Ref.	Question *(comments in italic are not in the standard)*	Comments *[evidence - data - collection plan]*
4.1	**General requirements**	
4.2	**Documentation Requirements**	
4.2.1	**General**	
4.2.2	**Quality Manual**	
4.2.3	**Control of documents** – is there a documented procedure ?	
4.2.3 a	Are documents approved for adequacy prior to issue.	
4.2.3 b	Are documents reviewed, updated as necessary, and then re-approved?	
4.2.3 c	Is there a method that identifies the current version status of documents?	
4.2.3 d	Are documents (procedures, instructions) available at points of use (locations where quality activities are performed)?	
4.2.3 e	Are documents legible and readily identifiable ?	
4.2.3 f	Are external origin documents identified and distribution controlled.	
4.2.3 g	Are obsolete documents (retained for legal and/or knowledge purposes) suitably identified to prevent unintended use.	
4.2.4	**Control of quality records**	
	Is there a documented procedure in use for identifying, storing, retrieval, retention time, and disposing of quality records?	
5	**Management Responsibility**	
5.1	**Management commitment** Is there evidence of top management commitment by: a) Communicating the importance of meeting customer and regulatory requirements; b) Establishing a quality policy and objectives; c) Conducting management reviews; and d) Ensuring availability of resources. *[Verify a through d. See quality policy, verify management reviews taking place and top management involved. a) is linked to 5.5.3 c)*	

5.2	**Customer focus** Does top management ensure customer requirements are determined and fulfilled with an aim to ***enhance customer satisfaction***? *[This requirement is linked to 7.2.1 (determining requirements and 8.2.1monitoring customer satisfaction.]*	
5.3	**Quality policy** a) Is the policy appropriate for the purpose of the organization? b) Does the policy include commitment to comply with requirements and continually improve? c) Does the policy statement providing a framework for establishing/ reviewing objectives? d) Has the quality policy been communicated, understood? e) Is the policy reviewed for continuing suitability? *[Note: Reviewing should link with management review (5.6) of the suitability of the quality system]*	

5.4	**Planning**	
5.4.1	**Quality objectives**	
5.4.1-1	Are objectives established for each relevant function and level? Are the objectives measurable and consistent with the quality policy including a commitment to continual improvement? *[Note: Seek to determine relevant functions (such as from an organizational chart) and verify that there are objectives for each.]*	
5.4.1-2	Do objectives include those needed to meet requirements for products and/or services? *[Note: This requirement is linked to 7.1. For example: objectives must include product requirements such as purity or tolerance levels. There may be a matrix (not required) to show relationship between objectives and product/ service requirements.*	
5.4.2	**Quality planning**	
5.4.2-1	Is planning performed to meet the quality objectives requirements of 4.1?	
5.4.2-2	Does quality planning include: - Processes of the quality management system? - Resources needed? - Continual improvement? *[Plans must include the three areas above. The 'processes' are the realization processes in 7]*	

5.4.2-3	Are organizational changes planned, controlled and is the integrity of the management system maintained during the change? *[Note: Control can be established by using a method and generating records of actions]*	
5.5	**Responsibility, authority and communication**	
5.5.1	**Responsibility and Authority** Have responsibilities and authorities been defined and communicated? *[May be defined in job descriptions & communicated via organization charts, outline, and so on..]*	
5.5.2	**Management representative**	
5.5.2a	Has top management appointed a member within the management with defined authority and responsibility to ensure quality management requirements are established, implemented and maintained? *[Management representative may be the liaison with external parties.]*	
5.5.2b	Does the management rep. have authority to report performance to management for review and improvement of the quality system.	
5.5.2c	Does the management rep have authority to ensure awareness of customer requirements throughout the organization. *[Linked to 5.1 a)]*	
5.5.3	**Internal communications** Is information about quality management system **effectiveness** communicated to various levels and functions? *[Is there a means for communicating, can the organization provide evidence of this type of communication. e.g. newsletter, broadcast fax, meetings, etc.]*	
5.6	**Management Review**	
5.6.1	**General**	
5.6.1-1	Are management reviews conducted at planned intervals? Note: A management review of ISO 9001-2008 implementation must be conducted prior to upgrade from ISO 9000-1994	
5.6.1-2	Does top management review the quality system to ensure its continuing suitability, adequacy, and effectiveness?	
5.6.1-3	Are opportunities for improvement and needed changes to the quality management system, policy, objectives evaluated?	

5.6.1-4	Are records maintained?	
5.6.2	**Review Input**	
5.6.2-1	Does the review include: a. results of audits, b. customer feedback, c. process performance and product conformance, d. status of corrective and preventive actions, e. follow-up from prior reviews, f. changes that could effect the QMS, and g. recommendations for improvement. *[This is also connected to 8.2.1 for customer satisfaction and internal audit performance, 8.2.2]*	
5.6.3	**Review Output** Does it include decisions and actions related to a. Improvement of the QMS and its processes, b. Improvement of product related customer requirements c. Resource needs?	

6	**Resource management**	
6.1	**Provision of Resources** Are the resources determined and provided to: a. Implement, maintain and continually improve the QMS b. Enhance customer satisfaction? *[Linked to t 5.4.2 and 7.1) .*	
6.2	**Human resources**	
6.2.1	**General** Are personnel performing work affecting product quality **competent (demonstrated the ability to apply knowledge and skills)**? Is competency based on education, training, skills, and experience?	
6.2.2	**Competence, Awareness and Training**	
6.2.2-1	Does the organization - Determine competency needs for those affecting product quality? - Provide training or take other actions? - Evaluate **effectiveness of actions?**	
6.2.2-2	Ensure employees are aware of the importance of their activities and how they contribute to achievement of objectives?	
6.2.2-3	Are training **records** of appropriate education, training, skills, experience records maintained?	
6.3	**Infrastructure** Has the organization determined, provided and maintained infrastructure to achieve conformity to product requirements? (buildings, workspace, process hardware/software, and support services).	

6.4	**Work Environment** Has the work environment needed to achieve conformity to product requirements been determined and managed? *[The organization may include health and safety conditions; work methods; work ethics; work conditions, ergonomics, and so on.]*	
7	**Product realization**	
7.1	**Planning of realization processes**	
7.1 -1	Are the processes needed for the realization processes planned and developed? *[Look for something that is documented such as a procedure or diagram. It can be an overall plan or individual plans for the realization processes.]*	
7.1 -2	Has the following been determined? a. objectives for the product, project or contract b. the need for establishing processes, documentation, and providing resources c. verification, validation, monitoring, inspection, test and associated criteria for acceptability d. records needed to establish requirements have been met	
7.2	**Customer-related processes**	
7.2.1	**Determination of product requirements** a. Customer specified b. Necessary, but not customer stated c. Statutory and regulatory d. Additional requirements by the organization *[This is a prescriptive list. Verify items are addressed such as under review of customer requirements. For example there could be a nonconformity for not determining necessary but customer unspecified requirements.]*	
7.2.2	**Review of product requirements**	
7.2.2.1	Are requirements (contracts, tenders and orders) reviewed prior to commitment?	
7.2.2.2	Are records of reviews and follow-up actions maintained?	
7.2.2.3	Are product requirements clearly defined?	
7.2.2.4	Are contracts or order requirements that differ from previous expressed (those in the tender or offer) resolved?	
7.2.2.5	Are customer requirements reviewed to ensure the organization has the ability to meet them?	

7.2.2.6	When requirements are not written, are they confirmed before acceptance?	
7.2.2.7	Are relevant documents amended and personnel notified of order changes?	
7.2.3	**Customer communication** Has the organization defined communication requirements for: a) product/ service information, b) inquiry, contracts, order handling and amendments customer feedback including **customer complaints**	
7.4	**Purchasing**	
7.4.1	**Purchasing process**	
7.4.1-1	Are there purchasing controls to ensure that incoming purchased product/ service conforms to requirements? Is the type and extent of control dependent on the effect on product realization or final product? *[Examples of ways to accomplish this include: receiving inspection, test verification, performance evaluation and test, 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 such. For many service organizations, purchasing is not critical as it is in manufacturing]*	
7.4.1-2	Are suppliers evaluated and selected on the basis of their ability to supply product that meets organization requirements?	
7.4.1-3	Are there established criteria for evaluation, re-evaluation and selection? *[A new requirement, that for most practical purposes, existed before]*	
7.4.1-4	Do supplier records show results of: evaluations and necessary follow-up actions.	
7.4.2	**Purchasing information**	
7.4.2-1	Does purchasing information (contracts and purchase orders) describe the product ordered? *[This may be type, class, style, grade, model, part number, etc.*]	
7.4.2-2	If appropriate, are requirements for approval of product, procedures, processes and equipment described?	

7.4.2-3	If appropriate, is the requirement for qualification of personnel identified?	
7.4.2-4	If appropriate, is the applicable quality management system requirements identified in purchase documents? *[This may be the ISO 9001 or other recognized standards.]*	
7.4.2-5	Is the adequacy of purchasing documents ensured prior to communication to the supplier?	
7.4.3	**Verification of purchased product**	
7.4.3-1	Are inspection or other activities established and implemented to ensure incoming purchased meets requirements	
7.4.3-2	When the organization or it's customer perform on-site supplier verification, are arrangements and methods for on-site (supplier) verification (source inspection) specified (defined) in purchasing documents?	

7.5	**Production and service provision**	
7.5.1	**Control of production and service provision**	
7.5.1-1	As applicable, does product/ service information specify product characteristics? [acceptance criteria]	
7.5.1-2	As applicable, are there work instructions ?	
7.5.1-3	As applicable, is suitable equipment used (production, service)? *[linked to 6.3]*	
7.5.1-4	As applicable, are measurement and monitoring implemented with devices available and used?	
7.5.1-5	Are processes for release, delivery, and applicable post delivery implemented?	
7.5.2	**Validation of processes**	
7.5.2-1	Are processes that result in a product/ service that cannot be verified by subsequent measurement and monitoring *(inspection and testing)* validated ?	
7.5.2-2	Does the validation demonstrate that the process achieves planned results? *[does evidence verify processes achieve results?]*	

7.5.2-3	Are criteria defined for review and approval of processes?	
7.5.2-4	Is equipment approved and personnel qualified?	
7.5.2-5	Are records required and maintained?	
7.5.2-6	Are arrangements defined for re-validation requirements?	
7.5.3	**Identification and traceability**	
7.5.3-1	Is product/ service identified throughout production, and service operations (delivery and installation) where appropriate?	
7.5.3-2	Is there provision to identify the status of the product/ service with regard to measurement and monitor activities?	
7.5.3-3	Are there controls for and records of unique identification of individual products (or batches) when traceability is a requirement?	
7.5.4	**Customer property**	
7.5.3-1	Does the organization exercise care with customer property?	
7.5.4-2	Is customer property, identified, verified, protected and safeguarded*? [Intellectual property can be included].*	
7.5.4-3	If customer property is lost, damaged, or otherwise unsuitable, is this recorded and reported to the customer?	
7.5.5	**Preservation of product** Does the organization ensure conformity (quality) is maintained (**including constituent parts**) from internal processing to final delivery. Is product/ service conformity maintained during identification, handling, packaging, storage, and protection? *[apply 7.1. verify plan exists]*	
7.6	**Control of measuring and monitoring devices**	
7.6-1	Have measuring and monitoring devices been identified that are necessary to assure conformity to requirements?	
7.6-2	Are there processes established to ensure measurement and monitoring are carried out in accordance with requirements?	

7.6a-3	Has inspection, measurement and test equipment (and measurement devices) been calibrated or verified at specified intervals or prior to use?	
7.6a-4	Has this equipment been calibrated or verified against certified equipment having a known valid relationship to nationally recognized standards?	
7.6a-5	Where no calibration standards exist, is the basis for calibration recorded?	
7.6b-6	Is this equipment adjusted or re-adjusted as necessary?	
7.6c-7	Is the equipment identified and can its calibration status be determined ?	
7.6d-8	Are there safeguards against adjustments that would invalidate calibration settings?	
7.6e-7	Is the equipment protected from damage and deterioration during handling, maintenance, and storage?	
7.6-9	Is the validity of previous results assessed when equipment is found to be out of calibration? Is corrective action taken?	
7.6-10	Are the calibration and verification results recorded?	
7.6-11	Is computer software used for monitoring/measurement confirmed prior to initial use and reconfirmed as necessary?	

8	**Measurement, analysis, and improvement**	
8.1	**General**	
8.1-1	Are measurement and monitoring activities planned and implemented to demonstrate conformity of the product?	
8.1-2	Are measurement and monitoring activities planned and implemented to ensure conformity of the QMS?	
8.1-3	Are measurement and monitoring activities planned and implemented to continually improve the effectiveness of the QMS?	
8.1-4	Have appropriate methodologies (including statistical tools) been identified?	
8.2	**Monitoring and measurement**	

8.2.1	**Customer satisfaction**	
8.2.1-1	Is customer perception monitored? *[cross check management review records].*	
8.2.1-2	Are methods and measures defined for obtaining *[collecting]* and using such information?	
8.2.2	**Internal auditing**	
8.2.2-1	Are internal quality audits conducted at planned intervals?	
8.2.2-2	Do audits determine conformance to ISO 9001, planned arrangements (7.1) and effective implementation of and conformance to the QMS? Note: Audits of new ISO 9001-2008 requirements must be completed prior to upgrade from ISO 9000-1994	
8.2.2-3	Does the audit program plan consider status and importance of the activities and areas to be audited and results of previous audits?	
8.2.2-4	Are audit criteria, scope, frequency, and methods defined?	
8.2.2-5	Are audits and auditors objective and impartial ?	
8.2.2-6	Are responsibilities, and requirements for planning, conducting, and reporting of audits in accordance with documented procedure(s)?	
8.2.2-7	Is timely corrective action taken by management on any deficiencies found during the audit?	
8.2.2-8	Are follow up actions carried out to verify the implementation of the corrective action? Are the verification results reported?	

8.2.3	**Monitoring and measurement of processes**	
8.2.3-1	Does monitoring and measuring of the quality management system processes demonstrate achievement of planned *(intended)* results?	
8.2.3-2	Is corrective action taken to ensure conformity of the product when planned results are not achieved?	
8.2.4	**Monitoring and measurement of product *[service]***	

8.2.4-1	Are the product characteristics measured and monitored at appropriate stages of the realization process to verify requirements are met?	
8.2.4-2	Is there evidence showing conformance to acceptance criteria? *[records]*	
8.2.4-3	Do the records indicate the person releasing the product?	
8.2.4-4	Is product/ service held until all planned activities are satisfactory completed, unless otherwise approved? *[quality waiver]*	
8.3	**Control of Nonconforming Product**	
8.3-1	Is nonconforming product identified and controlled to prevent unintended use or delivery in accordance with the documented procedure?	
8.3-2	Are the controls, responsibilities and authorities for dealing with nonconforming product defined in a documented procedure?	
8.3-3	Is nonconforming product dealt with *[dispositioned)* by*:* *a) eliminating the nonconformity* *b) accepted by concession (w/ or w/o rework)* *or* *a) taking action to preclude original use*	
8.3-4	Are records describing the nonconformity subsequent actions maintained?	
8.3-5	Is corrected product subject to re-verification activities to demonstrate conformity?	
8.3-6	Is appropriate action taken regarding the consequences of the nonconformities found after delivery or use?	
8.4	**Analysis of data**	
8.4-1	Is data collected and analyzed to determine the suitability, effectiveness, and adequacy of QMS and to identify areas for continual improvement?	

8.4-2	Does data provide information on: a) Customer satisfaction *(linked to 8.2.1)* b) Conformance to product requirements *(7.2.1)* c) Characteristics and trends of processes and products d) Suppliers	
8.5	**Improvement**	
8.5.1	**Continual improvement** Is there continual improvement of the QMS through the use of the quality policy, quality objectives, management review, audit results, corrective and preventive actions and analysis of data?	
8.5.2	**Corrective action**	
8.5.2-1	Has the documented procedure for corrective action been used?	
8.5.2-2	Are corrective actions implemented based on importance (effect of problems encountered)?	
8.5.2a-3	Are nonconformities (including customer complaints) reviewed? *[complaints may be handled separately, perhaps in the sales - marketing department]*	
8.5.2b-4	Are causes of nonconformities determined?	
8.5.2c-5	Is the need for actions (to ensure nonconformities do not recur) evaluated ?	
8.5.2d-6	Are actions determined and implemented ?	
8.5.2e-7	Are the results (actions) of the investigation recorded?	
8.5.2f-8	Are corrective actions taken reviewed?	
8.5.3	**Preventive action**	
8.5.3-1	Has the documented procedure for preventive action been used?	
8.5.3-2	Are preventive actions implemented based on importance (effects of the potential problems)?	
8.5.3a-3	Are potential nonconformities identified along with their causes?	

8.5.3b-4	Is the need for action to prevent occurrence evaluated?	
8.5.3b-5	Is the action determined and implemented?	
8.5.3c-6	Are results of preventive action recorded?	
8.5.3d-6	Are preventive actions taken reviewed?	

APPROVED BY: