Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	Key: Yellow text indicates potential new requirements that may need to be included in an organization's quality management system. Blue text indicates 2008 version requirements that are not in the 2015 version.		**Abbreviations used in the checklist:** DI = documented information QMS = quality management system. *The italic text is author comments.*
4	**Context of the organization**		**2008: 1.1—General (no requirements)**
4.1	**Understanding the organization and its context**		**2008: 1.1—General (no requirements)**
	(1) Does the organization determine external and internal issues that are relevant to its purpose and its strategic direction? NOTE 1: Issues can include positive and negative factors or conditions for consideration. NOTE 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3: Understanding the internal context can be facilitated by considering issues related to values, culture and location. *Comment: The business/operating environment has a context that is influenced by both internal and external issues. The auditor will need to know the purpose of the organization and its strategic direction. The purpose may be something that describes the operation or perhaps be in a mission statement. The idea that an organization must have a strategic direction new.*		
	(2) Does the organization determine external and internal issues that are relevant to its ability to achieve the intended results of the QMS? *Comment: Similar to the first question's requirement, but now an auditor will need to ask about the intended results of the QMS and follow up by asking about issues related to the organization's ability to achieve the intended results.*		
	(3) Does the organization monitor and review information about external and internal issues?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
4.2	**Understanding the needs and expectations of interested parties**		**2008: 1.1—General (no requirements)**
	(1) In the context of the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, does the organization determine: (1a) interested parties that are relevant to the QMS? (1b) requirements of these interested parties that are relevant to the QMS? *Comment: An interested party may be a stakeholder, person or organization (3.2.1) that can affect, be affected by or perceive itself to be affected by a decision or activity. In today's global environment, there are times when it is important to share information for the well-being of society, such as safety or security. It may be appropriate to share information up and down the supply chain for quality and/or availability concerns.*		
	(2) Does the organization monitor and review information about these interested parties and their relevant requirements?		
4.3	**Determining the scope of the quality management system**		**2008: 1.2—Application and 4.2.2—Quality manual**
	(1) Has the organization established the scope of the QMS? Does the scope address the boundaries and applicability of the QMS? *Comment: Boundaries could be North American operations, Southeast terminals or job shops, and applicability could be all operating units except sales and finance. The requirements in this clause are similar to the 2008 version but more descriptive.*		
	(2) When determining this scope, does the organization consider: (2a) the external and internal issues referred to in 4.1? (2b) the requirements of relevant interested parties referred to in 4.2? (2c) the products and services of the organization? *Comments: There is no requirement for a record or retained DI. As an auditor, you may seek documentation that a, b and c were considered or interview a person who is responsible for review and approval of the scope and then ask about a, b and c. There is no, if appropriate, qualification for this requirement. Meaning an organization cannot select which are appropriate, they must consider each requirement when determining the scope. If it makes more sense to you, use the word "factors," or external and internal factors.*		
	(3) Does the organization apply all the QMS standard requirements, if they are applicable, within the determined QMS scope? *Comment: This is very general, but questions will help surface areas where the QMS requirements have not been applied.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(4) Is the scope maintained as DI and available? *Comment: Maintained DI is the code for a document that must be under document control. Also, retained DI is the code for keeping a record.*		2008: A quality manual was required in the 2008 version.
	(5) Does the scope state the types of products and services covered, and provide justification for any requirement of this ISO 9001:2015 that the organization determines is not applicable? *Comment: Almost no applicable clauses would be in clause 7 or 8. Some organizations do not design the product or service they provide; service organizations may not use equipment that needs calibration control; and so on.* Conformity to ISO 9001:2015 may be claimed only if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products. *Comment: The above statement is not a "shall" requirement.*		2008: There were exclusions that had to be justified. Is there a quality manual that includes the scope of the QMS, justification for exclusions, and describes the interaction between the processes?

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
4.4	**4.4 Quality management system and its processes**		**2008: 4—QMS and 4.1—General requirements**
4.4.1	(1) Has the organization established, implemented, maintained and continually improved the QMS, including the processes needed and their interactions, in accordance with the requirements of this ISO 9001:2015? *Comment: There is a major emphasis on processes. Auditors need a good grasp of the dynamics and a fundamental understanding of what constitutes a process.*		.
	(2) Has the organization determined the processes needed for the QMS and their application throughout the organization? Has the organization: (2a) determined the inputs required and the outputs expected from these processes? (2b) determined the sequence and interaction of these processes? (2c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes? (2d) determined the resources needed for these processes and ensure their availability? (2e) assigned the responsibilities and authorities for these processes? (2f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1? (2g) evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results? (2h) improved the processes and the QMS? *Comment: Verify that the interaction of processes was determined in some manner. Many of the requirements will be verified during the audit. This is a great list to take with you when each process is visited, audited.*		.

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
4.4.2			**2008: 4.2.1d—General requirements**
	(1) Does the organization, to the extent necessary: (1a) maintain DI to support the operation of its processes? (1b) retain DI to have confidence that the processes are being carried out as planned? *Comment 1: It would be better guidance for an international quality standard to require control of its processes instead of supporting the operation of them.}* *Comment 2: Documents, documented procedures and records have been replaced with DI), maintained DI and retained DI. There is no requirement for an organization to change its terminology from documents and records to DI. In fact, world organizations, governments and legal systems understand what it means to have a record and do not understand what retained, DI means.*		2008: The 2015 version removed: ensure the effective planning, operation and control of its processes. <effect—perhaps minor>

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
5	**Leadership**		**08: 5—Management responsibility**
5.1	**Leadership and commitment**		**08: 5.1—Management commitment**
5.1.1	**General**		**08: 5.1—Management commitment**
	(1) Does top management demonstrate their leadership and commitment with respect to the QMS by: (1a) taking accountability for the effectiveness of the QMS? (1b) ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization? (1c) ensuring the integration of the QMS requirements into the organization's business processes? *Comment: Reference to "business" in this ISO 9001:2015 can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not-for-profit.* (1d) promoting the use of the process approach and risk-based thinking? (1e) ensuring that the resources needed for the QMS are available? (1f) communicating the importance of effective quality management and of conforming to the QMS requirements> (1g) ensuring that the QMS achieves its intended results? (1h) engaging, directing and supporting persons to contribute to the effectiveness of the QMS? (1i) promoting improvement? (1j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility? *Comment 1: Overall management must now demonstrate leadership. There must be evidence for applying a-j to verify they have demonstrated leadership. According to* Bloom's Revised Taxonomy*, the word "demonstrate" is linked to applying and actions such as implementing, carrying out, using and executing. This is a higher level than being able to understand or remember by identifying, explaining, describing or listing.* *Comment 2: Some of the key issues are compatible with the organizations strategic direction and c) the integration of QMS requirements into the business systems. This supports the process approach using elements/clauses of the standard. The organization needs to be able to communicate its intended results. Perhaps it has matrices. "Supporting other relevant management roles" (j) is vague. If top management is demonstrating leadership, how is it supporting others in management to demonstrate this leadership? One approach is to verify other managers are conforming to this same clause's requirements.*		2008: Meeting customer and regulatory requirements, and conducting management reviews were in the 2008 version but can be found elsewhere in 2015 version.

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
5.1.2	**Customer focus**		**2008: 5.2—Customer focus**
	(1) Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that: (1a) customer requirements and applicable statutory and regulatory requirements are determined, understood and consistently met? (1b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed? (1c) the focus on enhancing customer satisfaction is maintained? *Comment: This is a high level top management issue.*		
5.2	**Policy**		**2008: 5.3—Quality policy**
5.2.1	**Developing the quality policy**		
	Has top management established, implemented and maintained a quality policy?		
	(1a) Is the policy appropriate to the purpose and context of the organization and does it support its strategic direction?		
	(2b) Does the policy provide a framework for setting quality objectives?		
	(3c) Does the policy include a commitment to satisfying applicable requirements?		
	(4d) Does the policy include a commitment to continual improvement of the QMS?		2008: Reviewing for continuing suitability of the policy has been deleted in 2015. <effect—minor>
5.2.2	**Communicating the quality policy**		**2008: 5.3—Quality policy and 4.2.1—General**
	Is the quality policy: (1a) available and maintained as DI? (2b) communicated, understood and applied within the organization? (c3) available to relevant interested parties, as appropriate?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
5.3	**Organizational roles, responsibilities and authorities**		**2008: 5.5—Responsibility, authority and communication**
			2008: 5.5.1—Responsibility and authority
	(1) Has top management ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization? *Comment: An auditor needs to ask about who have relevant roles in the QMS that have been assigned. Then the auditor should verify responsibilities and authorities have been communicated and understood. During interviews an auditor may observe confusion about who has what responsibilities. This is a good general clause to verify throughout the audit.*		2008: required responsibilities/authorities be "defined." <effect—minor>
			2008: 5.5.2—Management representative
	(2) Has top management shall assigned the responsibility and authority to: (2a) ensure that the QMS conforms to the requirements of this ISO 9001:2015? (2b) ensure that the processes are delivering their intended outputs? *Comment: Even though there is no management representative requirement, organizations do not need to change personnel titles. Now organizations can assign responsibilities as they see fit. There could be an issue of no one being in charge and management of the QMS being **disjointed**. This could relate to effective leadership. The other aspect of the clause is linkage of the process results. Yes, there may be people responsible for elements of the QMS who are not a part of the organization's management. Some sectors, such as aerospace, have added back the requirement to have a management representative.*		2008: There is no clause titled management representative in the 2015 version, and the phrase "appointed a member within the organization's management" is no longer part of the clause. <effect—minor>
	(2c) report on the performance of the quality QMS and on opportunities for improvement, in particular to top management?		
	(2d) ensure the promotion of customer focus throughout the organization?		
	(2e) ensure that the integrity of the QMS is maintained when changes to the quality management system are planned and implemented *Comment: This requirement is not new but was under planning in the 2008 version}*		2008: Clause 5.4.2 b

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
6	**Planning**		**2008: 5.4.2—Quality management system planning**
6.1	**Actions to address risks and opportunities**		**2008: 5.4.2—Quality management system planning; 8.5.3—Preventive action**
6.1.1			
	(1) When planning for the QMS, does the organization consider the issues identified in clauses 4.1 and 4.2?		
	(2) When planning the QMS, does the organization determine the risks and opportunities (relative to clause 4.1 and 4.2) that need to be addressed regarding: (2a) assurance that the QMS can achieve it intended result(s) 4.4.1? (2b) enhancing desirable effects? (2c) preventing or reducing undesirable effects? (2d) achieving improvement? *Comment: This is the initial stage of finding or identifying risks and opportunities. The organization needs to determine or identity risks and opportunities, assess their significance and take corresponding action relative to their importance (6.1.2). This is new, but the 2008 version did require organizations to analyze data in 8.4 and 8.5.1. Therefore, an organization may need to ensure only the more prescriptive requirements (above) are addressed. There is no requirement to have a formal risk management program. FYI: Risk = effect of uncertainty.*		
6.1.2	**The organization shall plan:**		**2008: 8.5.3—Preventive action**
	(1a) Does the organization plan actions to address these risks and opportunities? NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk or retaining risk by informed decision. NOTE 2: Opportunities can lead to adopting new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs. *Comment: There needs to be a plan available in some form or media. It is also important to realize opportunity is not the opposite of risk.*		
	(2a) Does the plan include how to integrate actions into its QMS processes and implement them (see 4.4)?		
	(2b) Does the plan include how to evaluate the effectiveness of these actions?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(3) Are the actions taken to address risks and opportunities proportionate to the potential impact on the conformity of products and services? *Comment: Many organizations have some kind of matrix ranking system for opportunities or use the failure mode effects analysis (FMEA) approach to assess the level of risk.*		2008: Preventive action clause and the requirement to have a documented procedure have been deleted in the 2015 version. However many of the actions and steps in 6.1.2 are the same as in 2008: 8.5.3.<effect—minor>
6.2	**Quality objectives and planning to achieve them**		**2008: 5.4.1—Quality objectives**
6.2.1	(1) Does the organization establish quality objectives at relevant functions, levels and processes?		
	(2) Are the quality objectives: (2a) consistent with the quality policy? (2b) measurable? (2c) able to take into account applicable requirements? (2d) relevant to conformity of products and services and to enhance of customer satisfaction? (2e) monitored? (2f) communicated? (2g) updated as appropriate? *Comment: There are new requirements, but most organizations are already doing most of what is required. In particular, the auditee should be able to explain how the objectives relate to conformity of products and services and how they relate to enhancing customer satisfaction. A nonconformity here would help the organization stay focused on the QMS. Also, the requirement to monitor the objectives would be best if organizations understand how to establish good metrics to achieve desired results.*		2008: 5.4.1, Committing to continual improvement is no longer a requirement in 2015. However, continual improvement and improvement is mentioned in several other places in the 015 version. <effect—minor>
	(3) Does the organization maintain DI on the quality objectives? *Comment: "Maintained" DI is the code for creating a document that explains quality objective planning processes and putting it under DI control.*		
6.2.2			
	(1) When planning how to achieve its quality objectives, does the organization determine: (1a) what will be done? (1b) what resources will be required? (1c) who will be responsible? (1d) when it will be completed? (1e) how the results will be evaluated? *Comment: The requirements here are similar to any project plan. It makes sense but it is a new requirement. Classic plan-do-check-analyze.)*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
6.3	**Planning of changes**		**2008: 5.4.2—QMS planning**
	(1) Where the organization determines the need for change to the QMS (see 4.4), is the change carried out in a planned and systematic manner? Does the organization consider: (1a) the purpose of the changes and their potential consequences? (1b) the integrity of the QMS? (1c) the availability of resources? (1d) the allocation or reallocation of responsibilities and authorities? *Comment: Plan what you do and do what you plan.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7	**Support**		
7.1	**Resources**		
7.1.1	**General**		**2008: 6.1—Provision of resources**
	(1) Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS?		2008: "Enhance customer satisfaction" has been removed in 2015. <effect—minor>
	(2) Has the organization considered: (2a) the capabilities of and constraints on existing internal resources? (2b) what needs to be obtained from external providers? *Comment 1: The requirements (2a and 2b) are good additions to the standard. However, there is no requirement for a plan or a record or any kind of DI. Ask the auditee for available documentation. Without some kind of DI, evidence from interviews will need to be corroborated.* *Comment 2: It seems as if 2b should be in clause 8.4, but the intent of (2) above is to be at a higher level of decision making. Does the organization need to purchase certain services instead or doing it internally? Does the organization need certain components or parts to be supplied externally? Capabilities and constraints on existing internal resources may lead to needs from external resources. Resources include personnel, facilities, equipment, knowledge and skills, and so on. The resources relate to QMS needs as well as operational needs.*		
7.1.2	**People**		**2008: 6.2—Human resources**
	(1) Does the organization determine and provide the persons necessary for the effective implementation of its QMS and for the operation and control of its processes? *Comment: The expansion of requirements to include organization processes makes ISO 9001 more of a business/operations management standard, not just one about quality. Unless someone discloses he or she is shorthanded and as a result there are nonconforming products or services, there is unlikely to be nonconformity.*		
7.1.3	**Infrastructure**		**2008: 6.3—Infrastructure**
	(1) Has the organization determined, provided and maintained the infrastructure for the operation of its processes to achieve conformity of products and services. NOTE: Infrastructure can include: • buildings and associated utilities • equipment including hardware and software • transportation • information and communication technology		2008: The 2008 version has a prescriptive list of what comprises infrastructure. In the 2015 version, it is a note.. <effect—minor>

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7.1.4	**Environment for the operation of processes**		**2008: 6.4—Work environment**
	(1) Has the organization determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE: A suitable environment can be a combination of human and physical factors, such as: • Social (for example, nondiscriminatory, calm, nonconfrontational) • Psychological (for example, stress-reducing, burnout preventive, emotionally protective) • Physical (for example, temperature, heat, humidity, light, airflow, hygiene, noise) These factors can differ substantially depending on the products and services provided.		
7.1.5	**Monitoring and measuring resources**		**2008: 7.6—Control of measuring and monitoring equipment**
7.1.5.1	**General**		**2008: 7.6**
	(1) Has the organization determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. *Comment: Adding reliable requirement may make a difference for some organizations, but normally it is part of measurement system analysis program.*		
	(2) Does the organization ensure the resources provided are: (2a) suitable for the specific type of monitoring and measurement activities being undertaken? (2b) maintained to ensure their continued fitness for their purposes? *Comment: Fit for purpose is a new term for ISO 9001. It can be that the resources are capable of performing as intended. Other descriptions are: something that is fit for purpose is good enough to do the job it was designed to do or fitness for purpose equates quality with the fulfilment of a specification or stated outcomes.*		
	(3) Does the organization retain appropriate DI as evidence of fitness for purpose of monitoring and measurement? *Comment: Retained DI is code for record. The 2008 version specifically stated that records of calibration and verification activities should be kept. This requirement is open-ended. The auditee will need to explain what appropriate records are being maintained, and the auditor should be familiar with measurement error to assess conformance.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7.1.5.2	**Measurement traceability**		**2008: 7.6**
	(1) When measurement traceability is a requirement or essential for providing confidence in measurements, is measuring equipment: (1a) calibrated, verified or both, at specified intervals or prior to use against measurement standards traceable to international or national measurement standards? When no such standards exist, the basis used for calibration or verification shall be retained as DI.(1b) identified in order to determine its status? (1c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?		2008: b) Is equipment adjusted and readjusted as necessary? The removal of this requirement in 2015 seems minor in most all cases. <effect—minor>
	(2) Has the organization determined if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and taken appropriate action as necessary?		2008: The software verification/confirmation clause is not included in the 2015 version. If this area is not addressed by the organization, it could be a **major issue**. Software is such an integral part of our processes in today's world. Software support and development may be 10% or more of personnel resources and perhaps more of the budget. The 2008 version stated: When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use. <effect—could be significant.

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7.1.6	**7.1.6 Organizational knowledge**		**2008: no clause**
	(1) Has the organization determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services? *Comment: Hopefully, since the organization is successful, it has determined the knowledge necessary to operate. This could be a confusing requirement. An auditor should ask how an organization has determined what knowledge it needs. Annex A.7 of the 2015 version explains the reason for this clause is to ensure organizations properly safeguard their current knowledge from loss due to staff turnover, reorganization or other events. Also, ensure organizations seek out knowledge they need to maintain, grow or expand their operations. See Annex A7.*		
	(2) Has the knowledge been maintained and made available to the extent necessary? NOTE 1: Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives. *Comment: The standard uses the word "maintained," but it is not associated with DI. An auditor can ask how it is maintained, but issuing a nonconformity is unlikely unless the organization failed to address the requirement.*		
	(3) When there are changing needs and trends, does the organization consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates? NOTE 2: Organizational knowledge can be based on: • Internal sources (for example, intellectual property, knowledge gained from experience, lessons learned from failures and successful projects, capturing and sharing undocumented knowledge and experience or the results of improvements in processes, products and services. • External sources (for example, standards, academia, conferences or knowledge gathered from customers or external providers). *Comment: If an organization expands or makes adjustments due to budgets, efficiencies or pressure from competitors, it is very important that it acquire the knowledge and talent it needs to be successful. An auditor's job is to verify conformity. An auditor could ask to see documentation to verify actions or, if none (none is required), conduct interviews to collect evidence of conformity.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7.2	**Competence**		**2008: 6.2.1—General, and 6.2.2—Competence, training and awareness**
	(1a) Does the organization determine the necessary competence of person(s) doing work under its control that affects its quality performance?		
	(1b) Does the organization ensure that these persons are competent on the basis of appropriate education, training or experience?		
	(1c) Does the organization, where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken? NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of the reassignment of currently employed persons, or the hiring or contracting of competent persons.		
	(1d) Does the organization retain appropriate DI as evidence of competence. *Comment: Retained DI is kept as evidence of competence. The 2008 version specified keeping records of training, education, skills and experience instead of competence. Job descriptions may include competency needs for each position/job. An auditor can follow up by asking to be shown the records of evidence of competence for select positions such as inspector, quality manager, purchasing manager and auditor.*		
7.3	**Awareness**		**2008: 6.2.2 d—Competence, training and awareness**
	(1) Does the organization ensure that persons doing work under the organization's control are aware of: (1a) the quality policy? (1b) relevant quality objectives? (1c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance? (d) the implications of not conforming with the QMS requirements? *Comment: The requirements in this clause would apply to almost all interviews. It is interesting that this clause requires people to be aware of the quality policy, but clause 5.2.2 requires the policy to be communicated and understood. Persons are not required to memorize the quality policy, but an auditor can ask them if they are aware of it and have them explain it in their own words.*		
7.4	**Communication**		**2008: 5.5.3—Internal communication**

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(1) Does the organization determine the internal and external communication relevant to the QMS that includes: (1a) on what it will communicate? (1b) when to communicate? (1c) with whom to communicate? (1d) how to communicate? (1e) who communicates? *Comment: An auditor can start with 1a. No documentation is required, but the auditor must be able to verify the auditee conforms to requirements with verifiable objective evidence. Plan what you do, and do what you plan.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7.5	**Documented Information *(DI)***		
7.5.1	**General**		**2008: 4.2.1 c and d —General**
	(1) Does the organization's QMS include: (1a) DI required by this ISO 9001:2015? (1b) DI determined by the organization as being necessary for the effectiveness of the QMS? NOTE: The extent of DI for a QMS can differ from one organization to another due to: the size of organization and its type of activities, processes, products and services; the complexity of processes and their interactions; and the competence of people. *Comment: ISO 9001:2015 requires that the scope, objectives and policy be maintained as DI. The organization determines what other DI must be maintained to support the operation of its processes (4.4.2a) and retained to have confidence that processes are carried out as planned (4.4.2b).*		2008: No quality manual or documented procedures are required in 2015. Some regulatory bodies may still require a manual. <effect—minor>
7.5.2	**Creating and updating**		**2008: 4.2.3—Control of documents and 4.2.4—Control of records**
	(1) When creating and updating DI, are they appropriately: (1a) identified and described (for example, a title, date, author or reference number)? (b) formatted (for example, language, software version, graphics) and for appropriate media (for example, paper, electronic)? c) reviewed and approved for suitability and adequacy. *Comment: Documents can be easily created and updated electronically using available software. With intranets (internal networks) and/or the cloud, some documents can be updated in real time and always be current. Records (retained DI) should not be changed, but corrected only when appropriate.*		2008: No requirement in the 2015 version to approve for adequacy prior to release. <effect-minor>
7.5.3	**Control of documented information**		**2008: 4.2.3—Control of documents and 4.2.4—Control of records**
7.5.3.1			
	(1) Is DI required by the QMS and by ISO 9001:2015 controlled to ensure: (1a) it is available and suitable for use, where and when it is needed? (1b) it is adequately protected (example, from loss of confidentiality, improper use or loss of integrity)? *Comment: The requirement to adequately protect document information has been added and is appropriate given electronic storage and distribution issues. Auditors will need to verify documents are adequately protected. Also, using software, documents are easily controlled (control access) and distributed using a pull system (users must go and get the document).*		2008: No document control or records control procedure required in the 2015 version. The requirement for documents to be available at points of use has been replaced with being available where and when they are needed. <effect—unknown>

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
7.5.3.2	(1) When DI is controlled, does the organization address the following activities, as applicable? (1a) distribution, access, retrieval and use. (1b) storage and preservation, including preservation of legibility. (1c) control of changes (for example, version control). (1d) retention and disposition. NOTE Access can imply a decision regarding permission to view the DI only, or permission and authority to view and change the DI. *Comment: The requirements in this section come from the ISO 9001:2008 version document and records control clauses. Historically, most of the requirements such as retention and disposition applied to control of records. Now the same requirements apply to maintained DI (plans) as well. An organization may apply the requirements to documents and records or an organization may simply reference the "as applicable" phrase to avoid determining retention and disposition of procedures and other plans.*		
	(2) Is DI necessary for the planning and operation of the QMS determined? (3) Is DI of external origin identified as appropriate and controlled? Comment*: The 2008 version required the distribution be controlled. Dropping the word distribution requires the organization to address all aspects of external DI control.*		
	(4) DI retained as evidence of conformity shall be protected from unintended alterations. Comment*: Retained DI is a record. The 2008 version required records to be protected but did not specify from what (unintended alterations) they should be protected. This requirement was specifically added to the standard due to the confusion created by the fact that records could be changed (modified and updated) per clause 7.5.2—Creating and updating. Records should never be changed, only corrected.*		<effect—minor, if any>

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	Required Retained DI (records)		
	Do the following retained DI (records) exist? • Evidence of fitness for purpose of monitoring and measurement resources (7.1.5.1) *Comment: was limited to results of calibration in 2008.* • When no standards exist, the basis used for calibration or verification (7.1.5.2a) • Evidence of competence (7.2d) *Comment: goes beyond training records in 2008 version.* • Keep DI information as necessary (8.1) *Comment: this is a general requirement to keep retained DI under operational planning. It is open-ended but may be applied in situations where needed records are not being kept.* • Results of reviews related to products and services and any new requirements for products and services. (8.2.3.2) *Comment: When there were new customer requirements, the 2008 version required relevant documents be amended and relevant personnel informed, but did not require a specific record. Also, though this is in a section that addresses customer requirements, the scope is larger as it relates to any product and service requirements, not just customer requirements—for example regulatory requirements or those related to interested parties.* • Design and development inputs (8.3.3) • Design and development control activities (8.3.4) *Comment: The 2008 version required records of reviews, this is more open-ended to include reviews, verification and validation activities*. • Design and development inputs (8.3.5) • Design and development changes, results of reviews, authorizations and actions to prevent adverse impacts (8.3.6) *Comment: The 2008 version required a record of necessary actions as a result of the changes, but the 2015 version focuses on actions to prevent adverse impacts.}* • External provider evaluation, selection, performance and re-evaluation activities and any necessary actions arising for the evaluations. (8.4.1) *Comment: This is principally about suppliers but "external providers" is a more generic term.* • Necessary to enable the traceability process (8.5.2) • Customer or external provider property that is lost, damaged and unsuitable (8.5.3) • Results of the review of product and service provision changes, person(s) authorizing the change and necessary actions as a result of the review (8.5.6) • Release of products and services to include acceptance criteria and traceability to persons authorizing release. (8.6) • Nonconformity as well as actions taken, concession obtained and identifications of authority deciding actions (8.7.2) • Evaluation results of the performance and effectiveness of the QMS (9.1.1)		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	• Evidence of audit program implementation and audit results. (9.2.2) *Comment*: *The requirement for evidence of implementation could be as simple as seeing a schedule and other audit program management outputs. This is unclear since implementation is not the same as maintaining the audit program.* • Evidence of management reviews (9.3.3) • Nature of nonconformities, subsequent actions and results of corrective actions. (10.2.2) *Comment*: *The phrase "retain document information" is used 20 times in the requirements clauses of the standard but one requirement may contain several data points. The phrase is also used the notes and the pre and post matter of the standard.*		2008: No requirement to keep records of the validity of previous results when and instrument is found to be out of calibration. * No process validation (qualification) record (7.5.2), {*Comment: control yes, but no specific record required in the 2015 version.}* *Results and preventive action taken (8.5.3 d) *{Comment: now part of risks and opportunities, but no records required}*

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8	**Operation**		**2008: 7—Product realization**
8.1	**Operation planning and control**		**2008: 7.1—Planning and product realization**
	(1) Does the organization plan, implement and control the processes (see 4.4) needed to meet requirements for the provision of products and services? *Comment: Look for something that is documented, such as a quality plan, procedure or diagram. This can be an overall plan or individual plans for the operational processes.* NOTE: *Provision is the act or process of providing.*		
	(2) Does the organization implement the actions determined by clause 6 (*planning*), by: (2a) determining requirements for the product and services? (2b) establishing criteria for the processes and for the acceptance of products and services? (2c) determining the resources needed to achieve conformity to product and service requirements? (2d) implementing control of the processes in accordance with the criteria? (2e) determining and keeping DI (*retaining*) to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements? *Comment: An auditor will need the outputs of clause 6 to verify actions related to product and services (#2 above) are addressed. There is some redundancy with clause 6 and especially clause 6.2.2.}*		2008: Required product measuring, monitoring, verification, validation. <impact—minor>
	(3) Is the output of this planning suitable for the organization's operations?		
	(4) Does the organization control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?		
	(5) Does the organization ensure that outsourced processes are controlled? (8.4) Comment*: In the 2008 version, organizations were required to take responsibility for outsourced processes, but the 2015 version requires control of outsourced process per clause 8.4. This is the way it should be—in other words, control outsourced products and services just like any other purchased (externally provided) product or service. An organization may outsource a service such as heat treating or delivery of products such as a component part or material.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.2	**Requirements for products and services**		
8.2.1	**Customer communication**		**2008: 7.2.3—Customer communication**
	(1) Does communication with the customer include: (1a) providing information relating to products and services? (1b) handling enquiries, contracts or order handling, including changes? (1c) obtaining customer feedback relating to products and services, including customer complaints? NOTE: *The 2015 version qualifies feedback as related to products and services. Feedback related to financial issues or other programs would not be evidence of conformity.}* (1d) the handling or controlling of customer property, if applicable? (1e) establishing specific requirements for contingency actions, when relevant?		
8.2.2	**Determining requirements related to products and services**		**2008: 7.2.1—Determining requirements related to product**
	(1) When determining the requirements for the products and services to be offered to customers, does the organization ensure that: (1a) the requirements for the products and services are defined, including: any applicable statutory and regulatory requirements and those considered necessary by the organization? (1b) it meets the claims for the products and services it offers? *Comment: Possible issues are the organization defining requirements it considers necessary but that may not be specified by the customers, such traceability or appearance of the product or packaging. An auditor should ask to see product and service marketing and promotional materials to identify performance and specification claims and verify the organization has taken appropriate action to meet those claims (see 1b). This clause includes post-delivery activities such as warranty, contract maintenance, recycling and disposal.*		
8.2.3	**Review of requirements related to products and services**		**2008: 7.2.2 —Review of requirements related to product**
8.2.3.1	(1) Does the organization ensure that it has the ability to meet the requirements for products and services to be offered to customers?		
	(2) Does the organization conduct a review before committing to supply the products and services?		
	(3) Does the review include: (3a) requirements specified by the customer, including the requirements for delivery and post-delivery activities?		
	(3b) requirements not stated by the customer, but necessary for the specified or intended use, when known?		
	(3c) requirements specified by the organization?		
	(3d) statutory and regulatory requirements applicable to the products and services?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(3e) contract or order requirements differing from those previously expressed?		
	(4) Does the organization resolve any contract or order requirements differing from previously defined?		
	(5) When requirements are not in a documented statement (*documented by the customer*), are they confirmed by the organization before acceptance? NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material.		
8.2.3.2	(1) Does the organization retain DI (*records*) of the following, as applicable? (1a) results of reviews (1b) new requirements for products and services		
8.2.4	**Changes to requirements for products and services**		**2008: 7.2.2—Review of requirements related to product**
	(1) Does the organization ensure that relevant DI is amended, and that relevant persons are made aware of the changed requirements when the requirements for products and services are change?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.3	**Design and development of products and services**		**2008: 7.3—Design and development**
8.3.1	**General**		
	(1) Has the organization established, implemented and maintained a design and development process that is appropriate to ensure the subsequent provision of products and services? *Comment: Looking at the title of the design clause clearly limits design to products and services and not to internal processes as required by other management system standards such as for the automotive industry. This is new requirement but was expected in the 2008 version. Otherwise, how could an organization conduct design activities? An auditor should ask about the processes and verify they are established, implemented and maintained.*		
8.3.2	**Design and development planning**		**2008: 7.3.1—Design and development/ planning**
	(1) When the organization determines project stages and controls for design and development, does the organization consider the following: (1a) the nature, duration and complexity of the design and development activities? (1b) the required process stages, including applicable design and development reviews? (1c) the required design and development verification and validation activities? (1d) the responsibilities and authorities involved in the design and development process? (1e) the internal and external resource needs for the design and development of products and services? (1f) the need to control interfaces between persons involved in the design and development process? (1g) the need for involvement of customers and users in the design and development process? (1h) the requirements for subsequent provision of products and services? (1i) the level of control expected for the design and development process by customers and other relevant interested parties? (1j) the DI needed to demonstrate that design and development requirements have been met?		
8.3.3	**Design and development inputs**		**2008: 7.3.2—Design and development inputs**
	(1) Does the organization determine the requirements essential for the specific types of products and services to be designed and developed?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(2) Does the organization consider: (2a) functional and performance requirements? (2b) information derived from previous similar design and development activities? (2c) statutory and regulatory requirements? (2d) standards or codes of practice that the organization has committed to implement? (2e) potential consequences of failure due to the nature of the products and services?		
	(3) Are inputs adequate for design and development purposes, complete and unambiguous?		
	(4) Are conflicting design and development inputs resolved? *Comment: Many of the added requirements in the 2015 version are requirements that were expected to be part of the design process in the 2008 version but now are clarified.*		
	(5) Does the organization retain DI on design and development inputs?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.3.4	**Design and development controls**		**2008: 7.3.4 Design & dev. review; 7.3.5 Design & dev. verification; 7.3.6 Design & dev. validation**
	(1) Are controls in place to assure that: (1a) the results to be achieved are defined? (1b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements? (1c) verification activities are conducted to ensure that the design and development outputs meet the input requirements? *Comment: Verification tests include qualification tests, alternative calculations, comparison to similar designs, prototype testing and simulation.* (1d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use? *Comment: This may include evaluation of the final product or service to ensure it meets specification and performance requirements. The word "capable" was dropped in the context of "resulting product and services are capable of meeting requirements…. Now validation is simply validation ensures the product or service meets requirements or intended use.* (1e) any necessary actions are taken on problems determined during the reviews or during verification and validation activities? *Comment: The new version requires assurance that necessary action were taken, while the 2008 version only required them to be defined.* (1f) DI of these activities is retained? NOTE: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination suitable for the products and services of the organization. *Comment: This is a new clause. An auditor or manager would normally expect most of the controls to be in place, but they have not been specified in the past. Management control follows the plan-do-check-act (PDCA) cycle. Is there a plan or predetermined method, is it being followed, is there acceptance criteria and is the process modified/changed to conform when it not working properly?*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.3.5	**Design and development outputs**		**2008: 7.3.3—Design and development outputs**
	(1) Does the organization ensure that design and development outputs: (1a) meet the input requirements? (2b) are adequate for the subsequent processes for the provision *(act or process of providing)* of products and services? *Comment: Subsequent processes might include some type of start-up or transition plan.* (3c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria? *Comment: These may include items such as performance target values, tolerances and attributes, durability, safety, reliability, maintainability under storage and operating conditions, validation of computer systems and software, statistical validation of tests/inspections to the appropriate confidence level and others.* (3d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision? Comment: *These may include operating, storage, handling, maintenance, disposal, reliability and maintainability, serviceability for the product (project) life cycle, project/ product failure, decomposition and others.*		2008: Required design outputs in a form that is suitable for verification against inputs 2008 also required design outputs to be approved prior to release.
	(2) Does the organization retain DI on design and development outputs?		
	Comment: The 2008 7.3.4 08 clause was deleted but the controls are covered in the control clause 8.3.4}		1008: Clause 7.3.4 was removed. There is no requirement in the 2015 version to conduct reviews according to planned arrangements. There is no requirement that review meeting participants include representatives of functions concerned with the design stage being reviewed.
	Comment: Verification must be controlled, but there is no specific requirement for planned arrangements}		2008:7.3.5—Design and development verification. The 2015 version does not require verification according to planned arrangements.
	Comment: Validation must be controlled but no specific requirement for planned arrangements.}		08: 7.3.6 Design and development validation. The 015 version does not require validation activities be performed according to planned arrangements
	Comment: Some designs cannot be validated until they are installed or assembled in place.		2008: 7.3.6. The 2015 version does not require the validation to be conducted prior to delivery or implementation whenever practical.

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.3.6	**Design and development changes**		**2008: 7.3.7—Control of design and development changes**
	(1) Does the organization identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements? Comment: *Changes must go back through similar checks as for the original design.*		
	(2) Does the organization retain DI on: (2a) design and development changes? (2b) the results of reviews? (3c) the authorization of the changes? (4d) the actions taken to prevent adverse impacts? *Comment: The 2008 version required a record of subsequent actions but not specifically those regarding adverse impacts.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.4	**Control of externally provided products and services** *Comment: No organization is required to rename its purchasing function in order to control external providers. The reason for the awkward wording is that not all organization inputs that need to be controlled are from suppliers. An example of this is a buy-resale program with a competitor.*		**2008: 7.4—Purchasing**
8.4.1	**General**		**2008: 7.4.1 Purchasing process**
	(1) Does the organization ensure that externally provided processes, products, and services conform to requirements?		
	(2) Has the organization determined the controls to be applied to externally provided processes, products and services when: (2a) products and services from external providers are intended for incorporation into the organization's own products and services? (2b) products and services are provided directly to the customer(s) by external providers on behalf of the organization? (2c) a process or part of a process is provided by an external provider as a result of a decision by the organization? *Comment: In the 2008 version control was dependent on the effect of the realization processes. The 2015 version is more descriptive.* *Comment: Examples of ways to accomplish this include: receiving inspection, test verification, performance evaluation and testing, process capability results, supplier verification (certificate of compliance or conformance), pre-shipment (source) inspection and supplier audits. Control may be demonstrated by adherence to specified methods and records of this. For many service organizations, purchasing is not as critical as it is in manufacturing.*		
	(3) Does the organization 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 specified requirements?		
	(4) Has the organization retained DI of the results of these activities and any necessary actions arising from the evaluations?		
8.4.2	**Type and extent of control** *Comment: This clause has new language and new controls that relate to processes and product/services. This is linked to risk-based thinking (what if …?).*		**2008: 7.4.1—Purchasing process, 7.4.3—Verification of purchased product**
	(1) Does the organization ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers?		
	(2a) Does the organization ensure that externally provided processes remain within the control of its QMS?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(2b) Does the organization define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output? *Comment: This could be the type or level of verification activities. For example: external provider controls could be a certification or financial, and resulting output controls may be first-article inspection, tests by an independent laboratory, or specification limits or targets.*		
	(2c) Does the organization take into consideration: (2c1) 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? (2c2) the effectiveness of the controls applied by the external provider?		
	(2d) Has the organization determined the verification, or other activities, to be necessary?		
8.4.3	**Information for external providers**		**2008: 7.4.2—Purchasing information**
	(1) Does the organization ensure the adequacy of requirements prior to their communication to the external provider?		
	(2) Does the organization communicate to external providers its requirements for: (2a) the processes, products and services to be provided? (2b) the approval of: 1) products and services, 2) methods, processes and equipment, and 3) the release of products and services? (2c) competence, including any required qualification of persons? (2d) the external providers' interactions with the organization? (2e) control and monitoring of the external providers' performance to be applied by the organization? (2f) verification or validation activities that the organization or its customer intends to perform at the external providers' premises?		2008: The 2008 version stated that if appropriate, the applicable of QMS requirements could be identified in purchasing documents. *<effect-minor>*

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.5.1	**Control of production and service provision**		**2008: 7.5.1—Control of product and service provision control**
	(1) Does the organization implement production and service provision under controlled conditions? *Comment: This is a very open-ended requirement. What constitutes control is not defined by ISO 9000, but is a frequent requirement. Certainly the organization must comply with the requirements in the clause (see #2, the next question), but they would only apply when applicable. An auditor can also use PDCA to test for control.*		
	(2) Do control conditions include, as applicable: (2a1) the availability of DI that defines the characteristics of the products and services to be produced or provided or activities to be performed;		2008: 2008 required work instructions, however activities to be performed (processes) must be DI per 2015 version.
	(2a2) the availability of DI that defines the results to be achieved?		
	(2b) the availability and use of suitable monitoring and measuring resources?		2008: Is suitable equipment used on each of these identified processes? Not included in 2015.
	(2c) 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?		
	(2d) the use, and control of suitable infrastructure and environment operation of processes?		
	(2e) the appointment of competent persons, including any required qualifications?		
	(2f) the validation and periodic revalidation of the ability to achieve planned results of the processes for production and service provision when the resulting output cannot be verified by subsequent monitoring or measurement? *Comment: It is important to understand validation.* According to ISO 9000, 3.8.13, to validate is to confirm, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Note 1: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents; Note 2: The word “validated” is used to designate the corresponding status. Note 3: the use conditions for validation can be real or simulated. *For ISO 9000, validation is about end-use or performance as intended, while verification is about collecting evidence specified requirements have been met.*		2008—7.5.2: The 2015 version does not include a list of considerations to validate a process achieves planned results. Does the organization consider: • review and approval of the process? • approval of equipment? • qualification of personnel? • use of methods and procedures? • requirements for records? • revalidation requirements?
	(2g) the implementation of actions to prevent human error?		
	(2h) the implementation of release, delivery and post-delivery activities?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.5.2	**Identification and traceability**		**2008: 7.5.3—Identification and traceability**
	(1) Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and services?		
	(2) Does the organization identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision?		
	(3) Does the organization control the unique identification of the outputs when traceability is a requirement, and does it retain DI necessary to enable traceability?		
8.5.3	**Property belonging to customers or external providers**		**2008: 7.5.4 Customer property**
	(1) Has the organization exercised care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization? Note: Customer property can include material, components, tools and equipment, customer premises, intellectual property and personal data.		
	(2) Has the organization identified, verified, protected and safeguarded the customer's or external provider's property for use or incorporation into the products and services?		
	(3) When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, has the organization reported this to the customer or external provider?		
	(4) Does the organization retain information regarding lost, damaged customer or external provider's property or its property otherwise found to be unsuitable for use?		
8.5.4	**Preservation**		**2008: 7.5.5—Preservation of product**
	(1) Does the organization preserve the outputs during production and service provision to the extent necessary to ensure conformity to requirements?		
8.5.5	**Post-delivery activities**		**2008: 7.5.1—Control of production and service provision**
	(1) Does the organization meet requirements for post-delivery activities associated with the products and services? NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(2) When determining the extent of post-delivery activities that are required, does the organization consider: a) statutory and regulatory requirements? b) the potential undesirable consequences associated with its products and services? c) the nature, use and intended lifetime of its products and services? d) customer feedback?		
8.5.6	**Control of changes** *Comment: Ideally, when operations/production makes changes to a process, it should be reviewed according to design changes clause, but this was not a 2008 requirement.}*		**2008: 7.3.7—Control of design and development changes**
	(1) Does the organization review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements?		
	(2) Is there retained DI describing the results of the review of changes, the persons authorizing the change and any necessary actions arising from the review?		
8.6	**Release of products and services**		**2008: 8.2.4—Monitoring and measuring of processes** **7.4.3—Verification of purchased product**
	(1) Has the organization implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met? *Comment: Though the developers of the 2015 version eliminated most references to procedures or planned arrangements, it remains in this section.*		
	(2) Have planned arrangements been satisfactorily completed before the release of products and services to the customer? Or, is the release otherwise approved by a relevant authority and, as applicable, by the customer?		
	(3) Is there retained DI on the release of products and services?		
	(4) Does the DI include: (4a) evidence of conformity with the acceptance criteria? (4b) traceability to the person(s) authorizing the release?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
8.7	**Control of nonconforming outputs**		**2008: 8.3—Control of nonconforming product**
8.7.1			
	(1) Does the organization ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery? *Comment: This could mean containment, quarantine or marking/identification.*		
	(2) Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services? *Comment: Does the organization prioritize and work on the significant issues first?*		
	(3) Does the organization also address nonconforming products and services detected after delivery of products, during or after the provision of services? *Comment: How does the organization handle returns or services not performed properly?*		
	(4) Does the organization deal with nonconforming outputs in one or more of the following ways: a) correction? *Comment: correction includes rework, repair, blend, regarde* b) segregation, containment, return or suspension provision (*the act or process of providing*) of products and services? c) informing the customer? d) obtaining authorization for acceptance under concession. *Comment: includes use as-is, or a different application/use.}* *Comment: Segregation and containment are common but were not specifically referenced in the 2008 version as a response to nonconforming outputs. Holding products would be temporary until the organization determined their disposition. Scraping, dumping or disposal of nonconforming product is not mentioned in the 2015 or the 2008 versions, but the 2008 version was more open-ended to allow action to eliminate the nonconformity and/or take appropriate action.*		
	(5) When nonconforming outputs are corrected, is the conformity to the requirements verified?		
8.7.2			
	(1) Does the organization retain DI that: a) describes the nonconformity? b) describes the actions taken? c) describes any concessions obtained? d) identifies the authority deciding the action in respect of the nonconformity?		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
9	**Performance evaluation**		**2008** (new)
9.1	**Monitoring, measurement, analysis and evaluation**		**2008: 8—Measurement analysis and improvement**
9.1.1	**General**		**2008: 8.1—General**
	(1) Has the organization determined: (1a) what needs to be monitored and measured? (1b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results? (1c) when the monitoring and measuring shall be performed? (1d) when the results from monitoring and measurement shall be analyzed and evaluated?		2008: Had the organization determined what methods (extent and use) are applicable (including statistical techniques) for measuring, monitoring, analysis? See 9.1.3 note in 2015 version.
	(2) Does the organization evaluate the performance and the effectiveness of the QMS? *Comment: Check the management review clause (9.3).*		
	(3) Does the organization retain appropriate DI as evidence of the results?		
9.1.2	**Customer satisfaction**		**2008: 8.2.1—Customer satisfaction**
	(1) Does the organization monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled?		
	(2) Has the organization determined the methods for obtaining, monitoring and reviewing this information? NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.		
9.1.3	**Analysis and evaluation**		**2008: 8.4—Analysis of data**
	(1) Does the organization analyze and evaluate appropriate data and information arising from monitoring and measurement? (2) Are the results of analysis used to evaluate: (2a) conformity of products and services? (2b) degree of customer satisfaction? (2c) the performance and effectiveness of the QMS? (2d) that planning has been implemented effectively? (2e) the effectiveness of actions taken to address risks and opportunities? (2f) the performance of external provider(s)? (2g) the need for improvements to the QMS? Note: Methods to analyze can include statistical techniques.		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
9.2	**Internal audit**		**2008: 8.2.2—Internal audit**
9.2.1	(1) Does the organization conduct internal audits at planned intervals?		
	(2) Are audits conducted to verify that the QMS conforms to: (2.1) the organization's own requirements for its QMS? (2.2) the requirements of ISO 9001:2015?		
	(3) Are audits conducted to verify that the QMS is effectively implemented and maintained?		
9.2.2	(4a) Does the organization plan, establish, implement and maintain an audit program(s) including the frequency, methods, and responsibilities, planning requirements and reporting?		2008: The 2015 version does not require audit program documented procedures, but its reference to ISO 19011 links to the definition of audit as a document process.
	(5a) Does the organization take into consideration the importance of the processes concerned, changes affecting the organization and the results of previous audits? *Comment: This requirement should be applied to all audit activities including planning, establishing, implementing and maintaining the audit program and its frequency, methods, responsibilities, planning requirements and reporting. Examples include scheduling audits, their scope and frequency.*		
	(6b) Does the organization define the audit criteria and scope for each audit?		
	(7c) Does the organization select auditors and conduct audits to ensure the objectivity and impartiality of the audit process?		
	(8d) Has the organization ensured that the results of the audits are reported to relevant management?		
	(9e) Does the organization take necessary correction and corrective actions without undue delay?		
	(10f) Does the organization retain DI as evidence of the implementation of the audit program and the audit results? *Comment: Where the standard calls for records of implementation the organization could include results of review meetings.* NOTE: See ISO 19011 for guidance.		2008: The 2015 version does not require that follow-up activities be carried out to verify the effectiveness of actions taken and that verification results be reported, as does the 2008 version. However, this is covered in the 2015 version's clause 10.2 regarding corrective action.

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
9.3	**Management review**		**2008 5.6—Management review**
9.3.1	**General**		
	(1) Does top management review the organization's QMS at planned intervals? *Comment: Historically, certification bodies have recommended that reviews be conducted at least annually. Depending on the organization needs and changes, more frequent management reviews may be desirable.*		
	(2) Are the reviews conducted to ensure the QMS's continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization? *Comment: An auditor needs to know the strategic direction in order to assess this requirement.*		
9.3.2	**Management review inputs**		**2008 5.6.2—Review inputs**
	(1) Are management reviews planned and carried out? *Comment: A plan may be an agenda or other means.*		
	(2) When management reviews are carried out, does the organization take into consideration the following: (2a) the status of actions from previous management reviews? (2b) changes in external and internal issues that are relevant to the QMS, including its strategic direction? (2c) information on performance, including trends in: (2c1) customer satisfaction and feedback from relevant interested parties? (2c2) the extent to which quality objectives have been met? (2c3) process performance and conformity of products and services? (2c4) nonconformities and corrective actions? (2c5) monitoring and measurement results? (2c6) audit results? (2c7) the performance of external providers?		
	(2d) the adequacy of resources? (2e) the effectiveness of actions taken to address risks and opportunities (see 6.1)? (2f) opportunities for improvement? *Comment: The numbered topics/areas that management must review have increased. External party issues have been added along with more performance issues, c, c5, c7.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
9.3.3	**Management review outputs**		**2008 5.6.3—Review outputs**
	(1) Do the outputs of the management review include decisions and actions related to: (1a) opportunities for improvement? (1b) any need for changes to the QMS? (1c) resource needs? *Comment: The 2015 version scope is greater than the 2008 version of ISO 9001. The 2008 version specified improvement to products/services related to customer requirements and the QMS. The 2015 version leaves improvement open-ended to the extent that improvement may go beyond customer product/service requirements or the QMS. Improvement may relate to internal and external issues.*		
	(2) Does the organization retain DI as evidence of the results of management reviews? *Comment: This requirement is looking for evidence of results, not just that a management review meeting was held and people attended the meeting. This could include the decisions, actions and metrics that verify the effectiveness of actions taken.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
10	**Improvement**		**2008: 8.5—Improvement**
10.1	**General**		**2008: 8.5.1—Continual improvement**
	(1) Does the organization determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction? *Comment: Similar to the 2008 version but more descriptive to focus on customer requirements and satisfaction.*		
	(2) Do opportunities for improvement include: (2a) improving products and services to meet requirements as well as to address future needs and expectations? (2b) correcting, preventing or reducing undesired effects? (2c) improving the performance and effectiveness of the QMS? NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and reorganization. *Comment: There is no qualification such as "as appropriate" for this requirement. An auditor needs to verify that all three (a, b and c) are taking place. Improvement can be reactive (for example, corrective action), incremental (for example, a relatively small individual improvement project), step-by-step change (for example, a breakthrough, major project), creative (for example, innovation) or by reorganization (for example, transformation).*		
10.2	**Nonconformity and corrective action**		**2008: 8.5.2—Corrective action**
10.2.1			
	(1) When a nonconformity occurs (including complaints), does the organization address the following: (1a) react to the nonconformity, and as applicable: • take action to control and correct it? • deal with the consequences? *Comment: This is somewhat redundant compared to 8.7.1. It is a typical first step if there is a nonconformity or complaint. This clarifies what was expected in the 2008 version. Other terms associated with this requirement are remedial action, containment action, quick fix and a correction step. Consequences can be any manner of issues such as the customer's product quality, inefficiencies and substitutions, and can extend up and down the supply chain.*		2008: The requirement for a documented procedure has been dropped in 2015.

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
	(1b) Does the organization evaluate the need for action to eliminate the cause(s) of the nonconformity so it does not recur or occur elsewhere, by: 1) reviewing and analyzing the nonconformity? 2) determining the causes of the nonconformity? 3) determining if similar nonconformities exist or could potentially occur? *Comment: Many quality professionals link corrective action of a nonconformity with preventing it from recurring because it may happen again. The writers of Annex SL (common text) added the possibility that it could occur elsewhere. No. 3 is new and helps emphasize the importance of identifying systemic problems.*		
	(1c) Does the organization implement any action needed? (1d) Does the organization review the effectiveness of any corrective action taken?		
	(1e) Does the organization update risks and opportunities determined during planning, if necessary? (1f) Does the organization make changes to the QMS, if necessary?		
	(2) Are corrective actions appropriate to the effects of the nonconformities encountered?		
10.2.2			
	(1) Does the organization retain DI as evidence of: a) the nature of the nonconformities and any subsequent actions taken? b) the results of any corrective action? *Comment: Perhaps keeping a record of the nature of the nonconformities is new but, for practical reasons, most organizations record the nature of nonconformities as part of their document procedure.*		

Ref.	Questions from 9001:2015 *(comments in italic are not in the standard)*	Yes/ no	Observations/comments
10.3	**Continual improvement**		**2008: 8.5.1—Continual improvement**
	Does the organization continually improve the suitability, adequacy and effectiveness of the QMS?		
			2008: 8.5.3, the preventive action clause has been eliminated in 2015. Preventive action as a requirement has been confusing to many. The need to address potential nonconformities or undesirable situations is addressed when risks are assessed. 2008: A preventive action document procedure is not required in 2015.