The below chart provides (1) guidance in comprehending the meaning of the new ISO9001:2015 language and (2) provides examples of ASACB expectations of acceptable evidence to support compliance to the Standard. This is not an exhaustive list of examples and is not intended to be the only examples allowed.

Summary Of Requirement	Audit Evidence Sought	Company Evidence
4 Context of the organization **4.1 Understanding the organization and its context**		
The organization is required to determine both the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. In addition, the organization is required to then monitor and review the information about these external and internal issues going forward.	This could be accomplished as a standalone process or be part of an existing activity such as a strategic plan, business plan or the management review process. The auditor is expected to explore the issues noted and their impact on the organization results. See the notes in the Standard for additional guidance.	
4.2 Understanding the needs and expectations of interested parties		
Due to potential or actual effects on the organization and its customer, they are expected to determine any relevant interested party to the QMS including their requirements from the organization. Additionally, the organization must then monitor and review this information *3.2.3 Interested Party – person or organization that can affect, be affected by, or perceive itself to be*	As with 4.1, this could be accomplished as a standalone process or be part of an existing activity such as a strategic plan, business plan or the management review process. The auditor is expected to identify who are the interested parties and their requirements.	

affected by a decision or activity.		
4.3 Determining the scope of the quality management system		
The organization must establish the scope of the QMS and its boundaries considering: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) The products and services of the organization. The organization is expected to apply all the requirements of this ISO 9001 if they are applicable within the determined scope of its quality management system. The scope of the organization's QMS must be documented, available and maintained as documented information. The scope must state the types of products and services covered, and provide justification for any requirement of this International Standard	The auditor should verify the scope statement given 4.1 and 4.2, any parts of the Standard not to be addressed and make sure the statement covers the types of products and services offered. The idea of an "exclusion" has been deleted and the organization must apply those clauses of the Standard that are necessary given the scope statement or a justification for why not. This is likely to have no impact on the audit.	
4.4 Quality management system and its processes		
The organization is expected to continue to maintain their QMS and establish the processes needed to accomplish expected outcomes. This	The auditor must understand how the organization is fulfilling the new requirement to address risks and opportunities.	

includes inputs, outputs, sequence, criteria, methods, etc. in order to be effective. One addition is the need to address risks and opportunities in line with Clause 6.1. Also covered is need to maintain and retain documented information.		
5 Leadership **5.1 Leadership and commitment** **5.1.1 General**		
This is in part, the previous requirement for management commitment. However, some items have been added or verbiage changed including; a) taking <u>accountability</u> for the effectiveness of the quality management system; b) ensuring that the quality policy and <u>quality</u> objectives are established for the quality management system and are <u>compatible with the context and strategic direction of the organization</u>; c) ensuring the <u>integration</u> of the quality management system requirements into the organization's business processes; d) <u>promoting</u> the use of the process approach and risk-based thinking; h) <u>engaging, directing and supporting</u> persons to contribute to the	The auditor must interview the organizations leadership to understand how they are accomplishing the additional items (underlined for emphasis).	

effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.		
5.1.2 Customer focus		
This is a continuation of the previous clause 5.2 but did add: b) the risks and opportunities that **CAN** affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; *Note: "Can" indicates a possibility or capability.*	The auditor must interview the leadership to understand the risks and opportunities affecting conformity of product or their ability to enhance customer satisfaction.	
5.2 Policy		
Basically this is the old 5.3 with no substantive changes.	None Required.	
5.3 Organizational roles, responsibilities and authorities		
Basically this is combined the old 5.5.1 and 5.5.2 and partially 5.4.2. No substantive changes, but it does ask top management to assign the responsibilities and authorities for each item (e.g., a thru e).	None Required.	

6 Planning 6.1 Actions to address risks and opportunities		
This is a new requirement that is in part intended to replace the concept of preventive action. The new requirement in Para. 6.1.1 asks that when planning for the QMS the organization must consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement. It further states in Para. 6.1.2, that the organization must plan: a) actions to address these risks and opportunities; b) how to integrate and implement the actions into its quality management system processes (see 4.4) and evaluate the effectiveness of these actions. Actions taken to address risks and opportunities must be proportionate to the potential impact on the conformity	The auditor must interview those responsible for understanding and managing risk within the organization and verify a) thru d) are addressed. Care must be taken because the Standard uses the word “consider” and Annex 1 does not require formal risk management activity. However, the auditor should attempt to see evidence of “actions being taken” to address risk and to follow up and evaluate the effectiveness of the actions. Remember that actions taken must proportionate to the potential impact on the organizations products and services. The Notes in the Standard can also provide some additional clarity	

of products and services.		
6.2 Quality objectives and planning to achieve them		
This requirement expands on the previously addressed 5.4.1 objectives. The new requirements in Para. 6.2.1 ask that the quality objectives a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. Additionally, when planning how to achieve its quality objectives, the organization must determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated.	The auditor must interview those responsible to ensure that the objectives meet a) thru g). Also, the auditor must verify evidence that the organization has determined a) thru e) for each of the defined objectives	
6.3 Planning of changes		
This expands on the old requirement in 5.4.2 for managing organizational changes. Added is the requirement for the organization to consider:	The auditor will have to verify that when a change occurs within the organization that a) thru d) were considered.	

a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities.		
7 Support **7.1.1 Resources General** **7.1.2 People** **7.1.3 Infrastructure** **7.1.4 Environment for the operation of processes**		
This expands on the old requirement in Clause 6 Resources. Some minor language changes and additions that should not impact the organization.	None Required	
7.1.5 Monitoring and measuring resources		
This expands on the old requirement in Clause 7.6 IMT&E. Some minor language changes and a change in the order.	None Required	
7.1.6 Organizational knowledge		
This expands on the old requirement in Clause 6.1 Human Resource. The organization must determine the knowledge necessary for the operation	This will apply primarily when the organization is making a change (e.g., technology, products, processes, etc.). None Required	

of its processes and to achieve conformity of products and services. This knowledge must be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization must consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.	There are a couple of notes for additional clarification.	
7.2 Competence		
This repeats the old requirement in Clause 6.1 Human Resource.	None Required	
7.3 Awareness		
This expands on the old requirement in Clause 6.1.1d and 5.4.1. No Changes.	None Required.	
7.4 Communication		
This expand on the old requirement in Clause 5.5.3. The organization must determine the internal and external communications relevant to the QMS, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate;	The auditor must verify the organization has determined what, when with whom and how it wants to communicate info related to the QMS.	

e) who communicates.		
7.5 Documented information **7.5.1 General** **7.5.2 Creating and updating** **7.5.3 Control of documented information**		
This expands on the old requirement in Clause 4.2.1, 4.2.3 and 4.2.4. Some minor changes and additions in verbiage. Big thing to note there is no longer a requirement to have specific procedures. However, the organization must still have: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the QMS. It does expand a bit on the control of documented information. The organization must address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g. version control);	The auditor must verify the organization has sufficient documented information for an effective QMS and that a) thru d) are addressed. Probably will have no substantive change.	

d) retention and disposition.		
8 Operation **8.1 Operational planning and control**		
This verbiage is based on the previous Clause 7.1 and does not really expand requirements further. Added; The organization must control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization must ensure that outsourced processes are controlled (see 8.4).	If the organization had made changes, the auditor must verify the added text controlling such changes. Or at least the risk of adverse effects of such changes	
8.2 Requirements for products and services **8.2.1 Customer communication**		
This verbiage is based on the previous Clause 7.2.3 and 7.5.4. The language from 7.2.3 remains unchanged. One new item e) was added to require the organization to establish specific communication arrangements for contingency actions with the customer, when relevant. The requirements for customer property have been shortened and now just require that handle or control customer property.	The auditor must verify item e) is addressed in the organizations QMS. No other action is required.	
8.2.2 Determination of requirements related to products and services		

This verbiage is based on the previous Clause 7.2.1. The language from 7.2.1 remains unchanged with the exception of the old item c) which is now item b) and states that the organization must ensure it can meet the claims for the products and services it offers.	Suspect that this would extend out to include advertisements, marketing literature as well as contracts or agreements. No other action is required.	
8.2.3 Review of requirements related to products and services		
This verbiage is based on the previous Clause 7.2.2. A new subclause item was added under 8.2.3.2, Item b) that the organization retain a record of information, as applicable on any new requirements for the products and services.	The auditor must review evidence that the organization is keeping a record of any new requirements for the product and services. Sample several new contract files for evidence.	
8.2.4 Changes to requirements for products and services		
This verbiage is based on the previous Clause 7.2.3. The requirement to process changes is unchanged.	No action is required.	
8.3 Design and development of products and services **8.3.1 General** **8.3.2 Design and development planning**		
This verbiage is based on the previous Clause 7.3.1.	The auditor must verify that the design and development (D&D) process is robust and that the organization	

The language from 7.3.1 has changed dramatically. The Standard now requires a much more robust design and development process that occurs in stages. In determining the stages and controls for design and development, the organization must now consider: a) the nature, duration and complexity of the design and development activities; b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process	consider items a) thru j) during D&D. Sample several design records to verify these items were considered.	

by customers and other relevant interested parties; **j)** the documented information needed to demonstrate that design and development requirements have been met.		
8.3.3 Design and development inputs		
This verbiage is based on the previous Clause 7.3.2. The language from 7.3.2 remains unchanged with the exception of two new items added to the design input process: d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services;	The auditor must verify item d) and e) have been considered. Sample several design records to verify these items were considered.	
8.3.4 Design and development controls		
This verbiage is based on the previous Clause 7.3.3 and 7.3.4. The verbiage has changed and several new items added requiring that the organization must apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design	The auditor must verify the organization is ensuring that items a) and f) have been completed. Sample several design records to verify these items. See the Note for additional clarification regarding the distinction between the design steps and their purpose.	

and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained.		
8.3.5 Design and development outputs		
This verbiage is based on the previous Clause 7.3.5. The language from 7.3.5 has changed and several new requirements identified. The organization must ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance	The auditor must verify the organization has ensured items a) thru d). Sample several design records to verify these items.	

criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.		
8.3.6 Design and development changes		
This verbiage is based on the previous Clause 7.3.6 and 7.3.7. Deleted is the language previously known as verification and validation. The new language requires that the organization must 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. In addition, the organization must keep records on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; the actions taken to prevent adverse impacts.	The auditor must verify the organization is identifying, reviewing and controlling changes made to designs to the extent necessary to ensure there is no adverse impact. Sample several design records to verify this and to confirm that records exist of items a) thru d).	
8.4 Control of externally provided processes, products and services **8.4.1 General**		
This verbiage is based on the previous Clause 7.4.1 but expanded. The new language requires that the	This could expand the number of suppliers the organization will need to control. It will depend on the limits currently in place for the supplier	

organization must ensure that any externally provided (i.e., items purchased from an outside supplier) process, product and service, conform to requirements. The organization must also determine the controls it will apply on these suppliers when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The old requirement remains for the organization to determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization must continue to keep a record of these activities and any necessary actions arising from the evaluations.	control. If expanded, the auditor must verify the additional records.	

8.4.2 Type and extent of control		
This verbiage is based on the previous Clause 7.4.3 but expanded. The new language requires that the organization must ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. In addition, the organization must: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration: - the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; - the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to	The auditor must verify the organization ensures that externally provided products and services are not adversely impacting their ability to deliver conforming products. In addition, the auditor must ensure that a) thru d) is being accomplished. Interview procurement/receiving personnel and subsequently sample records to ensure a) thru d).	

ensure that the externally provided processes, products and services meet requirements.		
8.4.3 Information for external providers		
This verbiage is based on the previous Clause 7.4.2 but expanded to include several new areas of communication. The organization must communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: - products and services; - methods, processes and equipment; - the release of products and services; c) competence, including any required qualification of persons; d) the external provider's interactions with the organization; e) control and monitoring of the external provider's performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises.	The auditor must verify the expanded language in a) thru f) to verify the organization communicates these topics to external providers. Sample purchasing records to verify implementation of these requirements.	
8.5 Production and service provision **8.5.1 Control of production and service provision**		
This verbiage is based on the previous	Since this is a combined area that	

Clause 7.5.1 and 7.5.2. This section is a mixed bag of verbiage that has stayed the same, been revised and/or expands. The revised language now requires that controlled include, as applicable: a) the availability of documented information that defines: - the characteristics of the products to be produced, the services to be provided, or the activities to be performed; - the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the	includes changes, the auditor must verify the compliance with a) thru h). Sample product realization activities to verify compliance and effectiveness.	

resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities.		
8.5.2 Identification and traceability		
This verbiage is based on the previous Clause 7.5.3. Again, the word product has been replaced with outputs. The actual requirements have not changed.	No Action Required.	
8.5.3 Property belonging to customers or external providers		
This verbiage is based on the previous Clause 7.5.4. Added is a discussion of "external providers" other than customer's who provide property. The additional inclusion of external providers could expand impact. NOTE A customer's or external provider's property **CAN** include material, components, tools and equipment, customer premises, intellectual property and personal data.	Although the language has added a stakeholder to the discussion, this probably has very little impact on the audit.	
8.5.4 Preservation		
This verbiage is based on the previous Clause 7.5.5. No change, does not expand areas of preservation to consider.	No action required.	

NOTE: Preservation **CAN** include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.		
8.5.5 Post-delivery activities		
This verbiage is based on the previous Clause 7.5.1d. It has been greatly expanded with what the organization must consider. In determining the extent of post-delivery activities that are required, the organization must consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. 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.	The auditor must verify the organization has considered a) thru e), if applicable to the services provided. Sample several post-delivery activities records to verify these items were considered.	
8.5.6 Control of changes (production and service provision)		

This requirement typically would have been covered by 5.4.2, maintain the integrity of the QMS when changes were made. The new text states; The organization must review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. In addition, the organization must retain records describing the results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review.	If changes in product/service provision are noted, the auditor must review the changes and their control. The auditor must review the records.	
8.6 Release of products and services		
This verbiage is based on the previous Clause 8.2.4. Although the verbiage has been slightly changed, there really is no substantive difference in requirements.	No Action Required.	
8.7 Control of nonconforming outputs		
This is the requirement previously address in 8.3. The focus has shifted to address outputs that are nonconforming instead of products. In addition, there is some additional verbiage.	The auditor must verify that sample evidence to verify that the record resulting from dealing with nonconforming outputs covers a) thru d) in 8.7.1.	

Highlights of new verbiage to the Standard include; The organization must deal with nonconforming outputs in one or more of the following ways: a) correction; a) segregation, containment, return or suspension of provision of products and services; b) informing the customer; c) obtaining authorization for acceptance under concession. 8.7.2 The organization must retain a record that: a) describes the nonconformity; b) describes the actions taken; c) describes the concessions obtained; identifies the authority deciding the action in respect of the nonconformity		
9 Performance evaluation **9.1 Monitoring, measurement, analysis and evaluation** **9.1.1 General**		
This is the requirement previously addressed in 8.2.3 and 8.2.4. The new verbiage expands on the topic. The organization must determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation	The auditor must interview personnel and sample what the organization has elected to monitor and measure. It was always assumed that the information would be analyzed and evaluated. Typically, some of these areas will be tied into and connected with the	

needed to ensure valid results; c) when the monitoring and measuring must be performed; d) when the results from monitoring and measurement must be analyzed and evaluated. The organization must also evaluate the performance and the effectiveness of the quality management system.	organization objectives.	
9.1.2 Customer satisfaction		
This is the requirement previously address in 8.2.1. No changes.	None Required	
9.1.3 Analysis and evaluation		
This is an expansion to the previously defined clause 8.4. The results of 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	The auditor must interview and sample evidence that the organization is analyzing a) thru g) in the Standard.	

providers; g) the need for improvements to the quality management system.		
9.2 Internal audit		
This is the same as previously defined clause 8.2.2. No Changes.	None Required	
9.3 Management review **9.3.1 General** **9.3.2 Management review inputs** **9.3.3 Management review outputs**		
This is the requirement previously address in 5.6 management review. The agenda for the management review process should be given careful thought by the organization to discuss: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the QMS including trends in: - customer satisfaction and feedback from relevant interested parties; - the extent to which quality objectives have been met; - process performance and	The auditor must interview personnel and sample minutes from the management review to ensure that the required agenda has been addressed.	

conformity of products and services; - nonconformities and corrective actions; - monitoring and measurement results; - audit results; - the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.		
10 Improvement **10.1 General**		
This changes the verbiage and expands on the old requirement in Clause 8.1. The organization must determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These must include: a) improving products and services to meet requirements as well as to address future needs and expectations; b) correcting, preventing or reducing undesired effects; c) improving the performance and	The auditor should continue to look for improvement activities including correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.	

effectiveness of the quality management system.		
10.2 Nonconformity and corrective action		
This changes the verbiage and expands on the old requirement in Clause 8.3 and 8.5.2. It now states; that the organization must: a) react to the nonconformity and, as applicable: - take action to control and correct it; - deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: - reviewing and analyzing the nonconformity; - determining the causes of the nonconformity; - determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary.	The auditor should continue to look for how the organization deals with nonconforming and other undesirable conditions. Probably will mean a change in the organization process for dealing with such issues and any form used to process them.	

The organization must retain records as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action		
10.3 Continual improvement		
This requirement is addressed in other areas such as management review and improvement (general).	None Required	