ISO 9001:2008 – 2015 Correlation Matrix

ISO 9001:2015 clause	ISO 9001:2008 clause	Comments
4 Context of the organization		
4.1 Understanding the organization and its context The organization shall determine 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. The organization shall monitor and review information about these external and internal issues. 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, knowledge and performance of the organization.	No equivalent clause	Generally organizations address this by developing a vision statement and a mission statement; these are developed into a long term strategic direction and a strategic plan. These further lead to shorter 3 to 5 year business development plans, which are supported by annual goals and objectives. For small to medium size organizations, these may be unstated and undocumented and be in the mind of the owner or may not exist at all. The issues can relate to: Legal (FDA, FAA, DOT, EPA, OHSA) Market & competition Technology development Cultural & social directions Economic development International Trade
4.2 Understanding the needs and expectations of interested parties Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system.	**No equivalent clause**	Organization's interested parties include: Owner(s) – individuals, investment companies, corporate ownership, stockholders Employees Regulators Customers Competitors Trade Associations State and local business community Owners Suppliers Neighbors

The organization shall monitor and review information about these interested parties and their relevant requirements.		
4.3 Determining the scope of the quality management system The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: 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 shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.	**4.2.2 Quality manual** The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),	Scope requirements are more explicit **Required Content** Types of products & services Application of all requirements from ISO 9001 that are applicable – if they have activities/processes they are to be included Boundaries of the QMS Justification for any exclusions Scope determined by considering external & internal issues, requirements of interested parties & products & services

4.4 Quality management system ***4.4.1 The o***rganization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: a) determine the inputs required and the outputs expected from these processes; b) determine the sequence and interaction of these processes; c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; d) determine the resources needed for these processes and ensure their availability; e) assign the responsibilities and authorities for these processes; f) address the risks and opportunities as determined in accordance with the requirements of 6.1; g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; h) improve the processes and the quality management system. 4.4.2 To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have	4.1 **General requirements** The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure where applicable, and analyze these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system. NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement. NOTE 2 An “outsourced process” is a process that the organization needs for its quality management	**Process Approach additions/changes** Assign responsibilities & authorities for the processes Address risks and opportunities with link to 6.1 Discussion of outsourced processes move to a reference in clause 8.1 which refers to control described in clause 8.4 basically the purchasing requirements

confidence that the processes are being carried out as planned.	system and which the organization chooses to have performed by an external party. NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.	
5 Leadership		
5.1 Leadership and commitment ***5.1.1 General*** Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the Process Approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality	**5.1 Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	**Top Management – new/now explicit commitments:** Accountability for effectiveness Ensuring QMS achieves intended results Compatible with Strategic Direction of organization Integration with business processes (interpreted in context of nature of organization – for profit; not for profit; private, public)

management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the 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. NOTE Reference to "business" in this International Standard 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. ***5.1.2 Customer Focus*** Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained.	**5.2 Customer focus** Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	Customer focus tie to risk as affecting products & services Customer focus tie to regulatory requirements as well as customer requirements
5.2 Policy **5.2.1 Developing the quality policy** Top management shall establish, implement and maintain a quality policy that: a) is appropriate to the purpose and	**5.3 Quality policy** Top management shall ensure that the quality policy a) is appropriate to the purpose of the	**Policy** ties to Context of organization Strategic direction Review for continuing suitability was

context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system. **5.2.2 Communicating the quality policy** The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate.	organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	removed Availability to interested parties added
5.3 ***Organizational roles, responsibilities and authorities*** Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority for: a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	**5.5.1 Responsibility and authority** Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. **5.5.2 Management representative** Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization. NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	There is no longer a position of "management representative" There are now 5 responsibilities and authorities that need to be assigned.

6 Planning		
6.1 Actions to address risks and opportunities **6.1.1** When planning for the quality management system, the organization shall 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. **6.1.2** The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. 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 the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	**5.4.2 Quality management system planning** Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	***There is not a comparable clause in 2008 version; only the very general that planning of the QMS should meet the Process Approach requirements and quality objectives*** ***This revision expects that the QMS addresses identified risks arising from the consideration of the context of the organization and the requirements of interested parties*** ***The context of the organization might lead to risks such as Product risks – FDA, DOT, EPA (examples gas mileage requirements on vehicles; product shipping risks- hazardous materials; vehicle lighting requirements; food and drug risks)*** ***The requirements of interested parties may lead to risks identified during contract review such as short delivery times or difficult product requirements or suppliers ability to provide raw materials or components*** ***Most of our clients will identify risks during contract review and take actions such as negotiating delivery dates or taking exception to product requirements or***

		evaluating risks during design activities (especially design reviews, verification and validation) or identifying risks when selecting and evaluating suppliers
6.2 ***Quality objectives and planning to achieve them*** **6.2.1** The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives. **6.2.2** When planning how to achieve its quality objectives, the organization shall 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.	**5.4 Planning** **5.4.1 Quality objectives** Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	An action plan is now expected for the quality objectives
6.3 **Planning of changes** When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider:	**5.4.2 Quality management system planning** Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and	QMS change control more detailed

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.	b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	
7 Support		
7.1 Resources ***7.1.1 General*** The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers. 7.1.2 **People** The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. 7.1.3 ***Infrastructure*** The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology. 7.1.4 ***Environment for the operation of processes*** The organization shall determine, provide	**6.1 Provision of resources** The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. **6.3 Infrastructure** The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport, communication or information systems). **Work environment** The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	

and maintain 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: a) social (e.g. non-discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c) physical (e.g. 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** **7.1.5.1 General** The organization shall determine and provide 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. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continuing fitness for their purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. **7.1.5.2 Measurement traceability** When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such	NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather). **7.6 Control of monitoring and measuring equipment** The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4); b) be adjusted or re-adjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage.	Appears that software is not covered any more but the wording was changed from "equipment" to "resources" so it still is covered

standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safe guarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). 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.	
7.1.6 Organizational knowledge The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.		There is no equivalent clause in ISO9001:2008. Most clients do not have any process for capturing this knowledge other than external standards and specifications. Will have to consider establishing a lessons learned database to capture tribal knowledge

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. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).		
7.2 ***Competence*** The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re- assignment of currently employed persons; or the hiring or contracting of competent persons.	**6.2 Human resources** **6.2.1 General** Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system. **6.2.2 Competence, training and awareness** The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the	**Awareness moved to next clause 7.3**

	quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	
7.3 *Awareness* The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements.	**5.3 d** Quality policy **5.5.2 c** **6.2.2 d**	These awareness requirements were dispersed in several clauses previously
7.4 *Communication* The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.	**5.5.3 Internal communication** Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	Additional detail, but no real changes
7.5 *Documented information* **7.5.1 General** The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another	**4.2.1 General** The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.	The term "documented information" is used to cover documents such as procedures and records. There is no longer a requirement for specific procedures For example: Instead of an internal audit procedure; an organization could present an internal audit schedule; and audit forms/records that demonstrate audit criteria, audit scope, audit

due to: — the size of organization and its type of activities, processes, products and services; — the complexity of processes and their interactions; — the competence of persons. 7.5.2 **Creating and updating** When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy. 7.5.3 **Control of documented Information** **7.5.3.1** Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). **7.5.3.2** For the control of documented information, the organization shall 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); d) retention and disposition. Documented information of external origin determined by the organization to be necessary for the planning and operation of	NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document. NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. NOTE 3 The documentation can be in any form or type of medium. **4.2.2 Quality manual** The organization shall establish and maintain a quality manual that includes b) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), c) the documented procedures established for the quality management system, or reference to them, and d) a description of the interaction between the processes of the quality management system. **4.2.3 Control of documents** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-	planning; audit reporting and corrective action on NCRs Controls still required but may be a little more specific or descriptive

the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.	approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. **4.2.4 Control of records** Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.	
8 Operation		
8.1 Operational planning and control The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for:	**7.1 Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the following, as appropriate:	This planning clause now includes a change control requirement and a reference to clause 8.4 for control of outsourced processes

1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining and keeping documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. NOTE "Keeping" implies both the maintaining and the retaining of documented information. The output of this planning shall be suitable for the organization's operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4).	a) quality objectives and requirements for the product; b) the need to establish processes and documents, and to provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). The output of this planning shall be in a form suitable for the organization's method of operations. NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan. NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.	
8.2 Requirements for products and services **8.2.1 Customer communication** Communication with customers shall include: a) providing information relating to products and services; b) handling inquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant. **8.2.2 Determining the requirements related to products and services**	**7.2.3 Customer communication** The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) inquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	***Rearranged order of subclauses*** ***Customer communication added a couple of communication topics*** ***Some reorganization & rewording of requirements*** ***Note on post delivery activities removed***

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers. **8.2.3 Review of requirements related to products and services** 8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: a) requirements specified by the customer, including the requirements for delivery and post- delivery activities; b) requirements not stated by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed. The organization shall ensure that contract or order requirements differing from those previously defined are resolved. The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their	**7.2.1 Determination of requirements related to the product** The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization. NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal. **7.2.2 Review of requirements related to the product** The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	

requirements. 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 The organization shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services. **8.2.4 Changes to requirements for products and services** The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. 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 catalogs or advertising material.	
8.3 Design and development of products and services 8.3.1 **General** The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. **8.3.2 Design and development planning** In determining the stages and controls for design and development, the organization shall 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	**7.3 Design and development** **7.3.1 Design and development planning** The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of	Clause introduction appears to require a design process Subclauses for design review, design verification and design validation were combined into a design control subclause New explicit requirement to consider potential consequences of failure due to the nature of the products & services - an aspect of risk in the design process

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 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** The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; 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.	responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization. **7.3.2 Design and development inputs** Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs. **8.3.4 Design and development controls** The organization shall 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 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. NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.	**7.3.4 Design and development review** At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4). **7.3.5 Design and development verification** Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4). **7.3.6 Design and development validation** Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall	

	be maintained (see 4.2.4).	
8.3.5 Design and development outputs The organization shall 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 criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs.	**7.3.3 Design and development outputs** The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. NOTE Information for production and service provision can include details for the preservation of product.	
8.3.6 **Design and development changes** The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts.	**7.3.7 Control of design and development changes** Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	

8.4 **Control of external provision of goods and services** 8.4.1 General The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; 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 organization shall 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 shall retain documented information of these activities and any necessary actions arising from the evaluations. 8.4.2 **Type and extent of control** The organization shall 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. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system;	**7.4 Purchasing** **7.4.1 Purchasing process** The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	Clause broadened to specifically cover externally provided processes, product and services – more clearly covers outsourced processes More clearly applies to product related products, processes and services Type & extent of control separated into new clause and verification of purchased product incorporated into this clause New clause "ensure that externally provided processes remain within the control of its QMS" – we **do not interpret** this to mean that an organization having an outsource drop ship to their customer is now not allowed

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: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. **8.4.3 Information for external providers** The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: 1) products and services; 2) methods, processes and equipment; 3) the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities	**7.4.3 Verification of purchased product** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. **7.4.2 Purchasing information** Purchasing information shall describe the product to be purchased, including, where appropriate, a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	

that the organization, or its customer, intends to perform at the external providers' premises.		
8.5 Production and service provision 8.5.1 **Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) 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 re-validation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release,	**7.5.1 Control of production and service provision** The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities. **7.5.2 Validation of processes for production and service provision** The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable, a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel,	The "special process requirements" are not in a separate clause; the process validation requirements are now a bullet in the list Added requirements Appointment of competent persons – if clients do not have a process/activity competence determination and matrix they need one Implementation of actions to prevent human error – nonconforming product; customer complaints should lead to at least consideration of mistakeproofing the process

delivery and post-delivery activities. 8.5.2 **Identification and traceability** The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability. **8.5.3 Property belonging to customers or external providers** The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information	c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. **7.5.3 Identification and traceability** Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4). NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained. **7.5.4 Customer property** The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4). NOTE Customer property can include intellectual property and personal data.	The note in reference to configuration management has been removed Note broadens the description of the applicability of customer owned property

on what has occurred. NOTE A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data. 8.5.4 **Preservation** The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. 8.5.5 **Post-delivery activities** The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall 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. 8.5.6 **Control of changes** The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented	7.5.5 Preservation of product The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	The examples of preservation were moved to a note. In ISO 9001:2008 post-delivery activities were very briefly mentioned in "contract review" and "production & service provision" This has been expanded to this subclause For most of our clients this subclause will not apply – they probably need to have a discussion that will lead to exclusion. If they do have post delivery activities, other than customer rejected product which is covered under nonconforming product and customer complaints; then they need to address this subclause Another change control subclause, which overlaps with change requirements in clause 8.1. ASR would have expected this change control under ISO 9001:2008

information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.		
8.6 **Release of products and services** The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release.	**8.2.4 Monitoring and measurement of product** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	
8.7 **Control of nonconforming outputs** 8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.	**8.3 Control of nonconforming product** The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. Where applicable, the organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected	**ASR interpretation – correction includes not only correcting the NCP but also includes regrading or approving the product for an alternate use** **Informing the customer (bullet c) applies to NCP that has already shipped**

The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected. 8.7.2 The organization shall retain documented information 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.	nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application; d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	
9 Performance evaluation		
9.1 Monitoring, measurement, analysis and evaluation ***9.1.1 General*** The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The	**8.2.3 Monitoring and measurement of processes** The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on	

organization shall retain appropriate documented information as evidence of the results. 9.1.2 ***Customer satisfaction*** The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine 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 of data*** The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. NOTE Methods to analyze data can include statistical techniques.	the effectiveness of the quality management system. **8.2.1 Customer satisfaction** As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports. 8.4 **Analysis of data** The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and d) suppliers (see 7.4).	

9.2 Internal Audit **9.2.1** The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained. **9.2.2** The organization shall: a) plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. NOTE See ISO 19011 for guidance.	***8.2.2 Internal audit*** The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). NOTE See ISO 19011 for guidance.	

9.3 ***Management review*** **9.3.1** General Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. **9.3.2** Management Review Inputs The management review shall be planned and carried out taking into consideration: 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 quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) 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. 9.3.3 Management Review Outputs	**Management review** **5.6.1 General** Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4). **5.6.2 Review input** The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement. **5.6.3 Review output**	Management review now needs to align with the strategic direction of the organization Management review inputs now include supplier performance; effectiveness of actions to address risks adequacy of resources changes in internal and external issues

The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews.	The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	
10 ***Improvement***	***8 Improvement***	
10.***1 General*** The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall 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 effectiveness of the quality management system. NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.	8.5.1 Continual improvement The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	Now need to select specific opportunities for improvement and take actions
10.2 Nonconformity and corrective action **10.2.1** When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it;	**8.5.2** corrective action The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	

2) 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: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) 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. Corrective actions shall be appropriate to the effects of the nonconformities encountered. . **10.2.2** The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action.	A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing the effectiveness of the corrective action taken.	
10.3 **Continual improvement** The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.		