standard that actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services i.e. not all risks will require actions. You may decide to keep the risk and only significant risks require major action. It is important to note that although the requirement for determining and addressing risks and opportunities is now a requirement, formal risk management is not. Your auditor will seek evidence that you have a systematic approach / methodology in place that enables you to effectively identify and address risks and opportunities, and that you are taking a planned approach to addressing the risks and realising the opportunities.	We have a systematic approach / methodology in place that enables us to effectively identify and address risks and opportunities?	☐
			We have identified the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended results?	☐
			We have planned actions to address the risks and realised the opportunities and have integrated the actions into system processes?	☐
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives	Quality objectives must be established at relevant functions, levels and processes within your organisation. You must decide what functions, levels and processes are relevant. Such objectives must be consistent with your organisations quality policy and be relevant to the conformity of products and services and the enhancement of customer satisfaction. Objectives must be measurable, take into account applicable requirements and be monitored in order to determine that they are being me. They must be communicated across your organisation and be updated as and when the need arises.	We have established quality objectives at relevant functions, levels and processes?	☐
			Our quality objectives are consistent with our quality policy?	☐
			Our quality objectives are relevant to the conformity of products and services and the enhancement of customer satisfaction?	☐
			Our objectives are measureable and take into account applicable requirements?	☐

		You are now required to plan how objectives are to be achieved, including determining activities required, assigning responsibility and dedicating resources for achieving objectives and timescales. You must also determine how you will evaluate the work completed. Finally you must maintain documented information on the quality objectives.	Our objectives are communicated across the organisation?	☐
			We have a mechanism to monitor our quality objectives to ensure they are being met?	☐
			Information on our quality objectives is retained as documented information?	☐
			We have planned how to achieve our quality objectives including: • Actions required • Resources required • Responsibilities • Timescales • How the results will be evaluated	☐
6.3 Planning of changes	5.4.2 Quality management system planning	When you determine that there is a need to change your QMS you must ensure that changes are carried out in a planned and systematic manner. You must consider the purpose and likely consequences of the change(s) and the necessary resources required, and any reallocation of responsibilities and authorities.	Is there a plan for determining the need for changes to the QMS and managing the implementation of any planned changes?	☐

7. Support

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
7.1.1 Resources	6 Resource management	Clause 7.1.1 requires you to determine and then provide all the resources necessary to establish, implement, maintain and continually improve your quality management system. Resources include people, infrastructure, the environment for the operation of processes, monitoring and measuring resources and organisational knowledge. In completing the above you must consider both the capabilities and constraints on existing internal resources as well as what needs to be sourced from external providers. Your auditor will seek evidence that you have considered the need for external resources in addition to the need for internal ones.	We have determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of our quality management system including internal and external resources?	☐
7.1.2 People	6.1 Provision of resources	Clause 7.1.2 requires you to provide those people necessary for the effective operation of your quality management system and its processes in order that it can consistently meet customer and applicable statutory and regulatory requirements.	We have determined and provided the people necessary for the effective implementation of our quality management system and operation of processes?	☐
7.1.3 Infrastructure	6.3 Infrastructure	Clause 7.1.3 requires you to identify provide and maintain the infrastructure necessary to enable processes to operate effectively and to achieve conformity of products and services. Infrastructure can include buildings and associated utilities, equipment including hardware and software, transportation resources and information and communication technology.	We have provided and maintained the infrastructure necessary for the operation of processes and to achieve conforming products and services?	☐
7.1.4 Environment for the operation of processes	6.4 Work environment	Clause 7.1.4 requires you to determine, provide and maintain a suitable environment for the operation of processes and to achieve conformity of products and services. A suitable environment for the operation of processes can include physical, social, psychological, environmental and other factors, such as temperature, humidity, ergonomics and cleanliness. These factors can differ substantially depending on the products and services provided and the examples shown are not exclusive and, most importantly, not mandatory. Auditors will want to see evidence that you are applying updated requirements to all processes determined necessary for your quality management system.	We have determined and provide and maintain a suitable environment for the operation of processes and to achieve conformity of products and services?	☐

7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment	If you use monitoring or measurement to demonstrate that your products and services are conforming to requirements, you must make sure that you provide the necessary resources to ensure that monitoring and measuring results are both valid and reliable. These resources need to be suitable to the type of monitoring or measurement being undertaken and must be maintained in order to ensure they remain fit for purpose. You must now retain documented information as evidence that the measuring and monitoring resources are fit for purpose, not just listing the monitoring or measuring equipment. In instances where measurement traceability has been identified as a requirement or is considered by your organisation as essential in order to provide confidence in the measurement results, measuring equipment must be verified or calibrated against international or national measurement standards at specific intervals or prior to their use. If no such standards exist, you must keep the basis you are using for calibrating or verifying the measuring instrument must be retained as documented information. Measuring instruments must be identified in such a way that their calibration status can be determined. They must also be protected to prevent them being adjusted, damaged or subjected to deterioration indeed anything that would invalidate their correct calibration status and therefore jeopardise any future measurement results. If measuring equipment is found to be defective, previous results need to be revisited to see if they have been adversely affected and appropriate action taken as necessary.	Where monitoring or measuring is used for evidence of conformity of our products and services to specified requirements, we have determined and provided the resources needed to ensure valid and reliable results?	☐
			We have documented information available as evidence, that identifies all measuring and monitoring resources and evidence that they are fit for purpose?	☐
			Where measurement traceability has been identified as an essential requirement, measuring equipment is calibrated against measurement standards at specific intervals or prior to their use?	☐
			The above measuring equipment is safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?	☐

7.1.6 Organisational knowledge	New requirement	This new clause requires you to determine the knowledge necessary for the operation of processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, you must consider current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. This new requirement ensures that you have or obtain the knowledge necessary to respond to changing business environments referred to in clause 4.1, changing customer and relevant interested party needs and expectations referred to in clause 4.2 and, where applicable, related improvement initiatives. As such, this requirement has strong links with management review activities. This knowledge needs to be maintained and made available to the extent necessary. You can choose how best to do this, note that there is no explicit requirement for this knowledge to be held as documented information. Your auditor will be looking to ensure that you have taken steps to identify and acquire the knowledge necessary to establish the continuing conformity of your products and services. Auditors will be looking for evidence that the knowledge has been communicated as necessary within your organisation and that it is being maintained and protected. They will be looking to ensure that an assessment of organisational knowledge has taken place prior to any changes made to the quality management system in response to changing needs or trends.	We have determined the knowledge necessary for the operation of processes and to achieve conformity of products and services?	☐
			The knowledge is maintained and is made available to the extent necessary?	☐
			We have a process for reviewing knowledge when addressing changing needs and trends to determine how to acquire or access any necessary additional knowledge and required updates?	☐

7.2 Competence	6.2.1 General 6.2.2 Competence, training and awareness	This clause requires you to determine the competency requirements for those people performing work under your organisations control. You must then ensure that those people possess the necessary competencies, either on the basis of appropriate education, training or experience. You are required to take applicable action to acquire the necessary competence to action any competency deficiency identified. Actions taken need to be evaluated for effectiveness. Examples of applicable actions include training, recruitment or use of external people. You must retain appropriate documented information to evidence competence.	We have ensured that those persons who can affect the performance and effectiveness of the QMS are competent on the basis of appropriate education, training, or experience?	☐
			If applicable, we have taken action to acquire the necessary competence and we have evaluated the effectiveness of the actions taken?	☐
			We have documented information available as evidence of competence?	☐
7.3 Awareness	6.2.2 Competence, training and awareness	This clause requires you to ensure that all people doing work under your organisation's control are aware of the organisation's quality policy, quality objectives that are relevant to them, how they are contributing to the effectiveness of the QMS and the implications for not conforming to the QMS requirements. It is important to note that the requirements now apply to **all persons** doing work under your organisation's control, this include contractors. You auditor will be looking for you to provide evidence that the enhanced requirements are being met.	We have ensured that people doing work under our control are aware of the quality policy and objectives, their contribution to these and the implications of not conforming? We have evidence available to demonstrate the above?	☐
7.4 Communication	5.5.3 Internal communication	This clause requires you to determine the internal and external communications relevant to the quality management system. You must determine those QMS-related matters on which you wish to communicate, when you will communicate who you will communicate to, the method of the communications and who will be responsible for the communication.	We have determined internal and external communications relevant to the QMS?	☐
			We have determined what, when, with whom, how and who will communicate?	☐
7.5 Documented information	4.2 Documentation requirements	This clause requires that your quality management system includes both documented information identified as required in ISO 9001:2015 and documented information identified by your organisation as necessary for the effective operation of your quality management system. Note: There is no longer an explicit requirement for a quality manual or documented procedures. However, if you find these documents useful, and they work well for the business there is no reason to remove them.	We have established the documented information necessary for the effective implementation and operation of the QMS?	☐
			We have established the documented information required by ISO 9001:2015?	☐

7.5.2 Creating and updating	4.2.3 Control of documents 4.2.4 Control of records	When documented information is created or updated, you must ensure that it is appropriately identified and described (e.g. title, date, author, reference number). It must be in an appropriate format (e.g. language, software version, graphics) and on appropriate media (e.g. paper, electronic). Documented information must be reviewed and approved for suitability and adequacy.	Our established documented information is appropriately identified and described, in an appropriate format and is available on appropriate media?	☐
			Our established documented information has been reviewed and approved for suitability and adequacy?	☐
7.5.3 Control of documented Information	4.2.3 Control of documents 4.2.4 Control of records	This clause requires you to control documented information in order to ensure that it is available where and when needed and that it is suitable for use. It must also be adequately protected against improper use, loss of integrity and loss of confidentiality. Documented information retained as evidence of conformity must be protected from unintended alterations	Our documented information is available and suitable for use, where and when it is needed?	☐
			Our documented information is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)?	☐
			For the control of documented information, we have addressed activities such as distribution, access, retrieval and use, storage and preservation, including preservation of legibility, c) control of changes (e.g. version control) and retention and disposition of our documented information?	☐
			Documented information of external origin determined to be necessary for the planning and operation of our quality management system is identified as appropriate, and is controlled?	☐
			Documented information retained as evidence of conformity is protected from unintended alterations?	☐

8. Operation

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
8.1 Operational planning and control	7.1 Planning of product realisation	This clause requires you to plan, implement and control those processes identified as required by clause 4.4, as necessary in order for you to meet the requirements for product and service delivery. You must also plan how you will address any risks and opportunities that may impact these processes as identified in clause 6. This process starts with you establishing the product/service requirements. You must then establish the criteria for the process, namely, how you will control the process, the product/service acceptance criteria and the resources necessary for product/service conformity. This means that the inputs (triggers for the process), outputs (products and/or services), resources and controls should be determined. In addition, what makes the output acceptable also needs to be determined. You must then control the processes using the criteria above. You are required to create and keep documented information to the extent necessary to allow you to ensure that processes are being carried out as planned, and that the products and services that are being produced conform to the identified requirements and acceptance criteria. You must control planned changes to the provision of product and services and must review the consequences of any unintended changes. Where necessary, you should mitigate any adverse effects. Auditors will be looking for evidence that the process (including process inputs, outputs, resources, controls, criteria, process monitoring and measuring as well as performance indicators) have been planned. For those risks and opportunities that you have determined as needing to be addressed, auditors will look for evidence that these actions have been integrated into the management system. As such, these actions should be verifiable at process level for example, evidence of controls, acceptance criteria and resources. Auditors will also need to see evidence that processes have been implemented and controlled as planned, and in so far as they relate to process planning and control, evidence that you have evaluated the	We have established processes for the provision of products and services that meet the specified requirements for the products and services, including criteria for the process, the product/service acceptance criteria and the resources necessary for product/service conformity?	☐
			We can demonstrate that we control the processes according to the defined criteria?	☐
			We have created and retained documented information to allow us to ensure that processes are being carried out as planned, and that the products and services that are being produced conform to the identified requirements and acceptance criteria.	☐

		effectiveness of actions taken to address risks and opportunities. Finally auditors will seek evidence relating to planned changes and to any unintended changes.	When changes are planned, are they carried out in a controlled way and actions are taken to mitigate any adverse effects?	☐
8.2.1 Customer communication	7.2.3 Customer communication	This clause requires you to put processes in place to communicate effectively with customers. Communication must include product and service information, enquiry, contract or order handling (including amendments); customer feedback relating to the organization's products and services (including complaints), the management of customer property and specific requirements for contingency actions when relevant.	We have established processes for communicating with customers in relation to information relating to products and services, inquiries, contracts or order handling?	☐
8.2.2 Determination of requirements related to products and	7.2.1 Determination of requirements related to the product services	You are required to determine requirements for the products and services you intend to offer to customers. In doing so, you must ensure that the requirements are defined. This includes the capture of any applicable statutory and regulatory requirements as well as any requirements you consider necessary. A new requirement is that you must then ensure that you can meet claims you make for the products and services you intend to offer.	We have defined the requirements for our products / services including any applicable statutory and regulatory requirements and others considered necessary?	☐
			We can demonstrate that we can meet the claims for the products / services we offer	☐
8.2.3 Review of requirements related to the products and services	7.2.2 Review of requirements related to the product	You must ensure that you can meet product and service requirements you offer to customers. This clause requires you to review product and service requirements for customer offerings before you commit to supply. This review needs to consider requirements set by the customer, including any relating to delivery and post-delivery activities. It must also include consideration of any requirements not expressly stated by the customer but that you know are necessary for the product or service to be suitable for the customer's specified or intended use. The review must also consider, any applicable statutory or regulatory requirements relating to the product or service, and any contract or order	We have a process for reviewing product and service requirements for customer offerings before we commit to supply.	☐
			Our review considers requirements set by the customer, requirements not expressly stated by the customer but we know are necessary for the product or service to be suitable for the	☐

		requirements that differ from those previously stated. You must resolve contract or order requirements that differ from those previously defined. If the customer does not provide a documented statement of their requirements then you must confirm the customer's requirements prior to acceptance. Finally you must keep documented information relating to requirement reviews including the results of the reviews and any new requirements for the products and services. Auditors will seek documented evidence to demonstrate that requirements for delivery and post-delivery activities are considered in your product and service requirement review.	customer's specified or intended use and, any applicable statutory or regulatory requirements relating to the product or service?	
			This review conducted prior to our commitment to supply products and services?	☐
			We have documented information on the results of the above review and on any new requirements for the products and services?	☐
8.3.1 General	New requirement – not in ISO 9001:2008 standard	This is a new clause that requires you to establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	Where we design and develop products or services, there are design and development processes established and implemented in line with the requirements of the standard?	☐
8.3.2 Design and development planning	7.3.1 Design and development planning	This clause requires you to plan the design and development of your products and services. The design and development process will comprise a number of stages, each of which must be subject to controls. When determining the stages and controls to be applied to your design and development process, you must consider the items listed in clause 8.3.2 a-j. There is a new requirement for you to consider the documented information required to confirm that the design and development requirements have been met.	In determining the stages and controls for design and development, we have considered all items listed in clause 8.3.2 a – j?	☐
8.3.3 Design and development inputs	7.3.2 Design and development inputs	This clause requires you to determine the essential requirements for the types of products and services that you will design and develop. You will need to consider the inputs listed in clause 8.3.3 a-e. You must ensure that design and development inputs are adequate, complete and unambiguous. If there are any conflicts between design	We have determine the requirements essential for the specific types of products and services to be designed and developed. We have considered all items listed in clause 8.3.3 a – e?	☐

		inputs, then these must be resolved. You must retain documented information on design and development inputs.	We have documented information available on design and development inputs?	☐
8.3.4 Design and development controls	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation	This clause requires you to apply controls to your design and development process in order to ensure that results are defined, reviews, verification and validation activities are conducted and any necessary actions are taken on problems determined during the reviews, or verification and validation activities as required by clause 8.3.4 a-e. You must retain documented information on the above activities.	We have applied controls to our design and development processes as required?	☐
			Documented information is available as required?	☐
8.3.5 Design and development outputs	7.3.3 Design and development outputs	This clause requires you to ensure that the outputs from design and development meet the input requirements for design and development, and are suitable for provision of products and services. Design and development outputs must include or reference monitoring and measuring requirements and acceptance criteria, as appropriate. Finally you must ensure that the design and development outputs specify the product and service characteristics that are essential for their intended purpose and their safe and proper provision. You are required to keep documented information on design and development outputs.	Design and development outputs:	
			Meet the input requirements?	☐
			Are adequate for the subsequent processes for the provision of products and services?	☐
			Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria?	☐
			Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision?	☐
			Documented information on design and development outputs is available?	☐

8.3.6 Design and development changes	7.3.7 Control of design and development changes	This clause requires you to 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. The requirements apply at all stages during the design and development	If changes are made either during or after design and development that have an adverse impact on conformity to requirements, we have identified, reviewed and controlled the changes?	☐

		of products or services and also subsequently; for example, post-delivery. You must keep documentary information relating to design and development changes, the review results and change authorisation.	Documentary information relating to design and development changes, the review results and change authorisation is available?	☐
8.4 Control of externally provided processes, products 8.4.1 General	7.4.1 Purchasing process and services	This clause requires you to employ controls to enable you to verify that externally provided processes, products or services meet requirements These controls must be put into effect when you are seeking to obtain: • products and services from external providers for incorporation into your own products and services; • products and services to be provided directly to the customer by the external provider on your behalf; • outsourced processes or parts of processes from an external provider based on your decision. You must determine and put in place criteria that allow you to evaluate and select external providers that allow you to monitor their performance and to subsequently re-evaluate them based on their ability to provide processes, products and services that conform to requirements. You must retain documented information evidencing the results of external provider evaluations, re-evaluations, the monitoring of their performance and any actions necessary from the evaluations.	We have controls in place to ensure that externally provided processes, products, and services conform to specified requirements?	☐
			We have and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?	☐
			We have documented information available of the above activities and any actions arising from evaluations?	☐

8.4.2 Type and extent of control	7.4.1 Purchasing process 7.4.3 Verification of purchased product	This clause requires you to determine the type and extent of controls that you want to apply to external providers. In deciding the nature and extent of these controls, you must make sure that there is no negative impact that the externally provided processes, products or services could have on your ability to supply conforming products and services to your customers.	We have ensured that externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products and services to our customers?	☐

		You must: • ensure that any outsourced processes stay within the control of your QMS. • define the controls for both the external provider and resulting outputs. • consider both the possible impact any externally provided process, product and service has on its ability to consistently meet customer, statutory and regulatory requirements and the effectiveness of the controls you apply to the external provider. • determine verification (or other) activities necessary to ensure conformance to requirements.	Externally provided processes remain in the control of our QMS?	☐
			We have defined the controls that we apply to external providers and to the resulting output?	☐
			We have determined the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements?	☐
8.4.3 Information for external providers	7.4.2 Purchasing information	This clause requires you to ensure that the requirements you intend to communicate to the external providers are reviewed for adequacy prior to them being communicated. You must communicate to external providers your requirements for: • the processes, products and services to be provided • the approval of the product and service • the approval of methods, processes and equipment • the approval of the release of products and services • the competence of personnel, including any necessary qualifications • the interactions between you and the external provider • how the external provider's performance will be monitored and controlled • verification or validation activities that you intends to perform at the external provider's premises.	All requirements we intend to communicate to the external provider are reviewed for adequacy prior to them being communicated?	☐
			We communicate our requirements as per clause 8.4.3 a-f to external providers?	☐
8.5 Production and service provision 8.5.1 Control of production and service provision	7.5 Production and service provision 7.5.1 Control of production and service provision	This clause requires you to implement production and service provision under controlled conditions. Controlled conditions must include, as applicable: • documented information that defines the characteristics of the	The provision of products and services are carried out in controlled conditions which include:	☐

		product or service or the activities to be performed • documented information that defines the results to be achieved • the availability and use of suitable monitoring and measurement resources • the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and outputs have been met. • the use of suitable process environment and infrastructure are used; • suitable monitoring and measurement resources are made available; • the appointment of competent personnel • for processes where the results cannot be verified by subsequent monitoring or measurement, the process itself must be initially validated and then periodically re-evaluated • implementation of actions to prevent human error • implementation of release, delivery and post-delivery activities.	the availability of documented information that defines the characteristics of the products to be produced or the services to be provided?	☐
			the availability of documented information that defines the results to be achieved?	☐
			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?	☐
			ensuring the people carrying out the tasks are competent?	☐
8.5.2 Identification and traceability	7.5.3 Identification and traceability	This clause requires you to use suitable means to identify outputs when it is necessary to ensure conformity of products and services. You must be able to identify the status of outputs in respect of any monitoring and measurement requirements it has set throughout production or service provision. In cases where traceability is a requirement, you must additionally ensure that outputs are uniquely identifiable and retain documented information necessary to enable traceability.	We have appropriate methods of ensuring identification and traceability of the outputs during production and service provision?	☐
			In cases where traceability is a requirement we retain documented information necessary to enable traceability?	☐
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property	This clause requires you to take care of property owned by customers or by external providers while it is being used by you or under your control. You must ensure that any such property provided for your use or for it to be included in your products and services is identified, verified, protected and safeguarded.	We have identified, verified, protected and safeguarded any property belonging to customers or external providers while it is being used by us or under our control?	☐

		If the property is lost, damaged or otherwise found to be unsuitable for use, you must make sure that this is reported back to the customer or external provider. You must retain documented information on what has occurred.		
8.5.4 Preservation	7.5.5 Preservation of product	This clause requires you to take appropriate measures during production and service provision to safeguard outputs, in order to maintain conformity to requirements.	We take appropriate measures during production and service provision to safeguard outputs, in order to maintain conformity to requirements?	☐
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision	This clause requires you to meet requirements for post-delivery activities associated with products and services. In determining the extent of post-delivery activities required you must consider: • statutory or legal requirements, • any possible unwanted consequences associated with the particular product or service, • the nature, use and intended lifetime of the product or service, • customer requirements • customer feedback	There is a requirement for post-delivery activities associated with our products and services such as warranty, maintenance services, recycling or final disposal. Such post-delivery activities associated with our products and services are these defined and managed?	☐
8.5.6 Control of changes	7.3.7 Control of design and development changes	This clause requires you to review and control any changes that are necessary in order to ensure that products or services continue to meet their specified requirements. In such instances, you must retain documented information describing the results of the review, the person(s) authorising the changes and any necessary actions arising from the review.	We control any changes that are necessary in order to ensure that products or services continue to meet their specified requirements?	☐
			We retain documented information describing the results of the review of the changes, the person(s) authorising the changes and any necessary actions arising from the review?	☐
8.6 Release of products and services	8.2.4 Monitoring and measurement of processes 7.4.3 Verification of purchased product	This clause requires you to carry out predetermined arrangements at appropriate stages of the production/service delivery in order to verify that products and services meet all requirements (including acceptance criteria). You must ensure that products or services are not be released to the customer until all of the planned arrangements have been satisfactorily	We have arrangements in place to ensure that we verify that products and services meet all requirements?	☐
			We ensure that products or services are not released to the customer until all of the planned arrangements have been satisfactorily completed,	☐

		completed, unless a relevant authority approves their early release. Where applicable, approval for early release must also be obtained from the customer You must retain documented information on the release of products or services including evidence of conformity with acceptance criteria and traceability to the individual(s) who authorised the release.	unless a relevant authority approves their early release?	
			We have documented information available on the release of products or services including evidence of conformity with acceptance criteria and traceability to the individual(s) who authorised the release?	☐
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product	This clause requires you to ensure that that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery Where nonconforming outputs are identified, you must take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This requirement also applies to nonconforming products or services that are detected after delivery of products, during or after the provision of services. You must deal with the nonconforming outputs in one or more of the ways prescribed in clause 8.7.1 a-d. Conformity to the requirements must be verified when nonconforming outputs are corrected. Finally where nonconformity is identified you must retain documented information that describes the nonconformity, the actions taken, any concessions obtained and that identifies the authority deciding the action in respect of the nonconformity.	We ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?	☐
			Where nonconforming outputs are identified we take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services?	☐
			Where nonconformity has been identified documented information is available that describes the nonconformity, the actions taken, any concessions obtained and that identifies the authority deciding the action in respect of the nonconformity?	☐

9. Performance evaluation

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement	This clause requires you to determine: • what needs to monitored and measured, • the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results, • when the monitoring and measuring will be performed, and • when the results from monitoring and measurement will be analysed and evaluated. You must ensure that where monitoring and measurement takes place, documented information is retained to evidence the results. Finally, there is a requirement for you to evaluate the performance and effectiveness of your quality management system. Auditors will seek evidence to confirm that you have considered what, how and when to measure and that the outcomes from this decision result are ensuring appropriate process control.	We have determined: • what needs to be monitored and measured? • the methods for monitoring, measurement, analysis and needed evaluation to ensure valid results? • when the monitoring and measuring will be performed? • when the results from monitoring and measurement will be analysed and evaluated?	☐
			Where monitoring and measurement takes place, documented information is available to evidence the results?	☐
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction	This clause requires you to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. You must determine the methods for obtaining, monitoring and reviewing this information. The above requirement means that you must put in place arrangements to monitor the degree to which customers believe their requirements for products and services have been met.	We have established arrangements and /or methods of monitoring and reviewing customer perceptions of the degree to which their needs and expectations have been fulfilled?	☐

9.1.3 Analysis and evaluation	8.4 Analysis of data	This clause requires you to analyse and evaluate appropriate data and information that has been obtained either internally or externally for a variety of pre-defined purposes. The results of the analysis must be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. Auditors will seek evidence to demonstrate that both analysis and evaluation of data and information has been completed. It is not sufficient just to carry out an analysis without interpreting the results. Auditors will seek evidence to demonstrate that through analysis and evaluation that planning has been effective.	We analyse and evaluate appropriate data and information arising from monitoring and measurement?	☐
			The results of the analysis are evaluated in accordance with clause 9.1.3 a-g?	☐
9.2 Internal audit	8.2.2 Internal audit	This clause requires you conduct internal audits at planned intervals to provide information on whether the QMS conforms to: • your own requirements for the QMS, • the requirements of ISO 9001:2015 and • that the QMS is effectively implemented and maintained. The clause also sets out a series of requirements relating to how audit programmes must be structured, what audits must cover, who should undertake audits and how audits are to be reported. When designing an audit programme, you must consider the importance of the processes concerned, changes affecting your organisation, and the results of previous audits. Documented information must to be retained to provide evidence that the audit programme has been implemented as well as the results of audits.	We have established a program for internal audit of our QMS to ensure that we conduct internal audits at planned intervals? The plan includes the frequency, methods, responsibilities, planning requirements and reporting methods?	☐
			We planning the audit programme we have considered the importance of the processes concerned, changes affecting our organisation, and the results of previous audits?	☐
			Documented information is available to demonstrate that the audit programme has been implemented as well as the results of audits?	☐

9.3 Management review	5.6 Management review	This clause requires top management to review the quality management system at planned intervals in order to ensure the quality management system's continuing suitability, adequacy and effectiveness. The management review must include inputs relating to all items listed in clause 9.3.2 a-f. The management review outputs must include decisions and actions relating to opportunities for improvement, any need for changes to the quality management system and any resource needs. You must retain documented information as evidence of the results of management reviews. Auditors will be expecting to see evidence of a more strategically focused management review. Context, risks and opportunities need to be considered, as well as the alignment of the quality management system to the overall strategic objectives.	We review our QMS at planned intervals at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of our organisation?	☐
			Our management review takes into consideration all items listed in clause 9.3.2 items a-f?	☐
			Our management review outputs include decisions and actions relating to opportunities for improvement, any changes to our QMS and resource needs?	☐
			We retain documented information as evidence of the results of our management reviews?	☐

10. Performance evaluation

ISO 9001:2015 Clause	ISO 9001:2008 Clause	Guidance	Readiness questions	
10.1 General	8.5.1 Continual improvement	Clause 10.1 is a new clause. It requires you determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. When doing this you must: • improve products and services to meet requirements as well as to address future needs and expectations • correct, prevent and reduce undesired effects • improve the performance and effectiveness of your QMS Auditors will continue to seek objective evidence that improvement is taking place. Auditors will seek evidence that you are considering improvement in respect of your products and services, and the performance of the QMS overall. In the case of products and services, this is to meet not just current requirements, but also future requirements.	We have determined and selected opportunities for improvement and implemented the necessary actions to meet customer requirements and enhance customer satisfaction?	☐
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action	This clause requires you take action when a nonconformity occurs. This includes those resulting from complaints. When nonconformity occurs you must take whatever action is necessary to control and correct the nonconformity, and to deal with any resultant consequences. Once this is complete you must then evaluate the need for action to eliminate the cause(s) of the nonconformity in order that it does not recur or occur elsewhere by reviewing and analysing the nonconformity, determining the causes of the nonconformity and determining if similar nonconformities exist, or could potentially occur. You must then implement any action needed, review the effectiveness of any corrective action taken, update risks and opportunities determined during planning, if necessary, make changes to the quality management system, if necessary. Finally you must retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.	We have established appropriate processes for managing nonconformities and the related corrective actions?	☐

		Auditors will seek evidence that, where nonconformities have been identified, an investigation has been conducted to determine whether other similar nonconformities actually do or potentially could exist elsewhere. They will also seek evidence that where a nonconformity has occurred, that you have considered whether it needs to make changes to the wider system to prevent a reoccurrence and if risk and opportunities during planning need updating. Auditors will no longer expect to find a documented corrective action procedure. However they will seek documentary evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.	Where nonconformity has occurred we have reacted to the nonconformity, evaluated the need for action to eliminate the causes(s), implemented any action needed and reviewed the effectiveness of any corrective actions taken?	☐
			Documented information is available as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action?	☐
10.3 Continual improvement	8.5.1 Continual improvement	Clause 10.3 requires you to work to continually to improve your QMS in terms of its suitability, adequacy and effectiveness. Suitability and adequacy are new. As part of continual improvement, you are required to use the outputs from analysis and evaluation (see sub-clause 9.1.3) and from management review (see clause 9.3.3) to determine areas of underperformance and to identify any opportunities for improvement. Auditors will seek evidence that you are using the outputs from analysis, evaluation and management review activities to identify improvement opportunities and quality management system underperformance.	We have decided how we will address the requirement to continually improve the suitability, adequacy, and effectiveness of our QMS?	☐